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Proclamation 10844 of October 23, 2024

The President

United Nations Day, 2024

By the President of the United States of America

A Proclamation

Nearly 80 years ago, our forebearers gathered for the first United Nations General Assembly. With the horrors of World War II weighing on their hearts and the hopes of humanity resting on their shoulders, they opened the General Assembly by declaring, “The whole world now waits upon our decisions . . . looking to us to show ourselves capable of mastering our problems.” Today, we reflect on the history of this storied institution. And together, we recommit to sustaining and strengthening it to master the challenges of our time.

Under my Administration, the United States has been a leader at the United Nations—rallying global action to advance democratic values, safeguard human rights, and address the issues our world faces. That includes standing against Russia’s brutal aggression against Ukraine and Hamas’ despicable terrorist attack on Israel. At the United Nations, we have been working to secure a ceasefire in Gaza, with the release of hostages, and we have been pushing to expand humanitarian access and assistance. The United States has also played a key role in helping bring security to the people of Haiti and addressing the conflict and dire humanitarian situation in Sudan, where millions are displaced and facing famine.

But we know people need more than the absence of war. They need the chance to live with dignity. They need to be protected from the ravages of climate change, hunger, and disease. That is why my Administration has invested over \$150 billion to accelerate progress on the Sustainable Development Goals, including ending poverty, eliminating hunger, promoting health and well-being, and promoting gender equality. We also forged a historic consensus on the first-ever General Assembly Resolution on Artificial Intelligence to help people everywhere seize the potential—and minimize the risks—of this technology.

As we look ahead, countries need to work together to continue reforming the United Nations to be more effective. The United States will keep pushing for a stronger, more inclusive United Nations, including a reformed and expanded United Nations Security Council. And the Security Council, like the United Nations itself, needs to focus on making peace, brokering deals to end wars and suffering, stopping the spread of the most dangerous weapons, and stabilizing troubled regions.

Finally, the United Nations’ work is carried out by brave and committed United Nations humanitarian workers, development professionals, peacekeepers, and members of special political missions. And every day, they risk their own lives to save the lives of others, undertaking often dangerous work. Like nations around the world, the United States honors their sacrifices and those of their families.

Today and every day, let us remember that the forces holding us together are stronger than those pulling us apart. Let us continue to work together to unleash the power of humanity and give people the opportunity to live freely, think freely, breathe freely, and love freely. And in the face of difficult challenges, let us prove that we are capable of building a better world together.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 24, 2024, as United Nations Day. I urge the governors of the United States and its territories, and the officials of all other areas under the flag of the United States, to observe United Nations Day with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-third day of October, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-ninth.

A handwritten signature in black ink, appearing to read "J. R. Biden Jr.", is positioned to the right of the main text. The signature is written in a cursive style with a prominent diagonal stroke at the beginning.

Rules and Regulations

Federal Register

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Monday, October 28, 2024

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2023–1957; Airspace Docket No. 23–AAL–28]

RIN 2120–AA66

Amendment of Jet Route J–133 and Establishment of Area Navigation Route Q–801 in the Vicinity of Anchorage, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule correction published in the **Federal Register** of September 19, 2024, that amends Jet Route J–133 and establishes Area Navigation Route (RNAV) Q–801 in the vicinity of Anchorage, AK. This action corrects a typographical error in the regulatory text for J–133.

DATES: Effective date: 0901 UTC October 31, 2024.

ADDRESSES: FAA Order JO 7400.11J, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Steven Roff, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule for Docket No. FAA–2023–1957 in the

Federal Register (89 FR 70474; August 30, 2024) that amended Jet Route J–133 and established RNAV Q–801 in the vicinity of Anchorage, AK. Subsequent to publication, the FAA published a final rule correction for Docket No. FAA–2023–1957 in the **Federal Register** (89 FR 76713; September 19, 2024) that corrected a typographical error in the rule section of the final rule preamble, but inadvertently retained a typographical error in the regulatory text for J–133. The final rule and final rule correction listed the J–133 route points in a North to South order in error. The route points should be listed in a South to North order. This action corrects that error.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, Amendment of Jet Route J–133 and Establishment of Area Navigation Route Q–801 in the Vicinity of Anchorage, AK, published in the **Federal Register** of September 19, 2024 (89 FR 76713), FR Doc. 2024–21260, is corrected as follows:

On page 76714, in the middle of column 1, the description for Jet Route J–133 is revised to read as follows:

J–133 [Amended]

From Anchorage, AK; to Galena, AK.

* * * * *

Issued in Washington, DC, on October 22, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024–24934 Filed 10–25–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, 524, 529, 556, and 558

[Docket No. FDA–2024–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsor Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (CNADAs) during April, May, and June 2024. The animal drug regulations are also being amended to improve their accuracy and readability.

DATES: This rule is effective October 28, 2024.

FOR FURTHER INFORMATION CONTACT:

George K. Haibel, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, George.Haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and CNADAs during April, May, and June 2024, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOIA Summaries) under the Freedom of Information Act (FOIA). These documents, along with marketing exclusivity and patent information, may be obtained at Animal Drugs @FDA: <https://animaldrugsatfda.fda.gov/adafda/views/#/search>.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS, ANADAS, AND CNADAS APPROVED DURING APRIL, MAY, AND JUNE 2024 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS

Date of approval	File No.	Sponsor (drug labeler code)	Product name	Effect of the action	21 CFR section
April 5, 2024	141-043	Zoetis Inc, 333 Portage St., Kalamazoo, MI 49007 (054771).	SYNOVEX CHOICE (trenbolone acetate and estradiol benzoate) and SYNOVEX PRIMER (trenbolone acetate and estradiol benzoate).	Supplemental approval for increased rate of weight gain in growing beef steers and heifers in a dry lot.	522.2478
April 9, 2024	141-550	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140 (058198).	PRADALEX (pradofloxacin injection)	Original approval for treatment of bovine respiratory disease and swine respiratory disease.	522.1860 556.530
April 10, 2024	200-777	Felix Pharmaceuticals PVT Ltd., 25-28 North Wall Quay, Dublin 1, Ireland (086101).	Carprofen Injectable Solution	Original approval as a generic copy of NADA 141-199.	522.304
April 25, 2024	200-728	Cronus Pharma Specialties India Private Ltd., Plot No. 9(B), Survey No. 99/1, GMR Hyderabad Aviation SEZ Ltd., Mamidipalle Village, Balapur Mandal, Shamshabad, Rangareddy, Hyderabad, Telangana, 500108, India (069043).	PIMOMEDIN (pimobendan) Tablets	Original approval as a generic copy of NADA 141-033.	520.1780
April 26, 2024	141-582	Warburton Technology Ltd., 36 Fitzwilliam Square, Dublin, Dublin, D02HX82, Ireland (066679).	MULTIMIN 90 (zinc, copper, manganese, and selenium injection).	Original approval as a supplemental source of zinc, copper, manganese, and selenium in cattle.	522.2694
May 8, 2024	200-780	Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057-3009 (051072).	COCCIAID (amprolium) for Calves	Original approval as a generic copy of NADA 013-149.	520.100
May 9, 2024	200-782	Cronus Pharma Specialties India Private Ltd., Plot No. 9(B), Survey No. 99/1, GMR Hyderabad Aviation SEZ Ltd., Mamidipalle Village, Balapur Mandal, Shamshabad, Rangareddy, Hyderabad, Telangana, 500108, India (069043).	ENROPRO Silver Otic (enrofloxacin/silver sulfadiazine) Otic Emulsion.	Original approval as a generic copy of NADA 141-176.	524.802
May 10, 2024	141-577	Vetoquinol USA, Inc., 4250 N Sylvania Ave., Fort Worth, TX 76137 (017030).	UPCARD-CA1 (torsemide oral solution).	Conditional approval as concurrent therapy with pimobendan, spironolactone, and an angiotensin converting enzyme (ACE) inhibitor for the management of pulmonary edema in dogs with congestive heart failure caused by myxomatous mitral valve disease (MMVD).	516.2475
May 16, 2024	200-781	Cronus Pharma Specialties India Private Ltd., Plot No. 9(B), Survey No. 99/1, GMR Hyderabad Aviation SEZ Ltd., Mamidipalle Village, Balapur Mandal, Shamshabad, Rangareddy, Hyderabad, Telangana, 500108, India (069043).	FLUNINE (flunixin meglumine injection).	Original approval as a generic copy of NADA 101-479.	522.970
May 23, 2024	131-675	Intervet, Inc., 126 E Lincoln Ave., Rahway, NJ 07065 (000061).	SAFE-GUARD 20% (fenbendazole) Type A medicated article.	Supplemental approval for the treatment and control of ceccal worms (<i>Aulonocephalus</i> spp.) in wild quail.	558.258
June 4, 2024	138-255	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215 (058005).	Iron Dextran 20% Injection (iron hydrogenated dextran injection) Injectable Solution.	Supplemental approval for the prevention or treatment of iron deficiency anemia in nursing piglets.	522.1182
June 11, 2024	200-787	ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534 (086117).	Phenylpropanolamine Hydrochloride Chewable Tablets.	Original approval for the control of urinary incontinence due to urethral sphincter hypotonus in dogs as a generic copy of NADA 141-324.	520.1760
June 17, 2024	200-785	Felix Pharmaceuticals PVT Ltd., 25-28 North Wall Quay, Dublin 1, IRELAND.	Maropitant Citrate Tablets (maropitant citrate).	Original approval as a generic copy of NADA 141-262.	520.1315
June 20, 2024	200-784	ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534 (086117).	Trimeprazine with prednisolone tablets.	Original approval as a generic copy of NADA 012-437.	520.2604

II. Change of Sponsor

Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140 has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-582 for LONCOR 300 (florfenicol) Injectable Solution to Zoetis Inc, 333 Portage St., Kalamazoo, MI 49007. As provided in the regulatory text of this

document, the animal drug regulations are amended to reflect this action.

III. Change of Sponsor Address

Ivaoes Animal Health (drug labeler code 086064 in 21 CFR 510.600(c)) has informed FDA that it has changed its address to 2101 W Atlantic Blvd., Suite 108, Pompano Beach, FL 33069. The entries in § 510.600(c) are amended to reflect this action.

IV. Technical Amendments

FDA is making the following amendments to improve the accuracy and readability of the animal drug regulations.

- 21 CFR 510.600 is amended to revise the entries for Ivaoes Animal Health Inc. in the lists of sponsors of approved applications and to add entries for Warburton Technology Ltd.

- 21 CFR 516.1760 is being amended to provide for additional strengths of phenobarbital tablets.
- 21 CFR 520.2130 is amended to revise body weights of dogs and cats for treatment with spinosad chewable tablets.
- 21 CFR 520.2598 is being amended to reflect an additional strength trilostane capsule.
- 21 CFR 522.772 is amended to revise specific parasite indications and to reflect the prescription marketing status of doramectin and levamisole injectable solution for use in cattle.
- 21 CFR 522.970 is amended to reflect approved food-producing animal species for separate sponsor products.
- 21 CFR 522.1696b is amended to revise the preslaughter withdrawal period for cattle administered a penicillin G procaine aqueous suspension.
- 21 CFR 529.1004 is amended to reflect approved conditions of use for formalin in finfish.
- 21 CFR 529.1150 is amended to reflect approved conditions of use for hydrogen peroxide in freshwater-reared salmonids.
- 21 CFR 556.275 is amended by adding a tolerance for residues of fenbendazole in edible tissues of quail established as a consequence of the supplemental approval of fenbendazole medicated quail feed.
- 21 CFR 556.530 is added to provide tolerances for residues of pradofloxacin in edible tissues of cattle and swine.

- 21 CFR 558.261 is being amended to reflect incorporation levels of florfenicol in medicated feed for freshwater-reared salmonids.
- 21 CFR 558.450 is being amended to provide inclusion rates for oxytetracycline in medicated feed for finfish.

V. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C.360b(i)). Although deemed a rule pursuant to the FD&C Act, this document does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a “rule of particular applicability” and is not subject to the congressional review requirements in 5 U.S.C. 801–808. Likewise, this is not a rule subject to Executive Order 12866.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Dairy products, Foods, Meat and meat products.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 516, 520, 522, 524, 529, 556, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600(c):

■ a. In the table in paragraph (c)(1), revise the entry for “Ivaoes Animal Health” and add in alphabetical order an entry for “Warburton Technology Ltd.”; and

■ b. In the table in paragraph (c)(2), add an entry in numerical order for “066679” and revise the entry for “086064”.

The revisions and additions read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

*	*	*	*	*	*
(c)	*	*	*		
(1)	*	*	*		

Firm name and address	Drug labeler code
Ivaoes Animal Health, 2101 W Atlantic Blvd., Suite 108, Pompano Beach, FL 33069	086064
Warburton Technology Ltd., 36 Fitzwilliam Square, Dublin 2, Dublin, D02HX82, Ireland	066679

(2) * * *

Drug labeler code	Firm name and address
066679	Warburton Technology Ltd., 36 Fitzwilliam Square, Dublin 2, Dublin, D02HX82, Ireland.
086064	Ivaoes Animal Health, 2101 W Atlantic Blvd., Suite 108, Pompano Beach, FL 33069.

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 3. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

■ 4. In § 516.1760, revise paragraph (a) to read as follows:

§ 516.1760 Phenobarbital.

(a) *Specifications.* Each tablet contains 15, 16.2, 30, 32.4, 60, 64.8, 97.2 or 100 milligrams (mg) phenobarbital.

■ 5. Add § 516.2475 to subpart E to read as follows:

§ 516.2475 Torsemide.

(a) *Specifications.* Each milliliter of solution contains 0.2 milligrams (mg) torsemide.

(b) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer orally once daily at a dose of 0.05 to 0.2 mg/lb (0.11 to 0.44 mg/kg) of bodyweight.

(2) *Indications for use.* For use as concurrent therapy with pimobendan, spironolactone, and an angiotensin converting enzyme (ACE) inhibitor for the management of pulmonary edema in dogs with congestive heart failure caused by myxomatous mitral valve disease (MMVD).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 6. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 7. In § 520.100, revise paragraph (b)(2), and remove paragraph (b)(3) to read as follows:

§ 520.100 Amprolium.

* * * * *

(b) * * *

(2) Nos. 051072 and 066104 for use of product described in paragraph (a)(1) of this section as in paragraph (d) of this section.

* * * * *

■ 8. In § 520.1315, revise paragraph (b) to read as follows:

§ 520.1315 Maropitant.

* * * * *

(b) *Sponsors.* See Nos. 054771, 086101, and 086117 in § 510.600(c) of this chapter.

* * * * *

■ 9. In § 520.1760, revise paragraph (b) to read as follows:

§ 520.1760 Phenylpropranolamine.

* * * * *

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) Nos. 055246 and 086117 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1)(i) and (c)(2) and (3) of this section.

(2) No. 055246 for use of product described in paragraph (a)(2) of this section as in paragraph (c)(1)(ii) and (c)(2) and (3) of this section.

* * * * *

■ 10. In § 520.1780, revise paragraph (b) to read as follows:

§ 520.1780 Pimobendan tablets.

* * * * *

(b) *Sponsors.* See Nos. 000010 and 069043 in § 510.600(c) of this chapter.

* * * * *

§ 520.2130 [Amended]

■ 11. In § 520.2130:

■ a. In paragraph (d)(1)(ii), remove the text “3.3 pounds” and in its place add the text “5.0 pounds”; and

■ b. In paragraph (d)(2)(ii), remove the text “2 pounds” and in its place add the text “4.1 pounds”.

■ 12. In § 520.2598, revise paragraph (a) to read as follows:

§ 520.2598 Trilostane.

(a) *Specifications.* Each capsule contains 5, 10, 20, 30, 60, or 120 milligrams (mg) trilostane.

* * * * *

■ 13. In § 520.2604, revise paragraph (b) to read as follows:

§ 520.2604 Trimeprazine and prednisolone tablets.

* * * * *

(b) *Sponsors.* See Nos. 054771 and 086117 in § 510.600(c) of this chapter.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 14. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 15. In § 522.304, revise paragraph (b) to read as follows:

§ 522.304 Carprofen.

* * * * *

(b) *Sponsors.* See Nos. 016729, 017033, 054771, 055529, 069043, and 086101 in § 510.600(c) of this chapter.

* * * * *

■ 16. In § 522.772:

■ a. Revise paragraph (d)(1)(ii); and

■ b. In paragraph (d)(1)(iii), add a sentence to the end of the paragraph.

The revision and addition read as follows:

§ 522.772 Doramectin and levamisole.

* * * * *

(d) * * *

(1) * * *

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms (adults and fourth stage larvae): *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *T. longispicularis* (adults only), *Oncophora*, *Cooperia pectinata* (adults only), *C. punctata*, *C. surnabada*, *Bunostomum phlebotomum* (adults only), *Strongyloides papillosus* (adults only), *Oesophagostomum radiatum*, *Trichuris* spp. (adults only) and *Nematodirus helvetianus* (adults only); lungworms (adults and fourth stage larvae): *Dictyocaulus viviparus*; eyeworms (adults): *Thelazia* spp.; grubs (parasitic stages): *Hypoderma bovis* and *H. lineatum*; sucking lice: *Haematopinus eurysternus*, *Linognathus vituli*, and *Solenopotes capillatus*; mange mites: *Psoroptes bovis* and *Sarcoptes scabiei* in beef cattle 2 months of age and older and replacement dairy heifers less than 20 months of age. Not for use in beef bulls intended for breeding over 1 year of age, dairy calves, and veal calves.

(iii) * * * Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

§ 522.955 [Amended]

■ 17. In § 522.955:

■ a. In paragraph (b)(3), remove the text “Nos. 058005, 058198, and 069043” and in its place add the text “Nos. 054771, 058005, and 069043”; and

■ b. In paragraph (d)(1)(ii)(C), in the second sentence, remove the text “Nos. 000061, 058005, 058198, and 069043” and in its place add the text “Nos. 000061, 054771, 058005, and 069043”.

■ 18. In § 522.970, revise paragraphs (b)(1) and (3) to read as follows:

§ 522.970 Flunixin.

* * * * *

(b) * * *

(1) See Nos. 000061, 055529, and 061133 for use as in paragraph (e) of this section.

* * * * *

(3) See Nos. 016592, 058198, and 069043 for use as in paragraphs (e)(1) and (2) of this section.

* * * * *

■ 19. In § 522.1182, revise introductory text of paragraph (b)(7) to read as follows:

§ 522.1182 Iron injection.

* * * * *

(b) * * *

(7) Nos. 016592, 042552, and 058005 for use product described in paragraph (a)(2) of this section as follows:

* * * * *

■ 20. In § 522.1696b, revise paragraph (d)(2)(iii)(B) to read as follows:

§ 522.1696b Penicillin G procaine aqueous suspension.

* * * * *

(d) * * *

(2) * * *

(iii) * * *

(B) For Nos. 016592 and 055529: treatment should not exceed 4 consecutive days. A withdrawal period has not been established for this product in pre-ruminating calves. Discontinue treatment for the following number of days before slaughter: cattle—14; sheep—9; and swine—7.

* * * * *

■ 21. Add § 522.1860 to read as follows:

§ 522.1860 Pradofloxacin.

(a) *Specifications.* Each milliliter (mL) of solution contains 200 milligrams (mg) pradofloxacin.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.530 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer a single dose of 10 mg/kg (2.3 mL/100 lb) body weight by subcutaneous injection.

(ii) *Indications for use.* Cattle intended for slaughter (beef calves 2 months of age and older, growing beef steers, growing beef heifers, and beef bulls intended for slaughter), and in cattle intended for breeding less than 1 year of age (replacement beef and dairy heifers less than 1 year of age and beef and dairy bulls less than 1 year of age): for the treatment of bovine respiratory disease associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*.

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 4 days of treatment. Not for use in female dairy cattle 1 year of age and older, including dry dairy cows; use in these cattle may cause drug residues in milk and/or in calves born

to these cows. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

(2) *Swine*—(i) *Amount.* Administer a single dose of 7.5 mg/kg (1.7 mL/100 lb) body weight by intramuscular injection.

(ii) *Indications for use.* Weaned swine intended for slaughter (nursery, growing, and finishing swine, boars intended for slaughter, barrows, gilts intended for slaughter, and sows intended for slaughter): for the treatment of swine respiratory disease associated with *Bordetella bronchiseptica*, *Glaeserella (Haemophilus) parasuis*, *Pasteurella multocida*, *Streptococcus suis*, and *Mycoplasma hyopneumoniae*.

(iii) *Limitations.* Swine intended for human consumption must not be slaughtered within 2 days of treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

■ 22. In § 522.2478:

■ a. Redesignate paragraphs (a)(1)(i) and (ii) as paragraphs (a)(1)(ii) and (iii);

■ b. Add new paragraph (a)(1)(i);

■ c. Revise paragraphs (d)(1)(i)(A), (B), and (D); and

■ d. Add paragraph (d)(3).

The revisions and additions read as follows:

§ 522.2478 Trenbolone acetate and estradiol benzoate.

(a) * * *

(1) * * *

(i) 50 milligrams (mg) trenbolone acetate and 7 mg estradiol benzoate (one implant consisting of two pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) An implant containing 100 mg trenbolone acetate and 14 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain in growing beef steers fed in confinement for slaughter and for increased rate of weight gain and improved feed efficiency in growing beef heifers fed in confinement for slaughter. For increased rate of weight gain for up to 200 days in a reimplantation program where an implant as described in paragraph

(a)(1)(ii) of this section is the first implant and an implant as described in paragraph (a)(1)(ii) or (iii) or (a)(2)(ii) of this section is administered 60 to 120 days later.

(B) An implant containing 200 mg trenbolone acetate and 28 mg estradiol benzoate as described in paragraph (a)(1)(iii) of this section for increased rate of weight gain and improved feed efficiency in growing beef steers fed in confinement for slaughter and for increased rate of weight gain in growing beef heifers fed in confinement for slaughter. For increased rate of weight gain for up to 200 days in a reimplantation program where an implant as described in paragraph (a)(1)(ii) of this section is the first implant and an implant as described in paragraph (a)(1)(iii) of this section is administered 60 to 120 days later.

* * * * *

(D) An extended-release implant containing 200 mg trenbolone acetate and 28 mg estradiol benzoate as described in paragraph (a)(2)(ii) of this section for increased rate of weight gain and improved feed efficiency for up to 200 days. For increased rate of weight gain for up to 200 days in a reimplantation program where an implant as described in paragraph (a)(1)(ii) of this section is the first implant and an implant as described in paragraph (a)(2)(ii) of this section is administered 60 to 120 days later.

* * * * *

(3) *Growing beef steers and heifers in a dry lot*—(i) *Amount and indications for use.* (A) An implant containing 50 mg trenbolone acetate and 7 mg estradiol benzoate as described in paragraph (a)(1)(i) of this section for increased rate of weight gain in growing beef steers and heifers in a dry lot.

(B) An implant containing 100 mg trenbolone acetate and 14 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain in growing beef steers and heifers in a dry lot.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers in a dry lot. Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle

may cause drug residues in milk and/or in calves born to these cows.

■ 23. Add § 522.2694 to read as follows:

§ 522.2694 Zinc, copper, manganese, and selenium.

(a) *Specifications.* Each milliliter (mL) of solution contains 60 milligrams (mg) zinc as zinc oxide, 15 mg copper as copper carbonate, 10 mg manganese as manganese carbonate, and 5 mg selenium as sodium selenite.

(b) *Sponsor.* See No. 066679 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Administer a single dose by subcutaneous injection to cattle up to 1 year of age, 1 mL/100 lb bodyweight; to cattle from 1 to 2 years of age, 1 mL/150 lb bodyweight, and to cattle over 2 years of age, 1 mL/200 lb bodyweight.

(2) *Indications for use.* As a supplemental source of zinc, copper, manganese, and selenium in cattle.

(3) *Limitations.* Cattle must not be slaughtered for human food consumption within 14 days of the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 24. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 25. In § 524.802, revise paragraph (b) to read as follows:

§ 524.802 Enrofloxacin and silver sulfadiazine otic emulsion.

(b) *Sponsors.* See Nos. 058198 and 069043 in § 510.600(c) of this chapter.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 26. The authority citation for part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 27. In § 529.1004, in the table in paragraph (d)(2)(ii), revise footnote 1 to read as follows:

§ 529.1004 Formalin.

- (d) * * *
- (2) * * *
- (ii) * * *

Aquatic species	Administer in tanks and raceways for up to 1 hour (microliter/liter or part per million (µL/L or ppm))	Administer in earthen ponds single treatment (µL/L or ppm)
*	*	*

¹ Use the lower concentration when ponds are heavily loaded with phytoplankton or fish to avoid oxygen depletion due to the biological oxygen demand by decay of dead phytoplankton. Alternatively, a higher concentration may be used if dissolved oxygen is strictly monitored.

■ 28. In § 529.1150, revise paragraph (c)(1)(iv) to read as follows:

§ 529.1150 Hydrogen peroxide.

- (c) * * *
- (1) * * *

(iv) Freshwater-reared salmonids for the treatment and control of *Gyrodactylus* spp: 100 mg/L for 30 minutes, or 50 mg/L for 60 minutes, in a continuous flow water supply or as a static bath once per day on alternate days for three treatments.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 29. The authority citation for part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 30. In § 556.275, add paragraph (b)(6) to read as follows:

§ 556.275 Fenbendazole.

- (b) * * *
- (6) *Quail.* (i) Liver (target tissue): 6 ppm fenbendazole sulfone (marker residue).
- (ii) [Reserved]

■ 31. Add § 556.530 to subpart B to read as follows:

§ 556.530 Pradofloxacin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of pradofloxacin is 2 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for pradofloxacin (marker residue) are:

- (1) *Cattle.* Kidney (target tissue): 30 ppb.

(2) *Swine.* Kidney (target tissue): 1 ppm.

(c) *Related conditions of use.* See § 522.1860 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 32. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

■ 32. In § 558.258, add heading to paragraph (e)(1) and add paragraph (e)(5)(iv) to read as follows:

§ 558.258 Fenbendazole.

- (e) * * *
- (1) *Turkeys.*
- (5) * * *

Species/class	Fenbendazole grams per ton	Indications for use	Limitations	Sponsor
(iv) Wild quail	90.7	For the treatment and control of Gastrointestinal worms: cecal worms (<i>Aulonocephalus</i> spp.).	Feed for 21 consecutive days. Prior withdrawal of feed is not necessary.	000061

■ 33. In § 558.261, revise paragraph (e)(2)(ii) to read as follows:

§ 558.261 Florfenicol.

- (e) * * *

- (2) * * *

Florfenicol in grams/ton of feed	Indications for use	Limitations
(ii) 182 to 2,724	Freshwater-reared salmonids: for the control of mortality due to coldwater disease associated with <i>Flavobacterium psychrophilum</i> and furunculosis associated with <i>Aeromonas salmonicida</i> .	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

* * * * * **§ 558.450 Oxytetracycline.**

■ 34. In § 558.450, revise paragraphs (e)(5)(iv), (v), and (vi) to read as follows:

(5) * * *

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(iv) 333 to 7,500 g/ton to provide 2.5 to 3.75 g/100 lb of fish/day.	1. Freshwater-reared salmonids: for control of ulcer disease caused by <i>Haemophilus piscium</i> , furunculosis caused by <i>Aeromonas salmonicida</i> , bacterial hemorrhagic septicemia caused by <i>A. hydrophila</i> , and pseudomonas disease. 2. Catfish: for control of bacterial hemorrhagic septicemia caused by <i>A. hydrophila</i> and pseudomonas disease.	Administer in mixed ration for 10 days. Do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed.	066104
(v) 500 to 7,500 g/ton to provide 3.75 g/100 lb of fish/day.	1. Freshwater-reared salmonids: for control of mortality due to coldwater disease associated with <i>Flavobacterium psychrophilum</i> or for control of mortality due to columnaris disease associated with <i>Flavobacterium columnare</i> . 2. Freshwater-reared salmonids weighing up to 55 grams: for marking of the skeletal tissue. 3. Catfish: for control of mortality due to columnaris disease associated with <i>Flavobacterium columnare</i> .	Administer in mixed ration for 10 days. Do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed. Do not administer when water temperature is below 16.7 °C (62 °F).	066104
(vi) 1.25 to 25 g/kg to provide 11.35 g/100 lb of fish/day.	Pacific salmon not over 30 grams body weight: for marking of the skeletal tissue.	Administer medicated feed as the sole ration for 4 consecutive days. Do not liberate for at least 7 days following last feeding of medicated feed.	066104

* * * * *
Dated: October 21, 2024.

Eric Flamm,
Acting Associate Commissioner for Policy.
[FR Doc. 2024-24820 Filed 10-25-24; 8:45 am]
BILLING CODE 4164-01-P

DEPARTMENT OF STATE

22 CFR Part 92

[Public Notice: 12553]

RIN 1400-AF89

Notarial and Related Services

AGENCY: Bureau of Consular Affairs, Department of State.
ACTION: Final rule.

SUMMARY: The Bureau of Consular Affairs amends its notarial rules to reflect that the Director, Deputy Directors, and regional Division Chiefs of the Office of American Citizens Services and Crisis Management, Overseas Citizens Services will

designate U.S. citizen employees of the Department of State abroad, who are not diplomatic or consular officers, to perform notarial services. This change will streamline the designation process allowing expedited designation to provide this and expedite notarial service where needed at U.S. embassies and consulates abroad.

DATES: This rule is effective on November 27, 2024.

FOR FURTHER INFORMATION CONTACT: Thales Dus, U.S. Department of State, CA/OCS/MSU, SA-17, 10th Floor, Washington, DC 20522-1707, OCSRegs@state.gov, 202-485-6020.

SUPPLEMENTARY INFORMATION: This final rule modifies the Department's regulations on Notarial and Related Services in 22 CFR part 92.

Amendments to § 92.1 authorize the Director, Deputy Directors and regional Division Chiefs of the Office of American Citizens Services and Crisis Management, Bureau of Consular Affairs, to designate U.S. citizen employees of the U.S. Department of

State abroad, who are not diplomatic or consular officers, to perform notarial services at U.S. diplomatic and consular offices abroad. This change will replace the authorization for the Deputy Assistant Secretary for Overseas Citizens Services as the sole Department official able to designate U.S. citizen employees of the Department abroad as notarizing officers.

The Department is making this change to improve efficiencies in the process of designating Department employees as notarizing officers at U.S. embassies and consulates abroad. Demand for notarial services at 230 diplomatic and consular posts abroad varies from year to year but the trend line for requests for notarial services is ever increasing. The authority to designate U.S. citizen Department employees as notarizing officers has been a key resource for addressing increasing demand at posts abroad. The changes to this regulation authorizing an increase in the number of persons able to make such designations will place the Department on a more

nimble, efficient footing able to better manage capacity demands.

Regulatory Findings

Administrative Procedure Act

This rule is a rule of agency organization, procedure, or practice, and thus is exempt from the “notice and comment” requirements of the Administrative Procedure Act. 5 U.S.C. 553(b). Pursuant to 5 U.S.C. 553(d), this rule will be effective 30 days after publication.

Regulatory Flexibility Act

The Department of State, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by 5 U.S.C. 804. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and import markets.

Executive Order 12866, 14094, and 13563

The Office of Information and Regulatory Affairs has designated this rulemaking as not significant under Executive Order 12866, section 3(f), *Regulatory Planning and Review*. The Department has reviewed the regulation to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866, as amended by Executive Order 14094.

The Department of State has considered this rule in light of Executive Order 13563, dated January 18, 2011, and affirms that this regulation is consistent with the guidance therein. Global notarial service volume in recent years was as follows:

2024–212,142 (as of August 2024)
2023–233,923
2022–263,036

The number of Designations of Notarizing Officers approved by the Deputy Assistant Secretary for Overseas Citizens Services in recent years are:

2024–130 (as of September 2024)
2023–114
2022–90

This rule will authorize more individuals than the Deputy Assistant Secretary to make designations of Notarizing Officers. The Department believes this will benefit both the public and the Department, and any cost associated with this change is outweighed by the efficiency this should add to the notary process.

Executive Orders 12372 and 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this regulation.

Paperwork Reduction Act

This rule does not impose any new reporting or record-keeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 92

Notarial and related services.

For the reasons set out in the preamble, 22 CFR part 92 is amended as follows:

PART 92—NOTARIAL AND RELATED SERVICES

■ 1. The authority citation for part 92 is revised to read as follows:

Authority: 22 U.S.C. 2651a, 2656, 4215 and 4221.

§ 92.1 [AMENDED]

■ 2. Amend § 92.1 by revising paragraph (d) and removing the undesignated paragraph following paragraph (d) to read as follows:

§ 92.1 Definitions.

* * * * *

(d) For purposes of this part, except §§ 92.36 through 92.42 relating to the authentication of documents, the term “notarizing officer” includes consular officers, officers of the Foreign Service who are secretaries of embassy or legation under section 24 of the Act of August 18, 1856, 11 Stat. 61, as amended (22 U.S.C. 4221), and such U.S. citizen Department of State employees as the Director or Deputy Directors, and regional Division Chiefs, Office of American Citizens Services and Crisis Management, Overseas Citizens Services, Bureau of Consular Affairs, U.S. Department of State may designate for the purpose of performing notarial acts overseas pursuant to Section 127(b) of the Foreign Relations Authorization Act, Fiscal Years 1994–1995, Public Law 103–236, April 30, 1994 (“designated employees”). The authority of designated employees to perform notarial services shall not include the authority to perform authentications, to notarize patent applications, or take testimony in a criminal action or proceeding pursuant to a commission issued by a court in the United States, but shall otherwise encompass all notarial acts, including but not limited to administering or taking oaths, affirmations, affidavits or depositions. The notarial authority of a designated employee shall expire upon termination of the employee’s assignment to such duty and may also be terminated at any time by the Director or Deputy Directors, or regional Division Chiefs of the Office of American Citizen Services and Crisis Management, Overseas Citizens Services, Bureau of Consular Affairs, U.S. Department of State.

Angela M. Kerwin,

Deputy Assistant Secretary, Bureau of Consular Affairs/Office of Overseas Citizen Services, Department of State.

[FR Doc. 2024–24890 Filed 10–25–24; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF THE TREASURY**31 CFR Part 33****DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Parts 435 and 600****Office of the Secretary****45 CFR Parts 153, 155, and 156**

[CMS–9895–F2]

RIN–0938–AV22

Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO–OP) Program; and Basic Health Program; Correcting Amendment**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Correcting amendment.

SUMMARY: This document corrects technical and typographical errors in the final rule that appeared in the April 15, 2024 issue of the **Federal Register** entitled, “Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO–OP) Program; and Basic Health Program.” The effective date of the final rule was June 4, 2024.

DATES: Effective October 28, 2024 and applicable beginning June 4, 2024.

FOR FURTHER INFORMATION CONTACT: Dolma Tsering, (301) 448–3925.

SUPPLEMENTARY INFORMATION:**I. Background**

In FR Doc. 2024–07274 of April 15, 2024 (89 FR 26218), the final rule entitled “Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO–OP) Program; and Basic Health Program” (hereinafter referred to as the 2025 Payment Notice), there were technical errors that are identified and corrected in the regulations text of this correcting amendment. The provisions of this correcting amendment are effective October 28, 2024 and are applicable beginning June 4, 2024.

II. Summary of Errors in the Regulation Text

On page 26424, in the amendatory instruction for § 156.111, we inadvertently noted changes to paragraph (b)(2) and not specifically paragraphs (b)(2)(i) and (ii). Therefore, paragraphs (b)(2)(iii) through (v) were inadvertently deleted.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the notice.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

Our policy on streamlining the process for States to update their Essential Health Benefits (EHB) benchmark plans in the 2025 Payment Notice has previously been subjected to notice and comment procedures. This correcting amendment is consistent with the discussion of this policy in the 2025 Payment Notice and does not make substantive changes to this policy. Instead this correcting amendment merely corrects technical errors, specifically an unintended deletion, in the regulations text caused by an error in the amendatory instructions of the 2025 Payment Notice. As a result, this correcting amendment is intended to ensure that the 2025 Payment Notice accurately reflects the policy adopted in the final rule, which did not otherwise indicate any intention to delete the regulations text that was unintentionally deleted. Therefore, we find that undertaking further notice and comment procedures to incorporate these corrections into the final rule is unnecessary and contrary to the public interest.

For the same reasons, we are also waiving the 30-day delay in effective

date for this correcting amendment. We believe that it is in the public interest to ensure that the regulations text accurately reflects the policy set forth in the 2025 Payment Notice streamlining the process for States to update their EHB-benchmark plans. Thus, delaying the effective date of this correcting amendment would be contrary to the public interest. Therefore, we also find good cause to waive the 30-day delay in effective date.

List of Subjects in 45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

For the reasons set forth in the preamble, HHS corrects 45 CFR part 156 by making the following correcting amendments:

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 1. The authority citation for part 156 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 2. Section 156.111 is amended by adding paragraphs (b)(2)(iii) through (v) to read as follows:

§ 156.111 State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020.

* * * * *

(b) * * *

(2) * * *

(iii) Not have benefits unduly weighted towards any of the categories of benefits at § 156.110(a);

(iv) Provide benefits for diverse segments of the population, including women, children, persons with disabilities, and other groups; and

(v) Not include discriminatory benefit designs that contravene the non-

discrimination standards defined in § 156.125.

* * * * *

Elizabeth J. Gramling,

*Executive Secretary to the Department,
Department of Health and Human Services.*

[FR Doc. 2024–24910 Filed 10–25–24; 8:45 am]

BILLING CODE 4120–01–M

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0391]

RIN 1625–AA00

Safety Zone; Choctawhatchee Bay, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Choctawhatchee Bay where unexploded ordnances were discovered and a moving safety zone around vessels relocating any unexploded ordnance from Choctawhatchee Bay to the disposal location. The safety zones are needed to protect mariners from the hazards associated with unexploded ordnance clearance operations. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Mobile (COTP), or a designated representative.

DATES: This rule is effective without actual notice from October 28, 2024 through 11:59 p.m. on December 31, 2024. For the purposes of enforcement, actual notice will be used from 1 p.m. on October 22, 2024, until October 28, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0391 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email MSTC Stacy Stevenson, Waterways Management Division, U.S. Coast Guard; telephone 251–382–8653, email Sectormobilewaterways@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary final rule under authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to public interest. It is impracticable to publish an NPRM because we must establish this safety zone by October 22, 2024, and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule. Publishing an NPRM is contrary to public interest because immediate action is needed to protect people and property on the waterway from potential hazards associated with unexploded ordnance operations.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule is contrary to public interest because it would delay the safety measures necessary to respond to potential safety hazards associated with the unexploded ordnance operations.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Mobile (COTP) has determined that the safety zones are necessary for the protection of persons and vessels from potential hazards associated with the unexploded ordnance operations.

IV. Discussion of the Rule

The Coast Guard is establishing a temporary safety zone on certain navigable waters of the Choctawhatchee Bay within a 5,000 foot radius of approximate position 30°25′38.1″ N, 86°33′32.5″ W, and a moving safety zone within a 600 yard radius from any vessel involved with relocating the unexploded ordnance upon leaving the area where the ordnance was discovered until it is safely positioned in the disposal location. The safety zones will be enforced from 1 p.m. on October 22,

2024, until 11:59 p.m. on December 31, 2024. The duration of the zone is intended to protect personnel, vessels, and ensure maritime safety and security in these navigable waters during unexploded ordnance clearing operations. No vessel or person will be permitted to enter the safety zones without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. This stationary safety zone will be enforced for approximately 11 weeks or less and prohibit vessel movement on a portion of the Choctawhatchee Bay and a moving safety zone around relocating unexploded ordnances to the disposal location. Moreover, the Coast Guard will issue on scene actual notice via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. While some owners or operators of vessels intending to transit the safety zone may be small entities, for the

reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule affects your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting eleven weeks or less that will prohibit entry on a portion of the Choctawhatchee Bay and a moving safety zone around a vessel involved in relocating any unexploded ordnance to the disposal location. It is categorically excluded from further review under paragraph L60(d) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Marine safety, Navigation (water), Reporting, recordkeeping requirements, and Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T08–0391 to read as follows:

§ 165.T08–0391 Safety Zone; Choctawhatchee Bay, FL.

(a) *Location.* The following area is a safety zone: All navigable waters of the Choctawhatchee Bay within a 5,000 foot radius of approximate position 30°25'38.1" N, 86°33'32.5" W, and a moving safety zone 600 yards around any vessel involved with relocating the unexploded ordnance upon leaving the area where the ordnance was discovered until it is safely positioned in the disposal location.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Sector Mobile Captain of the Port (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zones described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative. No person may anchor, dredge, or trawl in the safety zones unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's designated representative on VHF–CH 16. Those in the safety zones must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be subject to enforcement from 1 p.m. on October 22, 2024, through 11:59 p.m. on December 31, 2024. The enforcement period will be announced via on-scene actual notice via VHF–FM marine channel 16.

Dated: October 21, 2024.

M.O. Vega,

Captain, U.S. Coast Guard, Captain of the Port Sector Mobile.

[FR Doc. 2024–24932 Filed 10–25–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0895]

RIN 1625–AA00

Safety Zone; Upper Galveston Bay, Kemah, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within an 840-foot radius of the firework display barge in the Galveston Bay on the south side of the channel, near Kemah Boardwalk in Kemah, TX. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Houston-Galveston.

DATES: This rule is effective from 8 p.m. until 10 p.m. on November 9, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0895 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Rudy Ortega, Sector Houston-Galveston Waterways Management Division, U.S. Coast Guard; telephone (713) 398–5823, email houstonwww@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
 DHS Department of Homeland Security
 FR Federal Register
 NPRM Notice of proposed rulemaking
 § Section
 U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” The Coast Guard finds that

good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable due to notice period prior to the event. The Coast Guard must establish this safety zone by November 9, 2024 and prompt action is required to respond to the potential safety hazards associated with a fireworks display.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because prompt action is needed to respond to the potential safety hazards of the event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Houston-Galveston (COTP) has determined that potential hazards associated with the fireworks show on November 9, 2024, in Kemah, TX, will be a safety concern for anyone within an 840-foot radius of a fireworks display barge, located in Galveston Bay, TX at 29°32′52.72″ N, 95°00′54.38″ W, on the south side of the channel. The purpose of this rulemaking is to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone before, during, and after the scheduled fireworks display.

IV. Discussion of the Rule

This rule establishes a safety zone from 8 p.m. until 10 p.m. on November 9, 2024. The safety zone will cover all navigable waters within an 840-foot radius of a fireworks display barge, located in Galveston Bay, TX, at 29°32′52.72″ N, 95°00′54.38″ W, on the south side of the channel. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters before, during, and after the fireworks display. No vessel or person is permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. Persons or vessels seeking to enter the safety zone must request permission from the COTP on VHF–FM channel 16 or by telephone at 866–539–8114. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative. The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners, Local Notices to Mariners, or Safety Marine Information Broadcasts as appropriate.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, duration, and location of the safety zone. The safety zone will last for the limited duration of two hours. It covers an 840-foot radius of navigable waters of Galveston Bay, TX. The zone does not completely restrict vessel traffic and allows mariners to ask for permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the

person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023-01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone lasting only two hours that will prohibit entry within 840 feet of the fireworks display barge. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

- 2. Add § 165.T08-0895 to read as follows:

§ 165.T08-0895 Safety Zone; Galveston Bay, Galveston, TX.

(a) *Location.* The following area is a safety zone: All navigable waters within an 840-foot radius of a fireworks display barge, located in Galveston Bay, TX at 29°32'52.72" N, 95°00'54.38" W, on the south side of the channel.

(b) *Definition.* The term "designated representative" means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Houston-Galveston (COTP) in the enforcement of the regulated areas.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, no person will be permitted to enter, transit, anchor, or remain within the safety zone described in paragraph (a) of this section unless authorized by the COTP or a designated representative. If authorization is granted, persons and vessels receiving such authorization must comply with the lawful instructions of the COTP or designated representative.

(2) Persons or vessels seeking to enter the safety zone must request permission from the COTP on VHF-FM channel 16 or by telephone at 866-539-8114.

(d) *Enforcement period.* This section will be enforced from 8 p.m. until 10 p.m. on November 9, 2024.

Dated: October 22, 2024.

Keith M. Donohue,

Captain, U.S. Coast Guard, Captain of the Port Sector Houston-Galveston.

[FR Doc. 2024-24987 Filed 10-25-24; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 2 and 7

[Docket No. PTO-T-2024-0043]

Changes in Post-Registration Audit Selection for Affidavits or Declarations of Use, Continued Use, or Excusable Nonuse in Trademark Cases

AGENCY: United States Patent and Trademark Office, U.S. Department of Commerce.

ACTION: Policy update.

SUMMARY: To promote the accuracy and integrity of the trademark register, the United States Patent and Trademark Office (USPTO or Office) is amending its practice concerning the selection of registrations for audit during the post-registration maintenance process. When the USPTO implemented its audit program in 2017, it announced that it would conduct random audits of certain affidavits or declarations filed each year. To promote the accuracy and integrity of the trademark register, the USPTO is adding additional directed audits to its practice.

DATES:

Effective date: This policy change is effective October 28, 2024.

Comments due: Written comments must be received on or before November 27, 2024 to ensure consideration.

ADDRESSES: Written comments must be submitted through the Federal eRulemaking Portal at www.regulations.gov. To submit comments via the portal, commenters should go to www.regulations.gov/docket/PTO-T-2024-0043 or enter docket number PTO-T-2024-0043 on the www.regulations.gov homepage and select the “Search” button. The site will provide search results listing all documents associated with this docket. Commenters can find a reference to this document and select the “Comment” button, complete the required fields, and enter or attach their comments. Attachments to electronic comments will be accepted in Adobe portable document format (PDF) or Microsoft Word format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of comments is not possible, please contact the USPTO using the contact information below in the **FOR FURTHER INFORMATION CONTACT** section of this document for special instructions.

FOR FURTHER INFORMATION CONTACT: Montia Pressey, Office of the Deputy Commissioner for Trademark Examination Policy, at 571-272-8944 or TMPolicy@uspto.gov.

SUPPLEMENTARY INFORMATION: On January 19, 2017, the USPTO published in the **Federal Register** a final rule making permanent the program under which it conducts audits of the affidavits or declarations of continued use or excusable nonuse filed pursuant to section 8 of the Trademark Act (the Act) (15 U.S.C. 1058), and affidavits or declarations of use in commerce or excusable nonuse filed pursuant to section 71 of the Act (15 U.S.C. 1141k) (collectively, affidavits or declarations). See Changes in Requirements for Affidavits or Declarations of Use, Continued Use, or Excusable Nonuse in Trademark Cases (82 FR 6259). The final rule provided the USPTO with the authority to request additional information in connection with the submission of an affidavit or declaration under sections 8 or 71 to assess and promote the accuracy and integrity of the trademark register.

As explained in the final rule, the post-registration audit program benefits the public because it facilitates the USPTO’s ability to assess and promote the integrity of the trademark register by encouraging accuracy in the identification of goods or services for which use in commerce or continued use is claimed. The accuracy of the trademark register serves an important purpose for the public, as it is a reflection of marks that are actually in use in commerce in the United States for the goods/services identified in the registrations listed in the register. The public relies on the register to determine whether a chosen mark is available for use or registration. If a party’s search of the register discloses a potentially confusingly similar mark, that party may incur a variety of resulting costs and burdens, such as those associated with investigating the actual use of the disclosed mark to assess any conflict, proceedings to cancel the registration or oppose the application of the disclosed mark, civil litigation to resolve a dispute over the mark, or changing plans to avoid use of the party’s chosen mark. If a registered mark is not in use in commerce in the United States, or is not in use in commerce in connection with all the goods or services identified in the registration, these costs and burdens may be incurred unnecessarily. An accurate and reliable trademark register helps parties avoid such needless costs and burdens.

The statutory requirements in sections 8 and 71 exist to enable the USPTO to clear the register by canceling, in whole or in part, registrations for marks that are not in use in commerce for all or some of the goods or services identified in the registration. The final rule furthered this statutory purpose by allowing the USPTO to assess whether marks are actually in use for some or all of the goods or services covered by a registration, and to require deletion and/or cancellation of those goods or services for which a mark is not in use (and for which excusable nonuse does not apply).

To that end, the final rule provided the USPTO with the authority to require the submission of information, exhibits, affidavits or declarations, and such additional specimens of use as may be reasonably necessary for the USPTO to ensure that the register accurately reflects marks that are in use in commerce in the United States for all the goods or services identified in the registrations, unless excusable nonuse is claimed in whole or in part. This authority was not limited to random audits. However, because the USPTO previously announced that selection for

the audits would be done on a random basis, the agency now provides notice that it amends its practice under 37 CFR 2.161(b) and 7.37(b) to include directed audits.

Since the final rule was adopted in 2017, the USPTO has become aware of circumstances in which the accuracy and integrity of the trademark register would benefit from directed audits in addition to the current practice of random audits. Specifically, the USPTO discovered systemic efforts to subvert the requirements for use in commerce of a mark to support registration.

First, the USPTO became aware of an ongoing issue of applicants submitting specimens that were digitally created or altered or were mockups and thus did not show actual use in commerce, as is required. That awareness led to the publication in July 2019 of Examination Guide 3-19, Examination of Specimens for Use in Commerce: Digitally Created/Altered or Mockup Specimens, which was later incorporated into the Trademark Manual of Examining Procedure.

Second, the enactment of the Trademark Modernization Act in 2020, and its implementation by the USPTO in 2021, resulted in the creation of two new post-registration proceedings that allow the Office to examine whether a registered mark is, or was at the time of registration, in use in commerce for goods or services covered by the registration. See Changes To Implement Provisions of the Trademark Modernization Act of 2020, 86 FR 64300 (November 17, 2021). Certain disturbing trends have been discovered since the implementation of these proceedings, such as the use of specimen farms. These are websites that do not sell products in the ordinary course of trade. Instead, they provide applicants or registrants with documents to submit to the USPTO that appear to satisfy the requirement to show use of the mark in commerce on the goods recited in the application or registration. No two specimen farm websites are exactly alike, but many have the following: (1) incomplete contact information, blank pages, or missing or incomplete product descriptions; (2) place-holder text on many pages; (3) the same, sometimes incorrect, product information for multiple product listings; and/or (4) products that cannot be purchased in or shipped to the United States. Additional information about specimen farms has been published on the USPTO website at www.uspto.gov/trademarks/protect/challenge-invalid-specimens.

The USPTO plans to conduct directed audits of section 8 and 71 affidavits or declarations when the registration file

and/or the post-registration maintenance documents exhibit certain attributes that call into question whether a mark is in use in commerce in the ordinary course of trade. Among other things, these audits will focus on registration files in which it appears that a specimen accepted during examination or submitted with a section 8 or 71 affidavit or declaration was digitally altered, consistent with the parameters set forth in Examination Guide 3–19, or comprised printouts from a website determined to be a specimen farm. Under the directed audit program, the initial office action may request proof of use for all or some of the goods or services covered by the registration, in addition to other information deemed relevant to the USPTO to determine whether the mark is in use in commerce in the ordinary course of trade or whether the elements of excusable nonuse apply. The procedures will otherwise follow those for random audits.

After considering any public comments received in response to this notice, the USPTO will publish information about the program on its Post Registration Audit Program web page at www.uspto.gov/trademarks/maintain/post-registration-audit-program. The USPTO will likewise publish future changes to the post-registration audit program on its website.

These changes will better position the audit program to address obvious issues with registration, thus protecting the integrity of the federal trademark registration system and improving the overall accuracy of the trademark register.

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2024-24755 Filed 10-25-24; 8:45 am]

BILLING CODE 3510-16-P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201

[Docket No. 2023–5]

Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: In this final rule, the Librarian of Congress adopts exemptions to the provision of the Digital Millennium Copyright Act (“DMCA”) that prohibits circumvention of technological measures that control access to copyrighted works. As required under the statute, the Register of Copyrights, following a public proceeding, submitted a recommendation to the Librarian of Congress (“Register’s Recommendation”) regarding proposed exemptions. After careful consideration, the Librarian adopts final regulations based on the Register’s Recommendation.

DATE: Effective October 28, 2024.

FOR FURTHER INFORMATION CONTACT:

Rhea Efthimiadis, Assistant to the General Counsel, by email at mef@copyright.gov or telephone at 202–707–8350.

SUPPLEMENTARY INFORMATION: The Librarian of Congress, pursuant to section 1201(a)(1) of title 17, United States Code, has determined in this ninth triennial rulemaking proceeding that the prohibition against circumvention of technological measures that effectively control access to copyrighted works shall not apply for the next three years to persons who engage in certain noninfringing uses of specified classes of such works. This determination is based on the Register’s Recommendation.

The discussion below summarizes the rulemaking proceeding and the Register’s recommendations, states the Librarian’s determination, and adopts the regulatory text specifying the exempted classes of works. A more complete discussion of the rulemaking process, the evidentiary record, and the Register’s analysis with respect to each proposed exemption can be found in the Register’s Recommendation at www.copyright.gov/1201/2024/.

I. Background

A. Statutory Requirements

In 1998, as part of the Digital Millennium Copyright Act (“DMCA”), Congress added section 1201 to title 17 to provide greater legal protection for copyright owners in the emerging digital environment. Section 1201 generally makes it unlawful to “circumvent a technological measure that effectively controls access to” a copyrighted work.¹

Congress established a set of permanent exemptions to the prohibition on circumvention, as well a procedure to put in place limited temporary exemptions. Every three years, the Librarian of Congress, upon

the recommendation of the Register of Copyrights, is authorized to adopt temporary exemptions, with respect to certain classes of copyrighted works, to remain in effect for the ensuing three-year period. Congress established this rulemaking as a “fail-safe” mechanism² to ensure that the prohibition on circumvention would not adversely affect the public’s ability to make lawful uses of copyrighted works, including activities protected by the fair use doctrine.²

The triennial rulemaking occurs through a formal public process administered by the Register, who consults with the Assistant Secretary for Communications and Information of the Department of Commerce.³ Participants must meet specific legal and evidentiary requirements in order to qualify for a temporary exemption. The Register’s recommendations are based on her conclusions as to whether each proposed exemption meets those statutory requirements.⁴ As prescribed by the statute, she considers whether the prohibition on circumvention is having, or is likely to have, adverse effects on users’ ability to make noninfringing uses of a particular class of copyrighted works. Petitioners must provide evidence sufficient to allow the Register to draw such a conclusion.

B. Rulemaking Standards

Congress has specified the legal and evidentiary requirements for the section 1201 rulemaking proceeding; these standards are discussed in greater detail in the Register’s Recommendation⁵ and the Copyright Office’s 2017 policy study on section 1201.⁶ The Register will recommend granting an exemption only “when the preponderance of the evidence in the record shows that the conditions for granting an exemption have been met.”⁷ The evidence must

² *Id.* at 1201(a)(1)(B)–(D).

³ *Id.* at 1201(a)(1)(C).

⁴ The Office has provided detailed analyses of the statutory requirements in its 2017 policy study on section 1201 and elsewhere. See U.S. Copyright Office, Section 1201 of Title 17 at 105–127 (2017), <https://www.copyright.gov/policy/1201/section-1201-full-report.pdf> (“Section 1201 Report”).

⁵ Register of Copyrights, Section 1201 Rulemaking: Ninth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Register of Copyrights (Oct. 2024), https://cdn.loc.gov/copyright/1201/2024/2024_Section_1201_Registers_Recommendation.pdf (“Register’s Recommendation”).

⁶ Section 1201 Report at 111–12.

⁷ *Id.*; accord Register of Copyrights, Section 1201 Rulemaking: Seventh Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Register of Copyrights 12–13 (Oct. 2018). References to the Register’s recommendations in prior rulemakings

¹ 17 U.S.C. 1201(a)(1)(A).

show “that it is more likely than not that users of a copyrighted work will, in the succeeding three-year period, be adversely affected by the prohibition on circumvention in their ability to make noninfringing uses of a particular class of copyrighted works.”⁸ The Register develops a comprehensive administrative record to support her recommendation.

Section 1201(a)(1) enumerates five factors that guide the Register’s Recommendation and the Librarian’s determination regarding proposed exemptions: (1) the availability for use of copyrighted works; (2) the availability for use of works for nonprofit archival, preservation, and educational purposes; (3) the impact that the prohibition on the circumvention of technological measures applied to copyrighted works has on criticism, comment, news reporting, teaching, scholarship, or research; (4) the effect of circumvention of technological measures on the market for or value of copyrighted works; and (5) such other factors as the Librarian considers appropriate. The statute mandates that any exemption to be defined based on “a particular class of works.”⁹ Among other things, the determination of the appropriate scope of a “class of works” recommended for exemption can take into account the adverse effects an exemption may have on the market for or value of copyrighted works. Accordingly, “it can be appropriate to refine a class by reference to the use or user in order to remedy the adverse effect of the prohibition and to limit the adverse consequences of an exemption.”¹⁰

II. History of the Ninth Triennial Proceeding

The Copyright Office initiated the ninth triennial rulemaking proceeding by issuing a notice of inquiry (“NOI”) on June 8, 2023.¹¹ The NOI requested petitions for renewal, comments in response to petitions for renewal, and petitions for new exemptions, including proposals to expand current exemptions.¹² These public submissions

are cited by the year of publication followed by “Recommendation” (e.g., “2018 Recommendation”). Prior Recommendations are available on the Copyright Office website at <https://www.copyright.gov/1201/>.

⁸ Section 1201 Report at 112.

⁹ 17 U.S.C. 1201(a)(1)(B).

¹⁰ 2006 Recommendation at 19.

¹¹ Exemptions to Permit Circumvention of Access Controls on Copyrighted Works, 88 FR 37486, 37487 (June 8, 2023).

¹² *Id.* See Exemptions to Permit Circumvention of Access Controls on Copyrighted Works, 82 FR 29804, 29806 (June 30, 2017) (petitions to expand a current exemption are treated as petitions for new exemptions) (“Renewal may only be sought for

were due between July 7, 2023 and August 25, 2023.¹³ The Office received thirty-eight petitions for renewal of existing exemptions and eleven petitions for new and expanded exemptions. It grouped the petitions for new and expanded exemptions into seven classes.

On October 19, 2023, the Office issued a notice of proposed rulemaking (“NPRM”) identifying the existing exemptions that the Register intended to recommend for renewal, and providing a description of the proposed classes for new and expanded exemptions.¹⁴ Public submissions were due between December 22, 2023 and March 19, 2024. The Office received approximately 50 submissions in response to the NPRM.¹⁵ After analyzing the written comments regarding proposed new and expanded exemptions, the Office held three days of public hearings from April 16–18, 2024, via Zoom.¹⁶ Forty-one individuals representing nineteen stakeholder groups offered their views on specific proposed exemptions, and an additional four individuals took part in an audience participation session. After the hearings, the Office issued written questions to participants regarding two of the proposed classes and received

current exemptions as they are currently formulated, without modification. This means that if a proponent seeks to engage in any activities not currently permitted by an existing exemption, a petition for a new exemption must be submitted.”).

¹³ 88 FR 37486, 37486; Exemptions to Permit Circumvention of Access Controls on Copyrighted Works: Notice and Request for Public Comment, 88 FR 42891 (July 5, 2023). References to renewal petitions and comments in response are by party and class name (abbreviated where appropriate) followed by “Renewal Pet.,” “Renewal Opp’n,” and “Renewal Supp.” References to petitions for new exemptions and comments in response are by party name and class number followed by “Pet.,” “Initial,” “Opp’n,” or “Reply” for comments submitted in the first, second, or third round, as applicable.

¹⁴ Exemptions to Permit Circumvention of Access Controls on Copyrighted Works, 88 FR 72013 (Oct. 19, 2023).

¹⁵ Comments received in this rulemaking are available on the Office’s website. See *Ninth Triennial Section 1201 Proceeding, 2024 Cycle*, U.S. Copyright Office, <https://www.copyright.gov/1201/2024/> (last visited Oct. 17, 2024); see also *Late Filed Comments*, U.S. Copyright Office, <https://www.copyright.gov/1201/2024/late-filings/> (last visited Oct. 17, 2024).

¹⁶ Video recordings of these hearings are available on the Office’s website and YouTube pages. See *Ninth Triennial Section 1201 Rulemaking Public Hearings*, U.S. Copyright Office, <https://www.copyright.gov/1201/2024/hearings.html> (last visited Oct. 17, 2024); U.S. Copyright Office, YouTube, <https://www.youtube.com/uscopyrightoffice/> (last visited Oct. 17, 2024). Under each proposed class, citations to hearing transcripts refer to that particular class. Hearing transcripts for each individual class are available on the Office’s web page. *Transcripts of Public Hearings in the Ninth Triennial Section 1201 Rulemaking*, U.S. Copyright Office, <https://www.copyright.gov/1201/2024/hearing-transcripts/> (last visited Oct. 17, 2024).

seven responses.¹⁷ It then held three *ex parte* meetings with participants concerning three proposed classes.¹⁸ In addition, it received three letters about the rulemaking from other federal agencies and government officials.¹⁹

The Register consulted with the National Telecommunications and Information Administration (“NTIA”), in the Department of Commerce, as required by section 1201(a)(1). NTIA actively participated in the rulemaking process, providing input at key stages in meetings convened by the Office, and participated in the virtual public hearings where it engaged directly by asking questions. NTIA communicated its views on each of the proposed exemptions in writing to the Register on September 24, 2024.²⁰ The Office summarizes NTIA’s views below. NTIA’s full recommendation is available at https://cdn.loc.gov/copyright/1201/2024/2024_NTIA_DMCA_Letter.pdf.

III. Summary of Register’s Recommendation

A. Renewal Recommendations

The Register received petitions to renew all but one of the exemptions adopted pursuant to the eighth triennial rulemaking,²¹ and recommends renewal of all exemptions for which petitions were filed.²² She finds that the reasons

¹⁷ Participants’ post-hearing letter responses are available on the Office’s website. *Post-Hearing Questions*, U.S. Copyright Office, <https://www.copyright.gov/1201/2024/post-hearing/> (last visited Oct. 17, 2024).

¹⁸ *Ex Parte Communications*, U.S. Copyright Office, <https://www.copyright.gov/1201/2024/ex-parte-communications/> (last visited Oct. 17, 2024). The Office required participants to comply with its *ex parte* regulation, codified at 37 CFR 205.24. This regulation requires that parties submit a meeting request and summary to the Office after an *ex parte* meeting, which is substantially the same process employed in prior section 1201 rulemakings. Exemptions to Permit Circumvention of Access Controls on Copyrighted Works, 85 FR 65293, 65310 (Oct. 15, 2020).

¹⁹ The letters are available on the Office’s website. *Letters Between the U.S. Copyright Office, Other Agencies, and Other Government Officials*, U.S. Copyright Office, <https://www.copyright.gov/1201/2024/USCO-letters/> (last visited Oct. 17, 2024).

²⁰ Letter from Alan Davidson, Assistant Sec’y for Commc’ns & Info. Adm’r, Nat’l Telecomms. & Info. Admin., U.S. Dep’t of Commerce, to Shira Perlmutter, Register of Copyrights and Dir., U.S. Copyright Office (Sept. 24, 2024) (“NTIA Letter”).

²¹ A renewal petition was not filed for the exemption permitting circumvention of video games in the form of computer programs for the purpose of allowing an individual with a physical disability to use alternative software or hardware input methods. See 37 CFR 201.40(b)(21) (2023); 88 FR 72013, 72015 n.19.

²² See 85 FR 65293, 65295 (describing that there was no “meaningful opposition” to renewing exemptions when the Office had “not received comments actually disputing whether there [wa]s a continued basis for any exemptions”); see also Exemptions to Permit Circumvention of Access Controls on Copyrighted Works, 85 FR 37399,

for the Librarian's prior adoption of the exemptions are likely to continue during the next three-year period. The existing exemptions, and the bases for the recommendation to renew each exemption in accordance with the streamlined renewal process, are summarized below.

1. Audiovisual Works—Educational and Derivative Uses

Multiple individuals and organizations petitioned to renew the exemption covering the use of short portions of motion pictures for various educational and derivative uses.²³ The Office did not receive meaningful opposition to renewal. Renewal of each of this exemption's subparts was unopposed, except for noncommercial videos, as discussed below. The existing exemption and its various subparts collectively serve as the baseline in assessing whether to recommend any expansion to Classes 1 and 2.

a. Audiovisual Works—Criticism and Comment—Filmmaking²⁴

Two organizations petitioned to renew the exemption for motion pictures for uses in documentary films or other films where the use is in a parody or for the work's biographical or historically significant nature. No oppositions to the renewal were filed. Petitioners stated that they personally know many filmmakers who have found it necessary to rely on this exemption and will continue to do so. The petitions summarized the continuing need and justification for the exemption.

b. Audiovisual Works—Criticism and Comment—Noncommercial Videos²⁵

Two organizations petitioned to renew the exemption for motion pictures for uses in noncommercial videos. The Office did not receive meaningful opposition to renewal of this exemption.²⁶ Petitioners stated that they had personal knowledge that video creators have relied on this exemption and anticipate needing to do so in the future. The Organization for

Transformative Works ("OTW") included an account from an academic who stated that footage ripped from DVDs and Blu-ray is preferred for "vidders" (noncommercial remix artists) because "it is high quality enough to bear up under the transformations that vidders make to it."²⁷ The petitioners demonstrated the continuing need and justification for the exemption.

c. Audiovisual Works—Criticism and Comment—Multimedia E-books²⁸

Petitioners also sought renewal of the exemption for the use of motion picture excerpts in nonfiction multimedia e-books. No oppositions were filed against renewal. The petition demonstrated the continuing need and justification for the exemption. In addition, the petitioners demonstrated personal knowledge that high-resolution video is not available without circumvention of technological protection measures ("TPMs"). They provided, as an example, Bobette Buster's continued work on an e-book series based on her lecture series, "Deconstructing Master Filmmakers: The Uses of Cinematic Enchantment."²⁹

d. Audiovisual Works—Criticism, Comment, Teaching, or Scholarship—Universities and K–12 Educational Institutions³⁰

Multiple individuals and organizations petitioned to renew the exemption for motion pictures for educational purposes by college and university or K–12 faculty and students. No oppositions were filed against renewal. The petitions demonstrated the continuing need and justification for the exemption, indicating that educators and students continue to rely on excerpts from digital media for class presentations and coursework. For instance, a collective of individuals and organizations provided several examples of professors using DVD clips in the classroom. A group of individual educators and educational organizations³¹ broadly suggested that the "entire field" of video essays or multimedia criticism "could not have

existed in the United States without fair use and the 1201 educational exemption."³² Petitioners demonstrated personal knowledge and experience with this exemption based on their past participation in the section 1201 triennial rulemaking and the experience of their members—thousands of digital and literacy educators and other members supporting educators and students. The Register finds that petitioners demonstrated a continuing need and justification for the exemption.

e. Audiovisual Works—Criticism and Comment—Massive Open Online Courses ("MOOCs")³³

A collective of individuals and organizations petitioned to renew the exemption for educational uses of motion pictures in Massive Open Online Courses ("MOOCs"). No oppositions were filed against renewal. The petitions demonstrated the continuing need and justification for the exemption, stating that instructors continue to rely on the exemption to develop, provide, and improve MOOCs, as well as to increase the number of (and therefore access to) MOOCs in the field of film and media studies. As teachers and proponents of MOOCs—most of whom have advocated for this exemption in prior rulemakings—petitioners demonstrated personal experience with and knowledge of this exemption.

f. Audiovisual Works—Criticism and Comment—Digital and Media Literacy Programs³⁴

The Library Copyright Alliance ("LCA") and Renee Hobbs petitioned to renew the exemption for motion pictures for educational uses in nonprofit digital and media literacy programs offered by libraries, museums, and other organizations. No oppositions were filed against renewal. The petition stated that librarians across the country have relied on the current exemption and will continue to do so for their digital and media literacy programs, thereby demonstrating the continuing need and justification for the exemption. Petitioners have personal experience with this exemption, as they engage with institutions and individuals offering these programs.

²³ 37402 (June 22, 2020) (describing "meaningful opposition" standard).

²⁴ See 37 CFR 201.40(b)(1).

²⁵ The Register's analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register's Recommendation at IV.A.1.

²⁶ The Register's analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register's Recommendation at IV.A.2.

²⁷ Opposition to the Organization for Transformative Works' ("OTW") requested changes is addressed as Class 1 below. Commenters objected only to OTW's request for changes to the exemption, not to renewal of the exemption as-is.

²⁸ OTW Noncom. Videos Renewal Pet. at 3.

²⁹ The Register's analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register's Recommendation at IV.A.3.

³⁰ Buster, Authors All. & Am. Ass'n of Univ. Professors ("AAUP") Nonfiction Multimedia E-Books Renewal Pet. at 3.

³¹ The Register's analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register's Recommendation at IV.A.4.

³² The individuals and organizations include Peter Decherney, Michael Delli Carpini, Library Copyright Alliance ("LCA"), and the Society for Cinema and Media Studies ("SCMS") (collectively, "Joint Educators I").

³³ Joint Educators I AV Educ. Renewal Pet. at 3.

³⁴ The Register's analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register's Recommendation at IV.A.5.

³⁵ The Register's analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register's Recommendation at IV.A.6.

2. Audiovisual Works—Accessibility³⁵

The Association of Transcribers and Speech-to-Text Providers (“ATSP”) and LCA petitioned to renew the exemption for motion pictures for the provision of captioning and/or audio description by disability services offices or similar units at educational institutions for students, faculty, or staff with disabilities. No oppositions were filed against renewal. The petitioners demonstrated the continuing need and justification for the exemption, and, as “represent[atives of] disability services professionals and supporting entities collectively responsible for the regular provision of captioning and audio description services for thousands of students,” personal knowledge and experience with the exemption.³⁶ Petitioners stated that the “exemption enables disability services offices and similar units to ensure that students with disabilities have access to the same advantages as their peers in the pursuit of education.”³⁷

3. Audiovisual works—Preservation or Replacement—Library, Archives, and Museum³⁸

LCA petitioned to renew the exemption for motion pictures for preservation or the creation of a replacement copy by an eligible library, archives, or museum. No oppositions were filed against renewal. LCA petitioned for the exemption’s adoption in the eighth triennial rulemaking and demonstrated the continuing need and justification for the exemption.³⁹ For example, it asserted that institutions across the country have relied on the exemption to make preservation and replacement copies of movies in their collections, many of which are not available for purchase or streaming. LCA indicated that as DVD and Blu-ray discs deteriorate, institutions like libraries and museums will continue to need to circumvent technological protections to make such copies. LCA also demonstrated its personal knowledge of the exemption.

³⁵ The Register’s analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at IV.B.

³⁶ ATSP & LCA Captioning Renewal Pet. at 3.

³⁷ *Id.*

³⁸ The Register’s analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at IV.C.

³⁹ LCA Preservation Renewal Pet. at 3.

4. Audiovisual Works—Text and Data Mining—Scholarly Research and Teaching⁴⁰

Multiple organizations jointly petitioned to renew the exemption for text and data mining of motion pictures by researchers affiliated with a nonprofit institution of higher education, or at the direction of such researchers, for the purpose of scholarly research and teaching. Petitioners demonstrated the continuing need for this exemption, citing researchers who rely on it, such as professors using DVD clips in their classrooms and in their research. They also demonstrated their personal experience with this exemption, having advocated for its adoption in the eighth triennial rulemaking proceeding. Although two organizations jointly objected to renewal of this exemption, the comments seemed to have misunderstood the Register’s prior findings and did not demonstrate that the previous rulemaking record was no longer reliable. Petitioners asserted that there have not been any legal changes or market developments that would disturb the Office’s previous analysis or materially impact the record on which the Register had relied. This existing exemption serves as the baseline in assessing whether to recommend any expansions in Class 3(a).

5. Literary Works—Text and Data Mining—Scholarly Research and Teaching⁴¹

Multiple organizations jointly petitioned to renew the exemption for text and data mining of literary works that were distributed electronically, by researchers affiliated with a nonprofit institution of higher education, or at the direction of such researchers, for the purpose of scholarly research and teaching. No oppositions were filed against renewal. The petitions demonstrated the continuing need and justification for the exemption, highlighting various professors’ ongoing and developing research projects dependent on it. Petitioners also demonstrated personal knowledge of the exemption based on their ongoing relationships with researchers using it. This existing exemption serves as the baseline in assessing whether to recommend any expansions in Class 3(b).

⁴⁰ The Register’s analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at IV.D.

⁴¹ The Register’s analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at IV.E.

6. Literary Works—Text and Data Mining—Assistive Technologies⁴²

Multiple organizations jointly petitioned to renew the exemption for literary works or previously published musical works that have been fixed in the form of text or notation, distributed electronically, and include access controls that interfere with assistive technologies. No oppositions were filed against renewal. The petitioners demonstrated the continuing need and justification for the exemption, stating that individuals who are blind, visually impaired, or print-disabled are significantly disadvantaged with respect to obtaining accessible e-book content because TPMs interfere with the use of assistive technologies. Additionally, they demonstrated personal knowledge and extensive experience with the assistive technology exemption, as they are all organizations that advocate for the blind, visually impaired, and print-disabled.

7. Literary Works—Medical Device Data⁴³

The Coalition of Medical Device Patients and Researchers (“the Coalition”) petitioned to renew the exemption covering access to patient data on medical devices or monitoring systems. No oppositions were filed against renewal. The Coalition demonstrated the continuing need and justification for the exemption, stating that “the exemption is vital to patients’ ability to monitor the data output of medical devices that monitor and maintain their health” and to medical research.⁴⁴ It also demonstrated personal knowledge and experience with this exemption, citing member Hugo Campos’s experiences as a patient who has needed access data from his implanted defibrillator, and its research regarding medical devices.

8. Computer Programs—Unlocking⁴⁵

The Institute of Scrap Recycling Industries, Inc. (“ISRI”) petitioned to renew the exemption for computer programs that operate wireless devices, to allow connection of a new or used device to an alternative wireless network (“unlocking”). No oppositions

⁴² The Register’s analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at IV.F.

⁴³ The Register’s analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at IV.G.

⁴⁴ Coalition Medical Devices Renewal Pet. at 3.

⁴⁵ The Register’s analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at IV.H.

were filed against renewal. The petition demonstrated the continuing need and justification for the exemption, stating that users “continue to purchase or acquire donated cell phones, tablets, laptops, and a variety of other wireless devices no longer needed by their original owners and try to make the best possible use of them through resale or recycling,” which requires unlocking the devices so they may be used on other carriers.⁴⁶ ISRI demonstrated personal knowledge and experience with the exemption based on its involvement in previous triennial rulemakings and its representation of nearly 1,600 companies that process, broker, and consume scrap commodities.

9. Computer Programs—Jailbreaking⁴⁷

Multiple organizations petitioned to renew the four exemptions for computer programs that enable electronic devices to interoperate with or to remove software applications (“jailbreaking”). These exemptions permit circumvention for the purpose of jailbreaking (1) smartphones and other portable all-purpose computing devices, (2) smart televisions, (3) voice assistant devices, and (4) routers and dedicated networking devices. No oppositions were filed against renewal. The petitions demonstrated the continuing need and justification for the exemption and that petitioners have personal knowledge and experience with regard to this exemption. Petitioners described how users of a variety of products in each of these categories rely on this exemption to maintain functionality and security of older devices, to install alternative operation systems, and to customize software applications on electronic devices. Collectively, the petitions demonstrated that without this exemption, TPMs installed on the enumerated products would have an adverse effect on various noninfringing uses.

10. Computer Programs—Repair of Motorized Land Vehicles, Marine Vessels, or Mechanized Agricultural Vehicles or Vessels⁴⁸

iFixit and MEMA, The Vehicle Suppliers Association (“MEMA”), petitioned to renew the exemption for computer programs that control

motorized land vehicles, marine vessels, or mechanized agricultural vehicles or vessels for purposes of diagnosis, repair, or modification of a vehicle or vessel function. No oppositions were filed against renewal. The petitioners each represent or advise individuals and businesses that perform vehicle service and repair and have personal experience with this exemption through those activities. They demonstrated the continuing need and justification for the exemption. For example, MEMA stated that its membership “continues to see firsthand that the exemption is helping protect consumer choice and a competitive market, while mitigating risks to intellectual property and vehicle safety”—particularly as “every year vehicle computer programs become more important and essential to today’s motor vehicles.”⁴⁹ In the 2021 rulemaking, the Register concluded that the “prohibition against circumvention . . . [was] likely to adversely affect diagnosis, repair, and lawful modification of a vessel function for marine vessels,” as well as functions for land vehicles, including agricultural land vehicles such as tractors.⁵⁰ The Office did not receive any evidence indicating that these categories of vehicles and vessels should be treated differently in this proceeding.

11. Computer Programs—Repairs of Devices Designed Primarily for Use by Consumers⁵¹

The Electronic Frontier Foundation (“EFF”) petitioned to renew the exemption for computer programs that control devices designed primarily for use by consumers for diagnosis, maintenance, or repair of the device. The Office did not receive meaningful opposition to renewal.⁵² The petitioners demonstrated the continuing need and justification for the exemption. For example, EFF asserted that “[m]anufacturers of these devices continue to implement technological protection measures that inhibit lawful repairs, maintenance, and diagnostics, and they show no sign of changing course.”⁵³ EFF has personal knowledge of this exemption, as it has been involved with the section 1201 rulemaking process since its inception

and has specifically advocated for device repair exemptions.

12. Computer Programs—Repair of Medical Devices and Systems⁵⁴

Multiple organizations petitioned to renew the exemption to access computer programs that are contained in and control the functioning of medical devices or systems, and related data files, for purposes of diagnosis, maintenance, or repair. The petitioners repair, maintain, service, or sell medical systems and devices and thus have personal experience with this exemption. The petitions demonstrated the continuing need and justification for the exemption, for example stating that “the use of TPMs in medical systems and devices is widespread” and that manufacturers “have developed new systems that further restrict access to use of necessary software tools.”⁵⁵ Petitioners also emphasized that this exemption makes possible device repair and maintenance services that ensure continuity and efficiency of patient care.

Three organizations submitted timely opposition comments. Opponents asserted that the exemption undermines the U.S. Food and Drug Administration’s (“FDA”) maintenance and repair standards for the intricate equipment used in patient care and conflicts with other congressional policies. They also argued that the Supreme Court’s decision in *Andy Warhol Found. for the Visual Arts v. Goldsmith*⁵⁶ undermined the validity of the previous rulemaking’s analysis. As in the Register’s 2021 Recommendation, in this rulemaking the Register again emphasizes that the Office “generally does not consider other regulatory schemes as part of the . . . analysis because the focus of this proceeding is on copyright-related considerations,”⁵⁷ and notes that granting an exemption under section 1201 does not absolve any user from compliance with other relevant laws and regulations. The Register further concludes that the *Warhol* decision does not substantially change the Office’s analysis of the uses at issue in this exemption.

⁴⁹ MEMA Vehicle Repair Renewal Pet. at 3.

⁵⁰ 2021 Recommendation at 223.

⁵¹ The Register’s analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at IV.K.

⁵² Although Author Services filed a comment opposing renewal of the exemption “in its present form,” the comment only addressed devices outside the scope of the existing exemption. See 88 FR 72013, 72020–21.

⁵³ EFF Device Repair Renewal Pet. at 3.

⁵⁴ The Register’s analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at IV.L.

⁵⁵ Avante Health Sols., Avante Diagnostic Imaging, and Avante Ultrasound Medical Device Repair Renewal Pet. at 5.

⁵⁶ 598 U.S. 508 (2023).

⁵⁷ 2021 Recommendation at 229.

⁴⁶ ISRI Unlocking Renewal Pet. at 3.

⁴⁷ The Register’s analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at IV.I.

⁴⁸ The Register’s analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at IV.J.

13. Computer Programs—Security Research⁵⁸

Multiple organizations and security researchers petitioned to renew the exemption permitting circumvention for purposes of good-faith security research. No oppositions were filed against renewal, and one group of security and policy professionals submitted a comment in support of the petition. The petitioners demonstrated the continuing need and justification for the exemption, as well as personal knowledge of and experience with this exemption. They highlighted professors' critical research regarding vulnerabilities in voting machines, devices underpinning the financial industry, smart phones, and other devices. They also stated that this exemption enables security testing that is vital to ensure device users' privacy is protected and security issues are corrected.

14. Video Games—Preservation and Abandoned Video Games⁵⁹

The Software Preservation Network (“SPN”) and LCA jointly petitioned to renew the exemption for individual play by gamers and preservation of video games by a library, archives, or museum for which outside server support has been discontinued, and preservation by a library, archives, or museum, of discontinued video games that never required server support. No oppositions were filed against renewal, and one individual filed a comment in support. Petitioners demonstrated that there is a continuing need and justification for the exemption. They stated that video game collection librarians report an ongoing need to preserve TPM-encumbered video games in their collections and that the “[section] 1201 exemption has become a crucial tool in their ongoing efforts to save digital game culture before it disappears.”⁶⁰ They demonstrated personal knowledge and experience through past participation in section 1201 rulemakings and through their representation of members who have relied on this exemption.

This existing exemption serves as the baseline in assessing whether to recommend any expansions in Class 6(b).

⁵⁸ The Register's analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register's Recommendation at IV.M.

⁵⁹ The Register's analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register's Recommendation at IV.N.

⁶⁰ SPN and LCA Abandoned Video Game Renewal Pet. at 3.

15. Computer Programs—Preservation⁶¹

SPN and LCA jointly petitioned to renew the exemption for the preservation of computer programs other than video games, and computer program-dependent materials, by libraries, archives, and museums. No oppositions were filed against renewal, and one individual filed a comment in support. Petitioners demonstrated that there is a continuing need and justification for this exemption. For example, they asserted that remotely accessing preserved computer programs “fulfill[s] cultural heritage institutions' missions to support research, analysis, and other scholarly re-use of the historical record (and to do so equitably and inclusively).”⁶² In addition, they demonstrated personal knowledge and experience through past participation in section 1201 rulemakings relating to access controls on software and through representing major library associations with members who have relied on this exemption.⁶³

This existing exemption serves as the baseline in assessing whether to recommend any expansions in Class 6(a).

16. Computer Programs—3D Printers⁶⁴

Michael Weinberg petitioned to renew the exemption for computer programs that operate 3D printers to allow use of alternative material. No oppositions were filed against renewal. The petition demonstrated the continuing need and justification for the exemption, and the petitioner demonstrated personal knowledge and experience. Specifically, Mr. Weinberg declared that he is a member of the 3D printing community and has been involved with this exemption's renewal and modification in each section 1201 rulemaking it has been considered. Additionally, he stated that while 3D printer manufacturers “continue to use TPMs to limit the types of materials used in printers,” since the last rulemaking proceeding, there has been “an expansion of third-party materials available for 3D printers” due to the current exemption, which has assured manufacturers and users that their uses would not violate section 1201.⁶⁵

⁶¹ The Register's analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register's Recommendation at IV.O.

⁶² SPN & LCA Software Preservation Renewal Pet. at 3.

⁶³ *Id.*

⁶⁴ The Register's analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register's Recommendation at IV.P.

⁶⁵ Weinberg 3D Printers Renewal Pet. at 3.

17. Computer Programs—Copyright License Investigation⁶⁶

The Software Freedom Conservancy (“SFC”) petitioned to renew the exemption for computer programs, for the purpose of investigating potential infringement of free and open-source computer programs. No oppositions were filed against renewal. The petition demonstrated the continuing need and justification for the exemption, including through discussion of how TPMs, such as encryption, “prevent[] the investigation of computer programs” within various devices, such as laptops, IP-enabled doorbells, baby monitors, and thermostats, that use free and open source software (“FOSS”) to operate.⁶⁷ SFC indicated that barriers to investigating FOSS will “continue to exist . . . [and would] prevent . . . users from obtaining access to the relevant copyrighted works” without the exemption.⁶⁸ As a participant in the previous rulemaking and “the nonprofit home for dozens of FOSS projects representing well over a thousand volunteer contributors,” SFC demonstrated personal knowledge and experience regarding the exemption.⁶⁹

18. Computer Programs—Videogame Accessibility⁷⁰

In 2021, the Register found that the record “support[ed] an exemption to enable individuals with disabilities to use alternate input devices to play video games.”⁷¹ The Office previously noted the strong justifications for the exemption and recommended that Congress enact a permanent exemption to enable such accessibility. It did not, however, receive a petition to renew this exemption and, given the constraints of the rulemaking process, the Register is not able to recommend renewal.

B. New or Expanded Designations of Classes

Based upon the record in this proceeding regarding proposed expansions to existing exemptions or newly proposed exemptions, the Register recommends that the Librarian grant the following additional

⁶⁶ The Register's analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register's Recommendation at IV.Q.

⁶⁷ SFC Copyright License Investigation Renewal Pet. at 3.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ The Register's analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register's Recommendation at IV.R.

⁷¹ 2021 Recommendation at 315.

exemptions from the prohibition against circumvention of technological measures set forth in section 1201(a)(1):

1. Proposed Classes 3(a) and 3(b): Audiovisual Works and Literary Works—Text and Data Mining⁷²

Authors Alliance, the American Association of University Professors (“AAUP”), and LCA petitioned to expand the existing exemptions that permit circumvention of technological protection measures on copies of copyrighted audiovisual and literary works that were lawfully acquired, to enable researchers to perform text and data mining for the purpose of scholarly research and teaching. The current exemptions permit access to the corpora to outside researchers “solely for purposes of collaboration or replication of the research.”⁷³ Petitioners stated that additional research based on text and data mining techniques is stymied by uncertainty surrounding whether and when the corpora at issue may be used by researchers at outside institutions. Proposed Classes 3(a) and 3(b) would provide an exemption to allow academic researchers to share copies of corpora with researchers affiliated with other nonprofit institutions of higher education “for purposes of conducting independent text [and] data mining research and teaching, where those researchers are in compliance with the exemption.”⁷⁴

Association of American Publishers (“AAP”); Motion Picture Association (“MPA”), News Media Alliance, and the Recording Industry Association of America (“RIAA”) (collectively, “Joint Creators III”); DVD Copy Control Association (“DVD CCA”) and the Advanced Access Content System Licensing Administrator, LLC (“AACSLA”); and the International Association of Scientific, Technical and Medical Publishers opposed the proposed expansions for classes 3(a) and 3(b). They argued that the “proposed new language would dramatically enlarge the scope of the exemptions adopted in 2021” and could lead to “a wide range of potentially infringing uses” of copyrighted works.⁷⁵ They also raised

issues with the existing exemptions’ security measures and viewing provisions.

As discussed in the Register’s Recommendation, absent modifications to the current exemptions for text and data mining, researchers at other academic institutions will face adverse effects in their ability to make noninfringing use of copyrighted audiovisual and literary works. The Register recommends that the current exemptions be modified to permit researchers affiliated with other nonprofit institutions of higher education to access corpora solely for the purposes of text and data mining research or teaching. “Access” in this context means that an institution may provide outside researchers with credentials for security and authentication to use a corpus that is hosted on its servers; it does not mean that an institution or a researcher may disseminate a copy of a corpus (or copyrighted works included therein) to outside researchers or give outside researchers the ability to download, make copies of, or distribute any copyrighted works.

The Register also recommends amending the existing exemptions to clarify the security measures provisions and the viewing provisions to bring the regulatory text in line with the fair use analysis in the 2021 Recommendation. These amendments do not require a new fair use analysis. Specifically, she recommends amending the security measures provisions to: (1) include reasonable requests from trade associations; (2) permit inquiries into security measures regardless of whether they are based on individual agreements or the institution’s own standards; and (3) allow those inquiries when the copyright owners *reasonably believe* that their works are in the corpus. The Register also recommends amending the viewing provision to permit researchers to view the contents of copyrighted works as part of their research, provided that viewing takes place in furtherance of research objectives (e.g., processing or annotating works to prepare them for analysis) and not for the works’ expressive value.

2. Proposed Class 5: Computer Programs—Repair of Commercial Industrial Equipment⁷⁶

Public Knowledge and iFixit jointly petitioned for an expanded repair

LLC (“AACSLA”) Class 3(a) Opp’n at 12–13, 19–20.

⁷⁶ The Register’s analysis and conclusions for this class, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at V.E.

exemption that would permit circumvention for the purposes of diagnosis, maintenance, and repair of commercial and industrial equipment. The U.S. Department of Justice Antitrust Division and the Federal Trade Commission filed comments in support of the petition. Proponents asserted that there were sufficient commonalities to support a broad class by providing four representative examples, including commercial food preparation equipment. Opponents ACT v The App Association; Associated Equipment Distributors; Entertainment Software Association (“ESA”), MPA, and RIAA (“collectively, “Joint Creators I”); Philips North America, LLC; and the Association of Home Appliance Manufacturers primarily argued that the scope of the class was overly broad and unsupported by the record. NTIA supported the proposed exemption.

The Register recommends adopting a new exemption covering diagnosis, maintenance, and repair of retail-level commercial food preparation equipment because proponents sufficiently showed, by a preponderance of the evidence, adverse effects on the proposed noninfringing uses of such equipment. However, she declines to recommend an exemption for a broader class of software-enabled commercial and industrial devices in the absence of a sufficient showing of adverse effects on the record presented in this rulemaking.

3. Proposed Class 7: Computer Programs—Vehicle Operational Data⁷⁷

Class 7 proponents sought a new exemption to permit lawful owners and lessees, or those acting on their behalf, to access, store, and share vehicle operational and telematics data generated by motorized land vehicles and marine vessels. They argued that the proposed exemption would allow vehicle owners and lessees to make productive, noninfringing uses of that data, such as monitoring vehicle use and streamlining the vehicle repair process. In subsequent comments and at the public hearing, proponents agreed that any exemption should include limitations, such as the continued applicability of other laws.

Alliance for Automotive Innovation, Association of Equipment Manufacturers, National Association of Manufacturers, and the Joint Creators I opposed the exemption. They argued that consumers already have sufficient

⁷⁷ The Register’s analysis and conclusions for this class, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at V.G.

⁷² The Register’s analysis and conclusions for this class, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at V.C.

⁷³ 37 CFR 201.40(b)(4)–(5).

⁷⁴ Authors All., AAUP & LCA Class 3(a) Pet. at 2; Authors All., AAUP & LCA Class 3(b) Pet. at 2.

⁷⁵ Motion Picture Association (“MPA”), News Media Alliance, and the Recording Industry Association of America (“RIAA”) (collectively, “Joint Creators III”) Class 3(a) Opp’n at 5; *see* Ass’n of Am. Publishers (“AAP”) Class 3(b) Opp’n at 2–3; DVD Copy Control Ass’n (“DVD CCA”) and Advanced Access Content Sys. Licensing Adm’r,

access under current laws and market practices, particularly the existing vehicle repair exemption found in section 37 CFR 201.40(b)(13) (“Repair Exemption”). They further contended that the proposed exemption was overbroad and would raise issues related to safety, privacy, and trade secrets.

NTIA supported the proposed exemption and recommended that it operate as a “standalone” exemption, separate from the Repair Exemption. In addition, NTIA recommended including the term “analyze” within the proposed regulatory language, as furthering the intended goals of the exemption.

For the reasons detailed in the Register’s Recommendation, the Register concludes that the prohibition on circumvention adversely affects the ability of lawful owners and lessees, or those acting on their behalf, to access, store, and share operational and telematics data, which are likely to be noninfringing. She further finds that such uses would not adversely affect the market for or value of computer programs integrated into vehicles and vessels and that the purported alternatives do not sufficiently mitigate any adverse effects. She also recommends adopting regulatory provisions mirroring those within the Repair Exemption regarding the applicability of the exemption to other laws, separate subscription services, and unauthorized access to other copyrighted works.

C. Classes Considered but Not Recommended

Based upon the record in this proceeding, the Register recommends that the Librarian determine that the following classes of works shall not be exempt during the next three-year period from the prohibition against circumvention of technological measures set forth in section 1201(a)(1):

1. Proposed Class 1: Audiovisual Works—Noncommercial Videos⁷⁸

Proposed Class 1 proponents sought to expand the existing exemption that permits circumvention of access controls protecting excerpts of motion pictures on DVDs, Blu-ray discs, and digitally transmitted video for the purposes of criticism and comment, including for educational purposes by certain users. The Office received one petition from OTW seeking an amendment to the language of the

⁷⁸The Register’s analysis and conclusions for this subpart, including citations to the record and relevant legal authority, can be found in the Register’s Recommendation at V.A.

existing exemption.⁷⁹ Specifically, OTW proposed rewriting the text of the current exemption related to noncommercial videos, which is being renewed, by reverting to language used in the 2010 rulemaking, when the exemption was initially adopted. OTW maintained that its proposed changes would not substantively alter the exemption but would render it more understandable to users. It made essentially the same request in the 2021 proceeding, which the Register did not recommend adopting.

The Office received no comments in support of the proposal, no requests from OTW or other parties to participate in the public hearings, and no other evidence in support of the proposal. Two groups, however, filed opposition comments. These groups opposed the language changes that OTW proposed, but did not oppose renewal of the exemption as currently written. Opponents highlighted the Register’s previous findings in the 2021 rulemaking that OTW’s proposed changes were not warranted, as well as OTW’s failure in this proceeding to submit any evidence supporting its petition. NTIA acknowledged that petitioner did not submit its request in a procedurally proper manner, but supported petitioner’s proposed modifications to the class and structural alterations to the way exemptions are written in general. The Register does not recommend the expansion proposed as Class 1, which does not include substantive changes.

2. Proposed Class 2: Audiovisual Works—Online Learning⁸⁰

Proposed Class 2 would expand the existing exemption for circumvention of access controls protecting motion pictures on DVDs, Blu-ray discs, and digitally transmitted video for educational purposes in massive open online courses (“MOOCs”) by faculty and employees acting at the direction of faculty of accredited nonprofit educational institutions. Petitioner sought to expand the scope of the exemption for “educators . . . and preparers of online learning materials acting at the direction of educators” of “qualified online educational entities,” including for-profit entities and unaccredited educational institutions, to use short portions of motion pictures

⁷⁹OTW submitted a petition for renewal, which the Office construed as a request for expansion since petitioner requested alterations to the existing exemption.

⁸⁰The Register’s analysis and conclusions for this class, including citations to the record and relevant legal authority, can be found in the Recommendation at V.B.

“for the purpose of teaching registered learners . . . in courses requiring close analysis of film and media excerpts when the transformative fair use of the excerpts contributes significantly to learning, for the purpose of criticism, comment, illustration, or explanation.”⁸¹ Proponents argued that these entities should have free and efficient ways of accessing high-quality motion picture excerpts to educate nontraditional learners. Opponents argued against the proposed expansion, contending that proponents failed to meet their evidentiary burden, including that the conduct at issue would be noninfringing. Finally, AACS LA argued that screen capture technology has improved and remains an adequate alternative in some circumstances.

NTIA supported the proposed exemption with some modifications to address opponents’ concerns.

The Register finds that the record lacks support to expand the existing exemption to for-profit and/or unaccredited educational entities. She therefore does not recommend adopting the proposed exemption.

3. Proposed Class 4: Computer Programs—Generative AI Research⁸²

Class 4 proponents sought an exemption for the purpose of conducting “trustworthiness” research on AI systems. Specifically, they sought to conduct research on harmful or undesirable outputs from generative AI systems, including content that is biased, is sexually explicit, or infringes copyrights. They asserted that section 1201 inhibits this research by prohibiting the circumvention of various safeguards on online platforms, including account authentication systems.

Opponents asserted that the proposed language was overbroad, arguing that a broad exemption could damage all software markets and sweep in a variety of systems and products, such as Blu-ray disc players. They also contended that proponents failed to provide sufficient information about the TPMs at issue and whether they would be circumvented for the proposed research. Finally, they argued that an exemption would be premature, and that the rulemaking was not the appropriate venue to establish new law, given the nascent technology involved and

⁸¹Peter Decherney, Sarah Banet-Weiser, Shiv Gaglani & SCMS (collectively, “Joint Educators II”) Class 2 Reply at 2–3.

⁸²The Register’s analysis and conclusions for this class, including citations to the record and relevant legal authority, can be found in the Recommendation at V.D.

ongoing legislative and policy work on generative AI.

NTIA supported an exemption modeled after the current security research exemption,⁸³ but without the requirement that research be conducted on lawfully acquired devices, or with the authorization of the system owner or operator. Although NTIA concluded that section 1201 would not apply to most of the activities identified by proponents, it believed that the use of certain prompts could implicate the prohibition on circumvention. NTIA also found sufficient evidence of adverse effects, crediting statements from academic researchers describing the “chilling effect” of section 1201 on their work.

The Register recommends denying the proposed exemption. She acknowledges the importance of AI trustworthiness research as a policy matter and notes that Congress and other agencies may be best positioned to act on this emerging issue. She narrowed the proposed class to generative AI systems made available via software as a service based on the rulemaking record. She finds, however, that the adverse effects identified by proponents arise from third-party control of online platforms rather than the operation of section 1201, so that an exemption would not ameliorate their concerns.

4. Proposed Classes 6(a) and 6(b): Computer Programs and Video Games—Preservation⁸⁴

Proposed Classes 6(a) and 6(b) would amend the existing exemptions permitting libraries, archives, and museums to circumvent TPMs on computer programs and video games, respectively, for the purpose of preservation activities. The proposed amendment to Class 6(a) would remove the limitation that a preserved computer program must be accessible to only one user at a time (the “single-user limitation”). Petitioners sought clarification of the single-user limitation, arguing that it is currently open to two different interpretations. The existing exemption, they contended, could be read to allow multiple users to access circumvented copies at once, so long as the number of users does not exceed the number of copies the institution owns; or to mean that only one user at a time may access a copy of the circumvented work

regardless of how many copies the institution owns. Proposed Class 6(b) would also remove the current exemption’s limitation that a video game must not be distributed or made available outside of the physical premises of the institution (the “premises limitation”).

Proponents argued that researchers could make noninfringing uses of the exemption even if the single-user limitation and the premises limitation were removed. This position was based in part on their view that proposed uses would be transformative, and would not affect the potential market for or value of the copyrighted works because only works that are no longer reasonably available in the commercial marketplace would be subject to the exemption.

DVD CCA and AACS LA and Joint Creators I opposed removing the single-user limitation. They argued if a preservation institution were to allow multiple simultaneous uses of a preserved program, users’ conduct would not be fair use and would cause market harm.

DVD CCA and AACS LA, Joint Creators I, and ESA opposed removing the premises limitation. They contended that there would be a significant risk that preserved video games would be used for recreational purposes. They further argued that the expanded exemption would give preservation institutions too much discretion regarding how they provide remote users access to preserved works; and that it did not contain appropriately tailored restrictions to ensure that uses would be limited to teaching, research, or scholarship uses. They believe that removing the premises limitation would also adversely affect the existing market for older video games.

NTIA supported the removal of each limitation.

The Register concludes that proponents did not show that removing the single-user limitation for preserved computer programs or permitting off-premises access to video games are likely to be noninfringing. She also notes the greater risk of market harm with removing the video game exemption’s premises limitation, given the market for legacy video games. She recommends clarifying the single copy restriction language to reflect that preservation institutions can allow a copy of a computer program to be accessed by as many individuals as there are circumvented copies legally owned. This clarifying text will address the perceived ambiguity in the current exemption, while maintaining the single-user limitation’s intended purpose to minimize the risk of

substitutional uses of preserved computer programs.

D. Conclusion

Having considered the evidence in the record, the comments of proponents and opponents of the exemptions, and the objectives of section 1201, the Register recommends that the Librarian of Congress exempt for the next three years certain classes of works, as described above, from the prohibition against circumvention of technological measures that effectively control access to copyrighted works.

Dated: October 18, 2024.

Shira Perlmutter,

Register of Copyrights and Director of the U.S. Copyright Office.

Determination of the Librarian of Congress

Having duly considered the recommendation of the Register of Copyrights as summarized above, which recommendation is hereby incorporated by reference, the Librarian of Congress accepts that recommendation with respect to all the classes of works under consideration. The Librarian, exercising her authority pursuant to 17 U.S.C. 1201(a)(1)(C) and (D), hereby publishes as a new rule the classes of copyrighted works that shall for a three-year period be subject to the exemption found in 17 U.S.C. 1201(a)(1)(B) from the prohibition against circumvention of technological measures that effectively control access to copyrighted works set forth in 17 U.S.C. 1201(a)(1)(A).

The Librarian is aware that the Register and her legal staff have invested a great deal of time over the past two years in analyzing the many issues underlying the 1201 process and proposed exemptions.

Through this work, the Register has come to believe that the issue of research on artificial intelligence security and trustworthiness warrants more general Congressional and regulatory attention. The Librarian agrees with the Register in this assessment. As a regulatory process focused on technological protection measures for copyrighted content, section 1201 is ill-suited to address fundamental policy issues with new technologies.

The Librarian is further aware of the policy and legal issues involving a generalized “right to repair” equipment with embedded software. These issues have now occupied the White House, Congress, state legislatures, federal agencies, the Copyright Office, and the general public through multiple rounds of 1201 rulemaking.

⁸³ 37 CFR 201.40(b)(16) (2023). The current security research exemption is being renewed during this rulemaking proceeding.

⁸⁴ The Register’s analysis and conclusions for this class, including citations to the record and relevant legal authority, can be found in the Recommendation at V.F.

Copyright is but one piece in a national framework for ensuring the security, trustworthiness, and reliability of embedded software, and other copyright-protected technology that affects our daily lives. Issues such as these extend beyond the reach of 1201 and may require a broader solution, as noted by the NTIA.

The Librarian fully supports the Register in her examination of these issues and urges Congress to work with the Copyright Office and other federal agencies to consider these issues beyond the contours of this 1201 rulemaking.

List of Subjects in 37 CFR Part 201

Copyright, Exemptions to prohibition against circumvention.

Final Regulations

For the reasons set forth in the preamble, 37 CFR part 201 is amended as follows:

PART 201—GENERAL PROVISIONS

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 17 U.S.C. 702.

■ 2. Section 201.40 is amended by revising paragraph (b) to read as follows:

§ 201.40 Exemption to prohibition against circumvention.

* * * * *

(b) *Classes of copyrighted works.*

Pursuant to the authority set forth in 17 U.S.C. 1201(a)(1)(C) and (D), and upon the recommendation of the Register of Copyrights, the Librarian has determined that the prohibition against circumvention of technological measures that effectively control access to copyrighted works set forth in 17 U.S.C. 1201(a)(1)(A) shall not apply to persons who engage in noninfringing uses of the following classes of copyrighted works:

(1) Motion pictures (including television shows and videos), as defined in 17 U.S.C. 101, where the motion picture is lawfully made and acquired on a DVD protected by the Content Scramble System, on a Blu-ray disc protected by the Advanced Access Content System, or via a digital transmission protected by a technological measure, and the person engaging in circumvention under paragraphs (b)(1)(i) and (b)(1)(ii)(A) and (B) of this section reasonably believes that non-circumventing alternatives are unable to produce the required level of high-quality content, or the circumvention is undertaken using screen-capture technology that appears to be offered to the public as enabling the reproduction of motion pictures

after content has been lawfully acquired and decrypted, where circumvention is undertaken solely in order to make use of short portions of the motion pictures in the following instances:

(i) For the purpose of criticism or comment:

(A) For use in documentary filmmaking, or other films where the motion picture clip is used in parody or for its biographical or historically significant nature;

(B) For use in noncommercial videos (including videos produced for a paid commission if the commissioning entity's use is noncommercial); or

(C) For use in nonfiction multimedia e-books.

(ii) For educational purposes:

(A) By college and university faculty and students or kindergarten through twelfth-grade (K–12) educators and students (where the K–12 student is circumventing under the direct supervision of an educator), or employees acting at the direction of faculty of such educational institutions for the purpose of teaching a course, including of accredited general educational development (GED) programs, for the purpose of criticism, comment, teaching, or scholarship;

(B) By faculty of accredited nonprofit educational institutions and employees acting at the direction of faculty members of those institutions, for purposes of offering massive open online courses (MOOCs) to officially enrolled students through online platforms (which platforms themselves may be operated for profit), in film studies or other courses requiring close analysis of film and media excerpts, for the purpose of criticism or comment, where the MOOC provider through the online platform limits transmissions to the extent technologically feasible to such officially enrolled students, institutes copyright policies and provides copyright informational materials to faculty, students, and relevant staff members, and applies technological measures that reasonably prevent unauthorized further dissemination of a work in accessible form to others or retention of the work for longer than the course session by recipients of a transmission through the platform, as contemplated by 17 U.S.C. 110(2); or

(C) By educators and participants in nonprofit digital and media literacy programs offered by libraries, museums, and other nonprofit entities with an educational mission, in the course of face-to-face instructional activities, for the purpose of criticism or comment, except that such users may only circumvent using screen-capture

technology that appears to be offered to the public as enabling the reproduction of motion pictures after content has been lawfully acquired and decrypted.

(2)(i) Motion pictures (including television shows and videos), as defined in 17 U.S.C. 101, where the motion picture is lawfully acquired on a DVD protected by the Content Scramble System, on a Blu-ray disc protected by the Advanced Access Content System, or via a digital transmission protected by a technological measure, where:

(A) Circumvention is undertaken by a disability services office or other unit of a kindergarten through twelfth-grade educational institution, college, or university engaged in and/or responsible for the provision of accessibility services for the purpose of adding captions and/or audio description to a motion picture to create an accessible version for students, faculty, or staff with disabilities;

(B) The educational institution unit in paragraph (b)(2)(i)(A) of this section has a reasonable belief that the motion picture will be used for a specific future activity of the institution and, after a reasonable effort, has determined that an accessible version of sufficient quality cannot be obtained at a fair market price or in a timely manner, including where a copyright holder has not provided an accessible version of a motion picture that was included with a textbook; and

(C) The accessible versions are provided to students or educators and stored by the educational institution in a manner intended to reasonably prevent unauthorized further dissemination of a work.

(ii) For purposes of this paragraph (b)(2):

(A) “Audio description” means an oral narration that provides an accurate rendering of the motion picture;

(B) “Accessible version of sufficient quality” means a version that in the reasonable judgment of the educational institution unit has captions and/or audio description that are sufficient to meet the accessibility needs of students, faculty, or staff with disabilities and are substantially free of errors that would materially interfere with those needs; and

(C) Accessible materials created pursuant to this exemption and stored pursuant to paragraph (b)(2)(i)(C) of this section may be reused by the educational institution unit to meet the accessibility needs of students, faculty, or staff with disabilities pursuant to paragraphs (b)(2)(i)(A) and (B) of this section.

(3)(i) Motion pictures (including television shows and videos), as defined

in 17 U.S.C. 101, where the motion picture is lawfully acquired on a DVD protected by the Content Scramble System, or on a Blu-ray disc protected by the Advanced Access Content System, solely for the purpose of lawful preservation or the creation of a replacement copy of the motion picture, by an eligible library, archives, or museum, where:

(A) Such activity is carried out without any purpose of direct or indirect commercial advantage;

(B) The DVD or Blu-ray disc is damaged or deteriorating;

(C) The eligible institution, after a reasonable effort, has determined that an unused and undamaged replacement copy cannot be obtained at a fair price and that no streaming service, download service, or on-demand cable and satellite service makes the motion picture available to libraries, archives, and museums at a fair price; and

(D) The preservation or replacement copies are not distributed or made available outside of the physical premises of the eligible library, archives, or museum.

(ii) For purposes of paragraph (b)(3)(i) of this section, a library, archives, or museum is considered “eligible” if—

(A) The collections of the library, archives, or museum are open to the public and/or are routinely made available to researchers who are not affiliated with the library, archives, or museum;

(B) The library, archives, or museum has a public service mission;

(C) The library, archives, or museum’s trained staff or volunteers provide professional services normally associated with libraries, archives, or museums;

(D) The collections of the library, archives, or museum are composed of lawfully acquired and/or licensed materials; and

(E) The library, archives, or museum implements reasonable digital security measures as appropriate for the activities permitted by paragraph (b)(3)(i) of this section.

(4)(i) Motion pictures, as defined in 17 U.S.C. 101, where the motion picture is on a DVD protected by the Content Scramble System, on a Blu-ray disc protected by the Advanced Access Content System, or made available for digital download where:

(A) The circumvention is undertaken by a researcher affiliated with a nonprofit institution of higher education, or by a student or information technology staff member of the institution at the direction of such researcher, solely to deploy text and data mining techniques on a corpus of

motion pictures for the purpose of scholarly research and teaching;

(B) The copy of each motion picture is lawfully acquired and owned by the institution, or licensed to the institution without a time limitation on access;

(C) The person undertaking the circumvention or conducting research or teaching under this exemption views or listens to the contents of the motion pictures in the corpus solely to conduct text and data mining research or teaching;

(D) The institution uses effective security measures to prevent dissemination or downloading of motion pictures in the corpus, and upon a reasonable request from a copyright owner who reasonably believes that their work is contained in the corpus, or a trade association representing such author, provide information to that copyright owner or trade association regarding the nature of such measures; and

(E) The institution limits access to the corpus to only the persons identified in paragraph (b)(4)(i)(A) of this section or to researchers affiliated with other nonprofit institutions of higher education, with all access provided only through secure connections and on the condition of authenticated credentials, solely for purposes of text and data mining research or teaching.

(ii) For purposes of paragraph (b)(4)(i) of this section:

(A) An institution of higher education is defined as one that:

(1) Admits regular students who have a certificate of graduation from a secondary school or the equivalent of such a certificate;

(2) Is legally authorized to provide a postsecondary education program;

(3) Awards a bachelor’s degree or provides not less than a two-year program acceptable towards such a degree;

(4) Is a public or other nonprofit institution; and

(5) Is accredited by a nationally recognized accrediting agency or association.

(B) The term “effective security measures” is defined as:

(1) Security measures that have been agreed to by all interested copyright owners of motion pictures and institutions of higher education; or

(2) Security measures that the institution uses to keep its own highly confidential information secure.

(5)(i) Literary works, excluding computer programs and compilations that were compiled specifically for text and data mining purposes, distributed electronically where:

(A) The circumvention is undertaken by a researcher affiliated with a

nonprofit institution of higher education, or by a student or information technology staff member of the institution at the direction of such researcher, solely to deploy text and data mining techniques on a corpus of literary works for the purpose of scholarly research and teaching;

(B) The copy of each literary work is lawfully acquired and owned by the institution, or licensed to the institution without a time limitation on access;

(C) The person undertaking the circumvention or conducting research or teaching under this exemption views the contents of the literary works in the corpus solely to conduct text and data mining research or teaching;

(D) The institution uses effective security measures to prevent dissemination or downloading of literary works in the corpus, and upon a reasonable request from a copyright owner who reasonably believes that their work is contained in the corpus, or a trade association representing such author, provide information to that copyright owner or trade association regarding the nature of such measures; and

(E) The institution limits access to the corpus to only the persons identified in paragraph (b)(5)(i)(A) of this section or to researchers affiliated with other nonprofit institutions of higher education, with all access provided only through secure connections and on the condition of authenticated credentials, solely for purposes of text and data mining research or teaching.

(ii) For purposes of paragraph (b)(5)(i) of this section:

(A) An institution of higher education is defined as one that:

(1) Admits regular students who have a certificate of graduation from a secondary school or the equivalent of such a certificate;

(2) Is legally authorized to provide a post secondary education program;

(3) Awards a bachelor’s degree or provides not less than a two-year program acceptable towards such a degree;

(4) Is a public or other nonprofit institution; and

(5) Is accredited by a nationally recognized accrediting agency or association.

(B) The term “effective security measures” is defined as:

(1) Security measures that have been agreed to by all interested copyright owners of literary works and institutions of higher education; or

(2) Security measures that the institution uses to keep its own highly confidential information secure.

(6)(i) Literary works or previously published musical works that have been fixed in the form of text or notation, distributed electronically, that are protected by technological measures that either prevent the enabling of read-aloud functionality or interfere with screen readers or other applications or assistive technologies:

(A) When a copy or phonorecord of such a work is lawfully obtained by an eligible person, as such a person is defined in 17 U.S.C. 121; provided, however, that the rights owner is remunerated, as appropriate, for the market price of an inaccessible copy of the work as made available to the general public through customary channels; or

(B) When such a work is lawfully obtained and used by an authorized entity pursuant to 17 U.S.C. 121.

(ii) For the purposes of paragraph (b)(6)(i) of this section, a “phonorecord of such a work” does not include a sound recording of a performance of a musical work unless and only to the extent the recording is included as part of an audiobook or e-book.

(7) Literary works consisting of compilations of data generated by medical devices or by their personal corresponding monitoring systems, where such circumvention is undertaken by or on behalf of a patient for the sole purpose of lawfully accessing data generated by a patient’s own medical device or monitoring system. Eligibility for this exemption is not a safe harbor from, or defense to, liability under other applicable laws, including without limitation the Health Insurance Portability and Accountability Act of 1996, the Computer Fraud and Abuse Act of 1986, or regulations of the Food and Drug Administration.

(8) Computer programs that enable wireless devices to connect to a wireless telecommunications network, when circumvention is undertaken solely in order to connect to a wireless telecommunications network and such connection is authorized by the operator of such network.

(9) Computer programs that enable smartphones and portable all-purpose mobile computing devices to execute lawfully obtained software applications, where circumvention is accomplished for the sole purpose of enabling interoperability of such applications with computer programs on the smartphone or device, or to permit removal of software from the smartphone or device. For purposes of this paragraph (b)(9), a “portable all-purpose mobile computing device” is a device that is primarily designed to run

a wide variety of programs rather than for consumption of a particular type of media content, is equipped with an operating system primarily designed for mobile use, and is intended to be carried or worn by an individual.

(10) Computer programs that enable smart televisions to execute lawfully obtained software applications, where circumvention is accomplished for the sole purpose of enabling interoperability of such applications with computer programs on the smart television, and is not accomplished for the purpose of gaining unauthorized access to other copyrighted works. For purposes of this paragraph (b)(10), “smart televisions” includes both internet-enabled televisions, as well as devices that are physically separate from a television and whose primary purpose is to run software applications that stream authorized video from the internet for display on a screen.

(11) Computer programs that enable voice assistant devices to execute lawfully obtained software applications, where circumvention is accomplished for the sole purpose of enabling interoperability of such applications with computer programs on the device, or to permit removal of software from the device, and is not accomplished for the purpose of gaining unauthorized access to other copyrighted works. For purposes of this paragraph (b)(11), a “voice assistant device” is a device that is primarily designed to run a wide variety of programs rather than for consumption of a particular type of media content, is designed to take user input primarily by voice, and is designed to be installed in a home or office.

(12) Computer programs that enable routers and dedicated network devices to execute lawfully obtained software applications, where circumvention is accomplished for the sole purpose of enabling interoperability of such applications with computer programs on the router or dedicated network device, and is not accomplished for the purpose of gaining unauthorized access to other copyrighted works. For the purposes of this paragraph (b)(12), “dedicated network device” includes switches, hubs, bridges, gateways, modems, repeaters, and access points, and excludes devices that are not lawfully owned.

(13) Computer programs that are contained in and control the functioning of a lawfully acquired motorized land vehicle or marine vessel such as a personal automobile or boat, commercial vehicle or vessel, or mechanized agricultural vehicle or vessel, except for programs accessed

through a separate subscription service, when circumvention is a necessary step to allow the diagnosis, repair, or lawful modification of a vehicle or vessel function, where such circumvention is not accomplished for the purpose of gaining unauthorized access to other copyrighted works. Eligibility for this exemption is not a safe harbor from, or defense to, liability under other applicable laws, including without limitation regulations promulgated by the Department of Transportation or the Environmental Protection Agency.

(14) Computer programs that are contained in and control the functioning of a lawfully acquired motorized land vehicle or marine vessel such as a personal automobile or boat, commercial vehicle or vessel, or mechanized agricultural vehicle or vessel, except for programs accessed through a separate subscription service, to allow vehicle or vessel owners and lessees, or those acting on their behalf, to access, store, and share operational data, including diagnostic and telematics data, where such circumvention is not accomplished for the purpose of gaining unauthorized access to other copyrighted works. Eligibility for this exemption is not a safe harbor from, or defense to, liability under other applicable laws, including without limitation regulations promulgated by the Department of Transportation or the Environmental Protection Agency.

(15) Computer programs that are contained in and control the functioning of a lawfully acquired device that is primarily designed for use by consumers, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device, and is not accomplished for the purpose of gaining access to other copyrighted works. For purposes of this paragraph (b)(15):

(i) The “maintenance” of a device is the servicing of the device in order to make it work in accordance with its original specifications and any changes to those specifications authorized for that device; and

(ii) The “repair” of a device is the restoring of the device to the state of working in accordance with its original specifications and any changes to those specifications authorized for that device. For video game consoles, “repair” is limited to repair or replacement of a console’s optical drive and requires restoring any technological protection measures that were circumvented or disabled.

(16) Computer programs that are contained in and control the functioning of lawfully acquired equipment that is

primarily designed for use in retail-level commercial food preparation when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device, and is not accomplished for the purpose of gaining access to other copyrighted works. For purposes of this paragraph (b)(16):

(i) The “maintenance” of a device is the servicing of the device in order to make it work in accordance with its original specifications and any changes to those specifications authorized for that device; and

(ii) The “repair” of a device is the restoring of the device to the state of working in accordance with its original specifications and any changes to those specifications authorized for that device.

(17) Computer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system. For purposes of this paragraph (b)(17):

(i) The “maintenance” of a device or system is the servicing of the device or system in order to make it work in accordance with its original specifications and any changes to those specifications authorized for that device or system; and

(ii) The “repair” of a device or system is the restoring of the device or system to the state of working in accordance with its original specifications and any changes to those specifications authorized for that device or system.

(18)(i) Computer programs, where the circumvention is undertaken on a lawfully acquired device or machine on which the computer program operates, or is undertaken on a computer, computer system, or computer network on which the computer program operates with the authorization of the owner or operator of such computer, computer system, or computer network, solely for the purpose of good-faith security research.

(ii) For purposes of paragraph (b)(18)(i) of this section, “good-faith security research” means accessing a computer program solely for purposes of good-faith testing, investigation, and/or correction of a security flaw or vulnerability, where such activity is carried out in an environment designed to avoid any harm to individuals or the public, and where the information derived from the activity is used primarily to promote the security or safety of the class of devices or machines on which the computer program operates, or those who use such devices or machines, and is not

used or maintained in a manner that facilitates copyright infringement.

(iii) Good-faith security research that qualifies for the exemption under paragraph (b)(18)(i) of this section may nevertheless incur liability under other applicable laws, including without limitation the Computer Fraud and Abuse Act of 1986, as amended and codified in title 18, United States Code, and eligibility for that exemption is not a safe harbor from, or defense to, liability under other applicable laws.

(19)(i) Video games in the form of computer programs embodied in physical or downloaded formats that have been lawfully acquired as complete games, when the copyright owner or its authorized representative has ceased to provide access to an external computer server necessary to facilitate an authentication process to enable gameplay, solely for the purpose of:

(A) Permitting access to the video game to allow copying and modification of the computer program to restore access to the game for personal, local gameplay on a personal computer or video game console; or

(B) Permitting access to the video game to allow copying and modification of the computer program to restore access to the game on a personal computer or video game console when necessary to allow preservation of the game in a playable form by an eligible library, archives, or museum, where such activities are carried out without any purpose of direct or indirect commercial advantage and the video game is not distributed or made available outside of the physical premises of the eligible library, archives, or museum.

(ii) Video games in the form of computer programs embodied in physical or downloaded formats that have been lawfully acquired as complete games, that do not require access to an external computer server for gameplay, and that are no longer reasonably available in the commercial marketplace, solely for the purpose of preservation of the game in a playable form by an eligible library, archives, or museum, where such activities are carried out without any purpose of direct or indirect commercial advantage and the video game is not distributed or made available outside of the physical premises of the eligible library, archives, or museum.

(iii) Computer programs used to operate video game consoles solely to the extent necessary for an eligible library, archives, or museum to engage in the preservation activities described

in paragraph (b)(19)(i)(B) or (b)(19)(ii) of this section.

(iv) For purposes of this paragraph (b)(19), the following definitions shall apply:

(A) For purposes of paragraphs (b)(19)(i)(A) and (b)(19)(ii) of this section, “complete games” means video games that can be played by users without accessing or reproducing copyrightable content stored or previously stored on an external computer server.

(B) For purposes of paragraph (b)(19)(i)(B) of this section, “complete games” means video games that meet the definition in paragraph (b)(19)(iv)(A) of this section, or that consist of both a copy of a game intended for a personal computer or video game console and a copy of the game’s code that was stored or previously stored on an external computer server.

(C) “Ceased to provide access” means that the copyright owner or its authorized representative has either issued an affirmative statement indicating that external server support for the video game has ended and such support is in fact no longer available or, alternatively, server support has been discontinued for a period of at least six months; provided, however, that server support has not since been restored.

(D) “Local gameplay” means gameplay conducted on a personal computer or video game console, or locally connected personal computers or consoles, and not through an online service or facility.

(E) A library, archives, or museum is considered “eligible” if—

(1) The collections of the library, archives, or museum are open to the public and/or are routinely made available to researchers who are not affiliated with the library, archives, or museum;

(2) The library, archives, or museum has a public service mission;

(3) The library, archives, or museum’s trained staff or volunteers provide professional services normally associated with libraries, archives, or museums;

(4) The collections of the library, archives, or museum are composed of lawfully acquired and/or licensed materials; and

(5) The library, archives, or museum implements reasonable digital security measures as appropriate for the activities permitted by this paragraph (b)(19).

(20)(i) Computer programs, except video games, that have been lawfully acquired and that are no longer reasonably available in the commercial marketplace, solely for the purpose of

lawful preservation of a computer program, or of digital materials dependent upon a computer program as a condition of access, by an eligible library, archives, or museum, where such activities are carried out without any purpose of direct or indirect commercial advantage. Any electronic distribution, display, or performance made outside of the physical premises of an eligible library, archives, or museum of works preserved under this paragraph may be made to only one user at a time, for a limited time, and only where the library, archives, or museum has no notice that the copy would be used for any purpose other than private study, scholarship, or research.

(ii) For purposes of the exemption in paragraph (b)(20)(i) of this section, a library, archives, or museum is considered “eligible” if—

(A) The collections of the library, archives, or museum are open to the public and/or are routinely made available to researchers who are not affiliated with the library, archives, or museum;

(B) The library, archives, or museum has a public service mission;

(C) The library, archives, or museum’s trained staff or volunteers provide professional services normally associated with libraries, archives, or museums;

(D) The collections of the library, archives, or museum are composed of lawfully acquired and/or licensed materials; and

(E) The library, archives, or museum implements reasonable digital security measures as appropriate for the activities permitted by this paragraph (b)(20).

(iii) For purposes of paragraph (b)(20) of this section, the phrase “one user at a time” means that for each copy of a work lawfully owned by an eligible library, archives, or museum and preserved under paragraph (b)(20)(i) of this section, such library, archives, or museum may make an electronic distribution, display, or performance of that work outside of its physical premises. An eligible library, archives, or museum may make each copy of such lawfully owned and preserved work available to different users simultaneously. This provision does not permit an eligible library, archives, or museum to make multiple, simultaneous copies of the same copy of a work for the purposes of providing users access to the work.

(21) Computer programs that operate 3D printers that employ technological measures to limit the use of material, when circumvention is accomplished solely for the purpose of using

alternative material and not for the purpose of accessing design software, design files, or proprietary data.

(22) Computer programs, solely for the purpose of investigating a potential infringement of free and open source computer programs where:

(i) The circumvention is undertaken on a lawfully acquired device or machine other than a video game console, on which the computer program operates;

(ii) The circumvention is performed by, or at the direction of, a party that has a good-faith, reasonable belief in the need for the investigation and has standing to bring a breach of license or copyright infringement claim;

(iii) Such circumvention does not constitute a violation of applicable law; and

(iv) The copy of the computer program, or the device or machine on which it operates, is not used or maintained in a manner that facilitates copyright infringement.

* * * * *

Dated: October 18, 2024.

Carla D. Hayden,

Librarian of Congress.

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DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 225

[Docket No. FRA–2024–0034]

RIN 2130–AC98

Federal Railroad Administration Accident/Incident Investigation Policy for Gathering Information and Consulting With Stakeholders; Correction

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Final rule; correction.

SUMMARY: On October 1, 2024, FRA published a final rule amending its Accident/Incident Regulations governing reporting, classification, and investigations to codify FRA’s policy for gathering information from, and consulting with, stakeholders during an accident/incident investigation. The published final rule contains errors in the preamble text. FRA is correcting those errors so that the final rule conforms to FRA’s intent.

DATES: Effective on November 15, 2024.

FOR FURTHER INFORMATION CONTACT: Senya Waas, Senior Attorney, Office of

the Chief Counsel, FRA, telephone: 202–875–4158 or email: senyaann.waas@dot.gov.

SUPPLEMENTARY INFORMATION: In FR document 2024–22326 beginning on page 79767 in the **Federal Register** of October 1, 2024, make the following corrections:

1. On page 79767, in the first and second columns, correct the **DATES** section to read:

DATES: Effective date: This final rule is effective on November 15, 2024, unless FRA receives adverse, substantive comment by October 31, 2024. If no adverse, substantive comments are received, FRA will publish a notice in the **Federal Register** indicating that no adverse comment was received and confirming that the rule will become effective on November 15, 2024.

2. On page 79768, in the first column, correct the first paragraph to read:

FRA is publishing this rule without a prior proposed rule under FRA’s direct final rulemaking procedures in 49 CFR 211.33 because it views this as a noncontroversial action that generally codifies FRA’s current process for accident/incident investigations. Under the Administrative Procedure Act (APA), an agency may waive the normal notice and comment procedures if the action is a rule of agency organization, procedure, or practice. 5 U.S.C. 553(b)(3)(A). Additionally, under the APA, an agency may waive notice and comment procedures when the agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(3)(B). As noted above, this rule would codify FRA’s procedures for accident/incident investigations and FRA has already worked with stakeholders (both labor and the rail organizations) to develop the Policy Document which is posted on FRA’s website. Accordingly, FRA finds that notice and comment are unnecessary and anticipates no adverse, substantive comment on any of the provisions of the rule. If FRA receives an adverse, substantive comment on any of the provisions, it will publish in the **Federal Register** a timely withdrawal, informing the public that the direct final rule will not take effect.

3. In the *Section-by-Section Analysis*, on page 79769, in the 2nd column, correct the fourth paragraph to read:

Previous paragraphs (b), (c), (d), (e), and (f) remain substantively unchanged but are being redesignated as paragraphs (a)(2) through (6).

4. Under *Regulatory Impact and Notices*, on page 79770, correct table 1 to read as follows:

TABLE 1—TOTAL COSTS OF THE DIRECT FINAL RULE
[2023 Dollars]*

Year	Total stakeholder costs	Total government costs	Total costs	Discounted 7%	Discounted 3%	Discounted 2%
1	\$97,922	\$19,753	\$117,675	\$117,675	\$117,675	\$117,675
2	97,922	10,541	108,463	101,367	105,304	106,336
3	97,922	10,541	108,463	94,736	102,237	104,251
4	97,922	10,541	108,463	88,538	99,259	102,207
5	97,922	10,541	108,463	82,746	96,368	100,203
6	97,922	10,541	108,463	77,333	93,561	98,238
7	97,922	10,541	108,463	72,273	90,836	96,312
8	97,922	10,541	108,463	67,545	88,190	94,424
9	97,922	10,541	108,463	63,126	85,622	92,572
10	97,922	10,541	108,463	58,997	83,128	90,757
Total	979,220	114,622	1,093,842	824,336	962,180	1,002,975

Note: This table and some others throughout this analysis may not sum due to rounding.

* All figures are presented in a 2023 base year unless otherwise noted.

5. Under *Regulatory Impact and Notices*, on page 79774, correct the paragraph before table 13 and the table to read as follows:

Total Costs

FRA estimates a total 10-year cost of \$0.9 million (PV, 2 percent) to

stakeholders for this rule. Table 13 displays the total costs to stakeholders for this final rule.

TABLE 13—TOTAL 10-YEAR COST TO STAKEHOLDERS

Year	Travel	Investigation participation	Document submission	Total stakeholder costs	Discounted 7%	Discounted 3%	Discounted 2%
1	\$29,215	\$56,861	\$11,846	\$97,922	\$97,922	\$97,922	\$97,922
2	29,215	56,861	11,846	97,922	91,516	95,070	96,002
3	29,215	56,861	11,846	97,922	85,529	92,301	94,120
4	29,215	56,861	11,846	97,922	79,934	89,613	92,274
5	29,215	56,861	11,846	97,922	74,704	87,002	90,465
6	29,215	56,861	11,846	97,922	69,817	84,468	88,691
7	29,215	56,861	11,846	97,922	65,250	82,008	86,952
8	29,215	56,861	11,846	97,922	60,981	79,620	85,247
9	29,215	56,861	11,846	97,922	56,991	77,301	83,575
10	29,215	56,861	11,846	97,922	53,263	75,049	81,937
Total	292,150	568,610	118,460	979,220	735,907	860,354	897,185

6. Under *Regulatory Impact and Notices*, on page 79774, correct the paragraph above table 14 and the table to read as follows:

Total Costs

FRA estimates a total 10-year cost of \$0.1 million (PV, 2 percent) to FRA for

this rule. Table 14 displays the total costs to FRA for this final rule.

TABLE 14—TOTAL 10-YEAR COST TO FRA

Year	Notifications	Outreach/training	Documentation review	Document sharing site	Total government costs	Discounted 7%	Discounted 3%	Discounted 2%
1	\$929	\$631	\$6,311	\$11,882	\$19,753	\$19,753	\$19,753	\$19,753
2	929	631	6,311	2,670	10,541	9,851	10,234	10,334
3	929	631	6,311	2,670	10,541	9,207	9,936	10,132
4	929	631	6,311	2,670	10,541	8,605	9,647	9,933
5	929	631	6,311	2,670	10,541	8,042	9,366	9,738
6	929	631	6,311	2,670	10,541	7,516	9,093	9,547
7	929	631	6,311	2,670	10,541	7,024	8,828	9,360
8	929	631	6,311	2,670	10,541	6,564	8,571	9,177
9	929	631	6,311	2,670	10,541	6,135	8,321	8,997
10	929	631	6,311	2,670	10,541	5,734	8,079	8,820
Total	9,290	6,310	63,110	35,912	114,622	88,431	101,828	105,791

7. Under *Regulatory Impact and Notices*, on page 79775, correct the paragraph above table 15 and the table to read as follows:

Total Costs

FRA estimates a total 10-year cost of \$1.0 million (PV, 2 percent) for this direct final rule, shown in Table 15.

TABLE 15—10-YEAR TOTAL COSTS

Year	Total stakeholder costs	Total government costs	Total costs	Discounted 7%	Discounted 3%	Discounted 2%
1	\$97,922	\$19,753	\$117,675	\$117,675	\$117,675	\$117,675
2	97,922	10,541	108,463	101,367	105,304	106,336
3	97,922	10,541	108,463	94,736	102,237	104,251
4	97,922	10,541	108,463	88,538	99,259	102,207
5	97,922	10,541	108,463	82,746	96,368	100,203
6	97,922	10,541	108,463	77,333	93,561	98,238
7	97,922	10,541	108,463	72,273	90,836	96,312
8	97,922	10,541	108,463	67,545	88,190	94,424
9	97,922	10,541	108,463	63,126	85,622	92,572
10	97,922	10,541	108,463	58,997	83,128	90,757
Total	979,220	114,622	1,093,842	824,336	962,180	1,002,975

Issued in Washington, DC.

Allison Ishihara Fultz,
Chief Counsel, Federal Railroad
Administration.

[FR Doc. 2024-24967 Filed 10-25-24; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric
Administration

50 CFR Part 635

[Docket No. 220919-0193]

RTID 0648-XE334

Atlantic Highly Migratory Species;
Atlantic Bluefin Tuna Fisheries;
Closure of the General Category
October Through November Fishery
for 2024

AGENCY: National Marine Fisheries
Service (NMFS), National Oceanic and
Atmospheric Administration (NOAA),
Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS closes the General category fishery for Atlantic bluefin tuna (BFT) for the remainder of the October through November time period. The General category may only retain, possess, or land large medium and giant (i.e., measuring 73 inches (185 centimeters (cm)) curved fork length (CFL) or greater) BFT when the fishery is open. This action applies to Atlantic Tunas General category (commercial) permitted vessels and Atlantic highly migratory species (HMS) Charter/Headboat permitted vessels with a commercial sale endorsement when

fishing commercially for BFT. This action also waives the previously scheduled restricted-fishing days (RFDs) for the remainder of the October through November time period. With the RFDs waived during the closure, fishermen aboard General category permitted vessels and HMS Charter/Headboat permitted vessels may tag and release BFT of all sizes, subject to the requirements of catch-and-release and tag-and-release programs. On December 1, 2024, the fishery will reopen automatically.

DATES: Effective 11:30 p.m., local time, October 24, 2024, through November 30, 2024.

FOR FURTHER INFORMATION CONTACT:

Becky Curtis (becky.curtis@noaa.gov) and Larry Redd, Jr. (larry.redd@noaa.gov) by email or by phone at 301-427-8503.

SUPPLEMENTARY INFORMATION: Atlantic BFT fisheries are managed under the 2006 Consolidated HMS Fishery Management Plan (FMP) and its amendments, pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) and consistent with the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*). HMS implementing regulations are at 50 CFR part 635. Section 635.27(a) divides the U.S. BFT quota, established by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the 2006 Consolidated HMS FMP and its amendments. NMFS is required under the Magnuson-Stevens

Act at 16 U.S.C. 1854(g)(1)(D) to provide U.S. fishing vessels with a reasonable opportunity to harvest quotas under relevant international fishery agreements such as the ICCAT Convention, which is implemented domestically pursuant to ATCA.

Under § 635.28(a)(1), NMFS files a closure action with the Office of the Federal Register for publication when a BFT quota (or subquota) is reached or is projected to be reached. Retaining, possessing, or landing BFT under that quota category is prohibited on or after the effective date and time of a closure action for that category until the opening of the relevant subsequent quota period or until such date as specified.

As described in § 635.27(a), the current baseline U.S. BFT quota is 1,316.14 metric tons (mt) (not including the 25 mt ICCAT allocated to the United States to account for bycatch of BFT in pelagic longline fisheries in the Northeast Distant Gear Restricted Area per § 635.27(a)(3)). The General category baseline quota is 710.7 mt. The General category baseline quota is suballocated to different time periods. Relevant to this action, the baseline subquota for the October through November time period is 92.4 mt. Effective October 2, 2024, NMFS transferred 100 mt from the Reserve category to the General category October through November time period, resulting in an adjusted October through November time period subquota of 192.4 mt (89 FR 81032, October 7, 2024).

Closure of the October Through November 2024 BFT General Category Fishery

To date, reported landings for the BFT General category October through November time period total 170.9 mt. Based on these landings data, including average daily catch rates, as well as anticipated favorable fishing conditions in the coming days, NMFS has determined that the adjusted October through November time period subquota of 192.4 mt is projected to be reached and exceeded shortly. Therefore, retaining, possessing, or landing large medium or giant (*i.e.*, measuring 73 inches (185 cm) CFL or greater) BFT by persons aboard vessels permitted in the Atlantic Tunas General category and HMS Charter/Headboat permitted vessels (while fishing commercially) must cease at 11:30 p.m. local time on October 24, 2024. The BFT General category will automatically reopen December 1, 2024, for the December time period with a retention limit of one large medium or giant BFT per vessel per day/trip. This action applies to Atlantic Tunas General category (commercial) permitted vessels and HMS Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT and is taken consistent with the regulations at § 635.28(a)(1).

Waiver for Remaining October Through November RFDs

On May 31, 2024 (89 FR 47095), NMFS published a final rule that, among other things, implemented RFDs every Sunday, Tuesday, Friday, and Saturday from July 1 through November 30, 2024. Since the fishery will be closed for the remainder of the October through November time period, NMFS has decided to waive the previously-scheduled RFDs for the remainder of that time period.

With the RFDs waived during a closure, consistent with § 635.23(a)(7), fishermen aboard General category permitted vessels and HMS Charter/Headboat permitted vessels may tag and release BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs described at § 635.26(a). All BFT that are released must be handled in a manner that will maximize their survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the "Careful Catch and Release" brochure available at <https://www.fisheries.noaa.gov/resource/>

[outreach-and-education/careful-catch-and-release-brochure/](#).

Monitoring and Reporting

NMFS will continue to monitor the BFT fisheries closely. Per § 635.5(b)(2)(i)(A), dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustments, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General and HMS Charter/Headboat category vessel owners are required per § 635.5(a)(4) to report their own catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing <https://hmspermits.noaa.gov>, using the HMS Catch Reporting app, or calling 888-872-8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

After the fishery reopens on December 1, depending on the level of fishing effort and catch rates of BFT at that time, NMFS may determine that additional adjustments are necessary to ensure available subquotas are not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas as specified under § 635.27(a)(7). If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may access <https://hmspermits.noaa.gov>, for updates on quota monitoring and inseason adjustments.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act (16 U.S.C. 1855(d)) and regulations at 50 CFR part 635 and this action is exempt from review under Executive Order 12866.

The Assistant Administrator for NMFS (AA) finds that pursuant to 5 U.S.C. 553(b)(B), it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on this action, for the following reasons. Specifically, the regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason retention limit adjustments and fishery closures to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Providing for prior notice and an opportunity to comment is impracticable and contrary to the public interest as this fishery is

currently underway and, based on the most recent landings information, the available time period subquota is projected to be reached shortly. Delaying this action could result in BFT landings that exceed the October through November time period subquota, which may result in future potential quota reductions for other BFT categories, depending on the magnitude of a potential overharvest. Taking this action does not raise conservation and management concerns and would support effective management of the BFT fishery. NMFS notes that the public had an opportunity to comment on the underlying rulemakings that established the U.S. BFT quota and the inseason adjustment and closure criteria.

For all of the above reasons, the AA also finds that pursuant to 5 U.S.C. 553(d), there is good cause to waive the 30-day delay in effective date.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: October 23, 2024.

Karen H. Abrams,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024-25020 Filed 10-23-24; 4:15 pm]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[RTID 0648-XD487]

Amendment 8 Revisions to Essential Fish Habitat in the Fishery Management Plan for U.S. West Coast Fisheries for Highly Migratory Species

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of agency decision.

SUMMARY: NMFS announces the approval of amendment 8 to the Fishery Management Plan (FMP) for the U.S. West Coast Highly Migratory Species (HMS). This amendment updates essential fish habitat (EFH) provisions in the existing HMS FMP. This amendment promotes the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) which requires periodic review and revision of EFH components of FMPs as warranted based on available information.

DATES: The amendment was approved on October 21, 2024.

ADDRESSES: Electronic copies of the amendment may be obtained from <https://www.regulations.gov> or the West Coast Region website at <https://www.fisheries.noaa.gov/action/amendment-8-revisions-essential-fish-habitat-fishery-management-plan-us-west-coast-highly>. Additional documents can be found on the Council's website at <https://www.pcouncil.org>.

FOR FURTHER INFORMATION CONTACT:

Nicole Nasby-Lucas at (858) 334-2826, nicole.nasby-lucas@noaa.gov, or Eric Chavez at (562) 980-4064, eric.chavez@noaa.gov.

SUPPLEMENTARY INFORMATION:

Background

The MSA requires that each regional fishery management council submit any FMP amendment it prepares to NMFS for review and approval, disapproval, or partial approval by the Secretary (16 U.S.C. 1854(a)). NMFS manages the HMS fisheries off the U.S. Pacific Coast under the HMS FMP. The Pacific Fishery Management Council (Council) prepared the FMP under the authority of the MSA, 16 U.S.C. 1801 *et seq.* Regulations governing U.S. fisheries and implementing the FMPs appear at 50 CFR parts 600 and 660.

The MSA mandates that each FMP describe and identify EFH for the fishery (16 U.S.C. 1853(7)). EFH is defined as "those waters and substrate necessary to fish for spawning, breeding, feeding or growth to maturity" (16 U.S.C. 1802(10)). Under this authority, NMFS and the Council have developed a comprehensive strategy to conserve EFH. This includes incorporating EFH into each of the Council's FMPs, identifying fishing and non-fishing impacts and associated conservation recommendations, and other required EFH elements. EFH requirements and the process for periodic EFH reviews are described in the EFH regulations at 50 CFR 600.815(a). EFH components for each management unit species (MUS) were included in appendix A to the Final Environmental Impact Statement when NMFS approved the HMS FMP in 2004 and have not been reviewed since that time.

This FMP amendment includes eight major components that (1) update the description and identification of EFH,

(2) include new maps for each MUS in the HMS FMP, (3) update information on life history, (4) update information on fishing impacts, (5) update information on non-fishing impacts and conservation measures, (6) update text on habitat areas of particular concern (HAPCs), (7) update research and information needs, and (8) add a reference to Council's Operating Procedure 22 as a description of the review and revision process. The revised FMP text and appendix F include supporting information and rationale for the modifications adopted by the Council.

Further detail describing the amendments was provided in the Notice of Availability (NOA) for this action and is not repeated here.

Procedural Aspects of the Amendment

The Council submitted the amendments to the Secretary for review on June 28, 2024. On July 24, 2024, NMFS published the NOA for the amendment and requested public review and comment (87 FR 21603). Public comments were received pertaining to the HMS FMP amendment and are addressed below.

The amendment does not add any new reporting requirements and does not change any regulatory requirements. Therefore, no proposed or final rule was prepared. This action only adds to or updates HMS EFH provisions in the HMS FMP.

Comments and Responses

NMFS received seven comments during the comment period on amendment 8 revisions to EFH in the HMS FMP, which ended on September 23, 2024. Six comments were in support of the amendment, and two of those encouraged consideration of HAPCs. One of the comments was outside of the scope of this action.

Comments 1–4: The commenters expressed support for the amendment as a fishery management tool for the protection of species, including the creation of new maps, advisories on fishing impact, and recognition of needs for additional research.

Response: NMFS thanks the commenters for the support of this amendment. NMFS agrees that the updated maps will help achieve the overall EFH objectives of supporting a

sustainable fishery and the managed species' contribution to a healthy ecosystem. NMFS agrees that it is important to identify any potential adverse effects on EFH from fishing activities, including lost fishing gear and discharge of processing waste, and whether any additional measures are needed to address those adverse effects. NMFS also agrees that additional research is needed to improve our understanding of fish habitats, the functions they provide, and adverse effects from both fishing and non-fishing activities.

Comments 5–6: The commenters expressed support for the amendment and reaffirmed the importance of updating information, identifying fishing and non-fishing impacts, and considering HAPCs. One commenter was concerned about the risk of delaying protective measures for vulnerable areas, such as shark nurseries and migratory corridors.

Response: NMFS thanks the commenters for the support of this amendment. NMFS agrees that updating species information is important particularly since newer information is based on current fishery-independent information that was not available when the original EFH descriptions were adopted. NMFS agrees that it is important to identify potential adverse effects on EFH from fishing and non-fishing activities that may adversely affect HMS EFH along with any appropriate conservation measures. NMFS also agrees with the importance of HAPCs, although none were proposed at this time. Available data do not point to a focused pupping ground for sharks and available electronic tagging data across species reveals no specific migratory pathway within the U.S. Exclusive Economic Zone. However, we recommend additional research to collect more information that could inform consideration of HAPCs in the future.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 21, 2024.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2024-24869 Filed 10-25-24; 8:45 am]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 89, No. 208

Monday, October 28, 2024

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

Proposed Amendment of Class C Airspace at Palm Beach International Airport, FL; Public Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notification of meeting.

SUMMARY: This document announces a fact-finding informal airspace meeting regarding a plan to amend Class C Airspace at Palm Beach International Airport, FL (KPBI). The purpose of the meeting is to solicit aeronautical comments on the proposal's effects on local aviation operations. All comments received during the meeting, and the subsequent comment period, will be considered prior to the issuance of a notice of proposed rulemaking (NPRM).

DATES: The meeting will be held on Thursday, December 5, 2024, from 5 p.m. to 7 p.m. (Eastern Time). Comments must be received on or before January 4, 2025.

Format: This will be a virtual informal airspace meeting using the Zoom teleconferencing tool. The meeting will also be recorded and available to watch on the FAA YouTube social media channel.

ADDRESSES: *Comments:* Send comments on the proposal to: Matthew Cathcart, Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; or via email to: 9-AJO-PBI-Class-C-Comments@faa.gov.

FOR FURTHER INFORMATION CONTACT: Mark Siviglia, Acting Air Traffic Manager, Palm Beach Airport Traffic Control Tower, 3550 Belvedere Rd., West Palm Beach, FL 33406. Telephone Number (561) 275-1401, Email: Mark.Siviglia@faa.gov.

SUPPLEMENTARY INFORMATION:

Meeting Procedures

The meeting will provide interested parties an opportunity to present views, recommendations, and comments on the proposed airspace.

(a) *Registration:* To attend the meeting, the public can register here: https://airportnetwork.zoom.us/webinar/register/WN_v-ZwjHMTc6DxRjewMawAg.

(b) The meeting will be open to all persons on a space-available basis. There will be no admission fee or other charge to attend and participate. The meeting will be informal in nature and will be conducted by one or more representatives of the FAA Eastern Service Area. A representative from the FAA will present a briefing on the planned airspace modifications.

(c) Each participant will be given an opportunity to deliver comments or make a presentation, although a time limit may be imposed to accommodate closing times. Only comments concerning the plan to amend the Palm Beach International Airport Class C airspace area will be accepted.

(d) Each person wishing to make a presentation will be asked to note their intent when registering for the meeting so those time frames can be established. This meeting will not be adjourned until everyone registered to speak has had an opportunity to address the panel. This meeting may be adjourned at any time if all persons present have had an opportunity to speak.

(e) Position papers or other handout material relating to the substance of the meeting will be accepted. Participants submitting papers or handout materials should send them to the mail or email address noted in the COMMENTS section, above.

(f) This meeting will be formally recorded and available on the FAA YouTube channel. A summary of the comments made at the meeting will be filed in the rulemaking docket.

Information gathered through this meeting will assist the FAA in drafting a NPRM that would be published in the **Federal Register**. The public will be afforded the opportunity to comment on any NPRM published on this matter.

A graphic depiction of the proposed airspace modifications may be viewed at the following URL: www.faa.gov/go/palmbeach.

Agenda for the Meeting

- Presentation of Meeting Procedures

- Informal Presentation of the proposed amendment to the Class C Airspace area
- Public Presentations
- Discussions and Questions
- Closing Comments

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

Issued in Washington, DC, on October 22, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024-24935 Filed 10-25-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2024-2352; Airspace Docket No. 24-AEA-4]

RIN 2120-AA66

Establishment of United States Area Navigation Route Q-161 and Amendment of United States Area Navigation Routes Q-97, Q-133, Q-437, Q-439, Q-445, and Q-481; Eastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish United States Area Navigation (RNAV) Route Q-161 and amend RNAV Routes Q-97, Q-133, Q-437, Q-439, Q-445, and Q-481 in the eastern United States. This action supports the Northeast Corridor Atlantic Coast Route (NEC ACR) Optimization Project to improve the efficiency of the National Airspace System (NAS).

DATES: Comments must be received on or before December 12, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA-2024-2352 and Airspace Docket No. 24-AEA-4 using any of the following methods:

* *Federal eRulemaking Portal:* Go to www.regulations.gov and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation, 1200 New Jersey

Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493-2251.

Docket: Background documents or comments received may be read at www.regulations.gov at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11J, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Policy Directorate, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267-8783.

FOR FURTHER INFORMATION CONTACT: Brian Vidis, Rules and Regulations Group, Policy Directorate, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the route structure to maintain the efficient flow of air traffic within the NAS.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental,

and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA's web page at www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Avenue, College Park, GA, 30337.

Incorporation by Reference

United States Area Navigation Routes (Q-Routes) are published in paragraph 2006 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the

current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to establish RNAV Route Q-161 and amend RNAV Routes Q-97, Q-133, Q-437, Q-439, Q-445, and Q-481 in the eastern United States. This action supports the NEC ACR Optimization Project to improve the efficiency of the NAS. The proposed route changes are described below.

Additionally, the FAA identified that the route descriptions of RNAV Routes Q-133 and Q-437 list the KALDA, VA; VILLS, NJ; and LLUND, NY route points as Fixes, in error. These route points were modified on June 20, 2023, from a Fix to become a waypoint (WP). The KALDA, VILLS, and LLUND route points are identified as a WP in the National Airspace System Resource (NASR) database and charted as a WP accordingly. This proposal would correct these errors and refer to the KALDA, VILLS, and LLUND route points as a WP.

In place of a two-letter state abbreviation for multiple listed route points in route descriptions the "OA" means "Offshore Atlantic".

Q-97: Q-97 currently extends between the TOVAR, FL, WP and the Presque Isle, ME (PQI), Very High Frequency Omnidirectional Range/Distance Measuring Equipment (VOR/DME). The FAA proposes to remove the BYSEL, MD, WP from the route description as it is a turn of less than one degree. Additionally, the FAA proposes to add six route points between the ZJAAY, MD, WP and the Calverton, NY (CCC), VOR/DME. The route points that would be added are the PAJET, DE, WP; CAANO, DE, WP; TBONN, OA, WP; ZIZZI, NJ, WP; YAZUU, NJ, WP; and HEADI, NJ, WP. The proposed route modification would move RNAV Route Q-97 to the east to eliminate traffic conflicts between aircraft flying southbound on RNAV Route Q-97 and aircraft flying northbound on RNAV Route Q-439 descending into the New York and Connecticut areas. As amended, the route would continue to extend between the TOVAR WP and the Presque Isle VOR/DME.

Q-133: Q-133 currently extends between the CHIEZ, NC, WP and the

PONCT, NY, WP. The FAA proposes to remove the airway segments between the CHIEZ WP and the CONFR, MD, WP and replace it with the airway segment between the JAMIE, VA, Fix and the CONFR WP. The route segment between the CHIEZ WP and the KALDA, VA, WP is still needed for navigation, and this action proposes to continue to provide this RNAV connectivity to the KALDA WP as new RNAV Route Q-161 proposed in this action. Additionally, the FAA proposes to remove the airway segment between the Kennedy, NY (JFK) VOR/DME and the PONCT WP and replace it with the airway segments between the Kennedy VOR/DME and the PBERG, NY, WP. These proposed changes improve the connectivity of multiple airports along the east coast of the United States to the Montreal-Trudeau Airport, Canada, where the preferred arrival route is over the PBERG WP. As amended, the route would be changed to extend between the JAMIE Fix and the PBERG WP.

Q-161: Q-161 is a new RNAV route proposed to extend between the CHIEZ, NC, WP and the KALDA, VA, WP. This new proposed RNAV route overlays a portion of RNAV Route Q-133, proposed to be amended in this action, but would provide additional efficiency by becoming its own distinct route. The new proposed route would continue to provide RNAV connectivity between the CHIEZ WP and the KALDA WP.

Q-437: Q-437 currently extends between the VILLS, NJ, WP and the LLUND, NY, WP. The FAA proposes to remove the airway segments between the VILLS WP and the LLUND WP and replace it with the airway segments between the CRPLR, VA, WP and the PONCT, NY, WP due to high traffic density over the New York City area. These proposed changes would move aircraft from being directly over New York City to an area west of Newark, NJ. Additionally, the proposed would expand RNAV connectivity further to the south to Norfolk, VA area, and further to the north to the Albany, NY area. As amended, the route would be

changed to extend between the CRPLR WP and the PONCT WP.

Q-439: Q-439 currently extends between the HOWYU, DE, WP and the Presque Isle, ME (PQI), VOR/DME. The FAA proposes to remove the airway segments between the HOWYU WP and the MANTA, NJ, Fix and replace it with the airway segments between the KALDA, VA, WP and the MANTA Fix due to a need to separate aircraft arriving to the John F. Kennedy International Airport, NY from aircraft arriving to other airports in the New York City area. As amended, the route would be changed to extend between the KALDA WP and the Presque Isle VOR/DME.

Q-445: Q-445 currently extends between the SHAUP, OA, WP and the KYSKY, NY, WP. The FAA proposes to extend RNAV Route Q-445 to the south between the KALDA, VA, WP and the SHAUP WP. The proposed route extension would provide RNAV connectivity from the KALDA WP to the eastern Massachusetts area. As amended, the route would be changed to extend between the KALDA WP and the KYSKY WP.

Q-481: Q-481 currently extends between the CONFR, MD, WP and the Deer Park, NY (DPK), VOR/DME. The FAA proposes to extend RNAV Route Q-481 to the south between the JAMIE, VA, WP and the CONFR WP; and remove the LEEAH, NJ, Fix from the route and replace it with the SOSBY, OA, WP and the ECOIL, OA, WP. These proposed route modifications are necessary to ensure adequate separation with other parallel RNAV routes in the Atlantic City, NJ area. As amended, the route would be changed to extend between the JAMIE WP and the Deer Park VOR/DME.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a “significant

regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 2006 United States Area Navigation Routes.

* * * * *

Q-97 TOVAR, FL to Presque Isle, ME (PQI) [Amended]

TOVAR, FL	WP	(Lat. 26°33'05.09" N, long. 080°02'19.75" W)
MALET, FL	FIX	(Lat. 28°41'29.90" N, long. 080°52'04.30" W)
DEBRL, FL	WP	(Lat. 29°17'48.73" N, long. 081°08'02.88" W)
KENLL, FL	WP	(Lat. 29°34'28.35" N, long. 081°07'25.26" W)
PRMUS, FL	WP	(Lat. 29°49'05.67" N, long. 081°07'20.74" W)
WOPNR, OA	WP	(Lat. 30°37'36.03" N, long. 081°04'26.44" W)
JEVED, GA	WP	(Lat. 31°15'02.60" N, long. 081°03'40.14" W)
CAKET, SC	WP	(Lat. 32°31'08.63" N, long. 080°16'09.21" W)
ELLDE, NC	WP	(Lat. 34°24'14.57" N, long. 078°41'50.60" W)
PAAACK, NC	WP	(Lat. 35°55'40.26" N, long. 077°15'30.99" W)
SAWED, VA	WP	(Lat. 37°32'00.73" N, long. 075°51'29.10" W)
KALDA, VA	WP	(Lat. 37°50'31.06" N, long. 075°37'35.34" W)
ZJAAAY, MD	WP	(Lat. 38°03'09.95" N, long. 075°26'34.27" W)
PAJET, DE	WP	(Lat. 38°28'04.13" N, long. 075°03'00.55" W)

CAANO, DE	WP	(Lat. 38°31'46.37" N, long. 074°58'52.32" W)
TBONN, OA	WP	(Lat. 38°45'02.83" N, long. 074°45'03.77" W)
ZIZZI, NJ	WP	(Lat. 38°56'26.46" N, long. 074°31'44.28" W)
YAZUU, NJ	WP	(Lat. 39°24'44.82" N, long. 074°01'01.55" W)
HEADI, NJ	WP	(Lat. 39°57'49.56" N, long. 073°43'28.85" W)
Calverton, NY (CCC)	VOR/DME	(Lat. 40°55'46.63" N, long. 072°47'55.89" W)
NTMEG, CT	WP	(Lat. 41°16'30.75" N, long. 072°28'52.08" W)
VENTE, MA	WP	(Lat. 42°08'24.33" N, long. 071°53'38.08" W)
BLENO, NH	WP	(Lat. 42°54'55.00" N, long. 071°04'43.37" W)
FRIAR, ME	FIX	(Lat. 44°26'28.93" N, long. 069°53'04.38" W)
Presque Isle, ME (PQI)	VOR/DME	(Lat. 46°46'27.07" N, long. 068°05'40.37" W)

* * * * *

Q-133 JAMIE, VA to PBERG, NY [Amended]

JAMIE, VA	FIX	(Lat. 37°36'20.58" N, long. 075°57'48.81" W)
CONFR, MD	WP	(Lat. 38°16'10.90" N, long. 075°24'32.98" W)
MGERK, DE	WP	(Lat. 38°46'16.00" N, long. 075°18'09.00" W)
LEEAH, NJ	FIX	(Lat. 39°15'39.27" N, long. 074°57'11.01" W)
MYRCA, NJ	WP	(Lat. 40°20'42.97" N, long. 073°56'58.07" W)
Kennedy, NY (JFK)	VOR/DME	(Lat. 40°37'58.38" N, long. 073°46'17.01" W)
BIZEX, NY	WP	(Lat. 41°17'02.86" N, long. 073°34'50.20" W)
Cambridge, NY (CAM)	VOR/DME	(Lat. 42°59'39.44" N, long. 073°20'38.47" W)
PBERG, NY	WP	(Lat. 44°42'06.25" N, long. 073°31'22.18" W)

* * * * *

Q-161 CHIEZ, NC to KALDA, VA [New]

CHIEZ, NC	WP	(Lat. 34°31'05.93" N, long. 077°32'25.74" W)
KOOKI, NC	WP	(Lat. 35°54'21.71" N, long. 076°41'56.22" W)
PYSTN, VA	WP	(Lat. 37°05'19.78" N, long. 075°53'22.19" W)
KALDA, VA	WP	(Lat. 37°50'31.06" N, long. 075°37'35.34" W)

* * * * *

Q-437 CRPLR, VA to PONCT, NY [Amended]

CRPLR, VA	WP	(Lat. 37°36'24.01" N, long. 076°09'57.67" W)
TRPOD, MD	WP	(Lat. 38°20'20.33" N, long. 075°32'01.85" W)
OYVAY, OA	WP	(Lat. 39°01'03.58" N, long. 075°26'28.07" W)
VILLS, NJ	WP	(Lat. 39°18'03.87" N, long. 075°06'37.90" W)
SIZZR, NJ	WP	(Lat. 39°33'57.22" N, long. 074°53'58.83" W)
METRO, NJ	WP	(Lat. 40°25'21.77" N, long. 074°40'10.30" W)
CLAUS, NJ	WP	(Lat. 40°48'50.07" N, long. 074°10'08.96" W)
GANDE, NY	WP	(Lat. 41°30'36.66" N, long. 073°48'52.03" W)
PONCT, NY	WP	(Lat. 42°44'48.83" N, long. 073°48'48.07" W)

* * * * *

Q-439 KALDA, VA to Presque Isle, ME (PQI) [Amended]

KALDA, VA	WP	(Lat. 37°50'31.06" N, long. 075°37'35.34" W)
ZJAAY, MD	WP	(Lat. 38°03'09.95" N, long. 075°26'34.27" W)
BYSEL, MD	WP	(Lat. 38°15'02.70" N, long. 075°16'52.87" W)
RADDS, DE	FIX	(Lat. 38°38'54.80" N, long. 075°05'18.48" W)
SHHAY, DE	WP	(Lat. 38°47'04.08" N, long. 074°55'55.42" W)
BRIGS, NJ	FIX	(Lat. 39°31'24.72" N, long. 074°08'19.67" W)
MANTA, NJ	FIX	(Lat. 39°54'07.01" N, long. 073°32'31.63" W)
SARDI, NY	FIX	(Lat. 40°31'26.61" N, long. 072°47'55.87" W)
RIFLE, NY	WP	(Lat. 40°41'24.18" N, long. 072°34'54.89" W)
FOXWD, CT	WP	(Lat. 41°48'21.66" N, long. 071°48'07.03" W)
BOGRT, MA	WP	(Lat. 42°13'56.08" N, long. 071°31'07.37" W)
BLENO, NH	WP	(Lat. 42°54'55.00" N, long. 071°04'43.37" W)
BEEKN, ME	WP	(Lat. 43°20'51.95" N, long. 070°44'50.28" W)
Presque Isle, ME (PQI)	VOR/DME	(Lat. 46°46'27.07" N, long. 068°05'40.37" W)

* * * * *

Q-445 KALDA, VA to KYSKY, NY [Amended]

KALDA, VA	WP	(Lat. 37°50'31.06" N, long. 075°37'35.34" W)
ZJAAY, MD	WP	(Lat. 38°03'09.95" N, long. 075°26'34.27" W)
PAJET, DE	WP	(Lat. 38°28'04.13" N, long. 075°03'00.55" W)
CAANO, DE	WP	(Lat. 38°31'46.37" N, long. 074°58'52.32" W)
TBONN, OA	WP	(Lat. 38°45'02.83" N, long. 074°45'03.77" W)
ZIZZI, NJ	WP	(Lat. 38°56'26.46" N, long. 074°31'44.28" W)
YAZUU, NJ	WP	(Lat. 39°24'44.82" N, long. 074°01'01.55" W)
SHAUP, OA	WP	(Lat. 39°44'23.91" N, long. 073°34'33.84" W)
VALCO, OA	WP	(Lat. 40°05'29.86" N, long. 073°08'22.91" W)

KYSKY, NY

WP

(Lat. 40°46'52.75" N, long. 072°12'21.45" W)

* * * * *

Q-481 JAMIE, VA to Deer Park, NY (DPK) [Amended]

JAMIE, VA	WP	(Lat. 37°36'20.58" N, long. 075°57'48.81" W)
CONFR, MD	WP	(Lat. 38°16'10.90" N, long. 075°24'32.98" W)
MGERK, DE	WP	(Lat. 38°46'16.00" N, long. 075°18'09.00" W)
SOSBY, OA	WP	(Lat. 39°15'24.74" N, long. 074°55'30.57" W)
ECCOL, OA	WP	(Lat. 39°49'58.45" N, long. 074°14'06.07" W)
ZIGGI, NJ	FIX	(Lat. 40°03'07.01" N, long. 074°00'49.34" W)
Deer Park, NY (DPK)	VOR/DME	(Lat. 40°47'30.30" N, long. 073°18'13.17" W)

* * * * *

Issued in Washington, DC, on October 22, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024–24938 Filed 10–25–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–1282]

Possible Control of Phenethyl Bromide as a List I Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) finds that phenethyl bromide is used in the illicit manufacture of the controlled substance fentanyl, as well as fentanyl analogues and fentanyl-related substances, and is important to the manufacture of these substances because it is often used in synthetic pathways to illicitly manufacture fentanyl, fentanyl analogues, and fentanyl-related substances. Prior to proposing to list phenethyl bromide as a list I chemical under the Controlled Substances Act, DEA is soliciting information on the current uses of phenethyl bromide (other than for the synthesis of fentanyl) in order to properly determine the effect such a proposed action would have on legitimate industry.

DATES: Comments must be submitted electronically or postmarked on or before November 27, 2024. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA–1282” on all electronic and

written correspondence, including any attachments.

- **Electronic comments:** The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your comment submission, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on [Regulations.gov](https://www.regulations.gov). If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- **Paper comments:** Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) will make comments available for public inspection online at <https://www.regulations.gov>. Such information includes personal or business identifying information (such as name, address, State or Federal identifiers, etc.) voluntarily submitted by the commenter. Generally, all information

voluntarily submitted by the commenter, unless clearly marked as Confidential Information in the method described below, will be publicly posted. Comments may be submitted anonymously. The Freedom of Information Act applies to all comments received.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want made publicly available should submit two copies of the comment. One copy must be marked “CONTAINS CONFIDENTIAL INFORMATION” and should clearly identify all PII or business information the commenter does not want to be made publicly available, including any supplemental materials. DEA will review this copy, including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked “TO BE PUBLICLY POSTED” and must have all claimed PII and business information already redacted. DEA will post only the redacted comment on <https://www.regulations.gov> for public inspection.

For easy reference, an electronic copy of this document and a plain language summary of this advanced notice of proposed rulemaking are available at <https://www.regulations.gov>.

Legal Authority

The Controlled Substances Act (CSA) authorizes the Attorney General to specify, by regulation, chemicals as list I chemicals.¹ The Attorney General has delegated his authority to designate list I chemicals to the Administrator of DEA (Administrator).² A “list I chemical” is a chemical that is used in manufacturing a controlled substance in violation of the CSA and is important to the manufacture of the controlled substances.³ The current list of all listed chemicals is published at 21 CFR

¹ 21 U.S.C. 802(34).

² 28 CFR 0.100(b).

³ Id.

1310.02. DEA regulations set forth the process by which DEA may add a chemical as a listed chemical. As set forth in 21 CFR 1310.02(c), the agency may do so by publishing a final rule in the **Federal Register** following a published notice of proposed rulemaking with at least 30 days for public comments.

Background

The clandestine manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances remains extremely concerning as the distribution of illicit fentanyl, fentanyl analogues, and fentanyl-related substances continues to drive drug-related overdose deaths in the United States. Fentanyl is a synthetic opioid and was first synthesized in Belgium in the late 1950s. Fentanyl was introduced into medical practice and is approved for medical practitioners in the United States to prescribe lawfully for anesthesia and analgesia. Yet, due to its pharmacological effects, fentanyl can be used as a substitute for heroin, oxycodone, and other opioids in opioid dependent individuals. Therefore, despite its accepted medical use in treatment in the United States, DEA controls fentanyl as a schedule II controlled substance due to its high potential for abuse and dependence.⁴

Moreover, there are a substantial number of fentanyl analogues⁵ and fentanyl-related substances⁶ that are being distributed on the illicit drug market despite DEA's recent actions adding them as scheduled controlled substances.⁷ Illicit manufacturers of fentanyl, fentanyl analogues, and fentanyl-related substances attempt to utilize unregulated precursor chemicals to evade law enforcement detection and precursor chemical controls in order to keep manufacturing these substances. This strategy allows for the synthesis of a variety of fentanyl analogues and fentanyl-related substances by making slight modifications to the core fentanyl structure while maintaining the same synthetic methodology used to synthesize fentanyl, fentanyl analogues, and fentanyl-related substances.

The unlawful trafficking of fentanyl, fentanyl analogues, and fentanyl-related substances in the United States continues to pose an imminent hazard to public safety. Since 2012, fentanyl has shown a dramatic increase in the illicit drug supply as a single substance, in mixtures with other illicit drugs (*i.e.*, heroin, cocaine, and methamphetamine), and in forms that mimic pharmaceutical preparations including prescription opiates and benzodiazepines.⁸

DEA has noted a significant increase in overdoses and overdose fatalities

from fentanyl, fentanyl analogues, and fentanyl-related substances in the United States in recent years. According to the Centers for Disease Control and Prevention (CDC), opioids, mainly synthetic opioids (which includes fentanyl), are predominantly responsible for drug overdose deaths in recent years. According to CDC WONDER,⁹ drug-induced overdose deaths involving synthetic opioids (excluding methadone) in the United States increased from 36,359 in 2019, to 56,516 in 2020, and to 70,601 in 2021. Based on provisional data, the predicted number of drug overdose deaths involving synthetic opioids (excluding methadone) in the United States for the 12 months ending March 2023 is 76,472 individuals, or approximately 69.2 percent of all drug-induced overdose deaths for that time period.¹⁰ The increase in overdose fatalities involving synthetic opioids coincides with a dramatic increase in law enforcement encounters of fentanyl, fentanyl analogues, and fentanyl-related substances. According to the National Forensic Laboratory Information System (NFLIS-Drug),¹¹ reports from forensic laboratories of drug items containing fentanyl, fentanyl analogues, and fentanyl-related substances increased dramatically since 2014, as shown in Table 1.

TABLE 1—ANNUAL REPORTS OF FENTANYL AND SELECT FENTANYL ANALOGUES AND FENTANYL-RELATED SUBSTANCES IDENTIFIED IN DRUG ENCOUNTERS

Year	2014	2015	2016	2017	2018	2019	2020	2021	2022
Annual Fentanyl Reports	5,554	15,461	37,154	61,642	89,967	108,133	126,0099	165,104	165,920
Annual Reports of select fentanyl analogues and fentanyl-related substances	78	2,317	7,624	21,980	16,033	20,864	7,774	26,363	29,404

Role of Phenethyl Bromide in the Synthesis of Fentanyl

Fentanyl, fentanyl analogues, and fentanyl-related substances are not naturally occurring substances. As such, the manufacture of these substances requires them to be produced through synthetic organic chemistry. Synthetic organic chemistry is the process in

which a new organic molecule is created through a series of chemical reactions, which involve precursor chemicals. Through chemical reactions, the chemical structures of precursor chemicals are modified in a desired fashion. These chemical reaction sequences, also known as synthetic pathways, are designed to create a

desired substance. Several synthetic pathways to fentanyl, fentanyl analogues, and fentanyl-related substances have been identified in clandestine laboratory settings; these include the original “Janssen method,” the “Siegfried method,” and the “Gupta method.” In response to the illicit manufacture of fentanyl, fentanyl

⁴ 21 U.S.C. 812(c) Schedule II(b)(6); 21 CFR 1308.12(c).

⁵ Schedules of Controlled Substances: Temporary Placement of Seven Fentanyl-Related Substances in Schedule I. 83 FR 4580 (Feb. 1, 2018).

⁶ Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I. 83 FR 5188 (Feb. 6, 2018).

⁷ Schedules of Controlled Substances: Placement of 10 Specific Fentanyl-Related Substances in Schedule I. 86 FR 22113 (Apr. 27, 2021).

⁸ United Nations Office on Drugs and Crime, Global SMART Update Volume 17, March 2017.

https://www.unodc.org/documents/scientific/Global_SMART_Update_17_web.pdf.

⁹ Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Multiple Cause of Death Files, 2018–2021, and from provisional data for years 2022–2023, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at <http://wonder.cdc.gov/mcd-icd10-provisional.html> on March 16, 2023.

¹⁰ Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2023. Accessed at <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm> on August 17, 2023.

¹¹ NFLIS-Drug is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by Federal, State and local forensic laboratories in the United States. While NFLIS-Drug data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See 76 FR 77330, 77332 (Dec. 12, 2011). NFLIS-Drug data was queried on July 31, 2023, and August 17, 2023.

analogues, and fentanyl-related substances using these methods, DEA controlled *N*-phenethyl-4-piperidone (NPP),¹² *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl), *N*-phenylpiperidin-4-amine (4-anilinopiperidine; including its amides and carbamates),¹³ and 4-piperidone (piperidin-4-one)¹⁴ as list I chemicals, and 4-anilino-*N*-phenethylpiperidine (ANPP)¹⁵ and *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl)¹⁶ as schedule II immediate precursors under the CSA.

In 2017, the United Nations Commission on Narcotic Drugs placed NPP and ANPP in Table I of the Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (1988 Convention) in response to the international reintroduction of fentanyl on the illicit drug market. As such, member states of the United Nations are required to regulate these precursor chemicals at the national level. Importantly, the People's Republic of China regulated NPP and ANPP on February 1, 2018.¹⁷ Subsequently, in 2022, the United Nations Commission on Narcotic Drugs placed norfentanyl, 1-boc-4-anilinopiperidine, and 4-anilinopiperidine in Table I of the 1988 Convention in response to the international reintroduction of fentanyl on the illicit drug market and the introduction of new precursors used in the illicit manufacture of fentanyl.

Phenethyl Bromide

The original published synthetic pathway to fentanyl, known as the Janssen method, involves the list I chemical benzylfentanyl¹⁸ and schedule II immediate precursor norfentanyl.¹⁹ In this synthetic

pathway, benzylfentanyl, a list I chemical under the CSA, is then converted to norfentanyl, the schedule II immediate precursor in this synthetic pathway. Norfentanyl is reacted with phenethyl bromide (also known as 2-bromoethyl benzene) to complete the synthesis of fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

Phenethyl bromide also serves as a precursor chemical in the Siegfried method. In this synthetic pathway, phenethyl bromide is reacted with 4-piperidone, a list I chemical under the CSA, to produce NPP, another list I chemical, which is further converted to ANPP,²⁰ the schedule II immediate precursor in the Siegfried method. One additional step completes the synthesis of fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

In addition to the Janssen and Siegfried methods, clandestine manufacturers are using other methods to synthesize fentanyl, one of which is known as the Gupta method. In this synthetic pathway, 4-piperidone, a list I chemical under the CSA, is used to synthesize 4-anilinopiperidine, another list I chemical under the CSA,²¹ which serves as an alternative precursor chemical to NPP, a list I chemical, in the synthesis of ANPP, a schedule II immediate precursor, albeit through a different synthetic process. 4-Anilinopiperidine is reacted with phenethyl bromide to produce ANPP, which is then converted to the schedule II controlled substance, fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

Phenethyl Halides and Sulfonates

Phenethyl bromide is attractive to illicit manufacturers due to the lack of regulations on this chemical; it is readily available from chemical suppliers. Additionally, related phenethyl halides (*i.e.*, phenethyl chloride, phenethyl iodide, etc.) and phenethyl sulfonates (*i.e.*, phenethyl tosylate, phenethyl mesylate, etc.) can be used as substitutes for phenethyl bromide in many of the known synthetic pathways. These pathways

can be easily used, and modified, in the illicit manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances.

Solicitation for Information

With this advanced notice of proposed rulemaking, DEA is soliciting information on any possible legitimate uses of phenethyl bromide, and related halides and sulfonates, unrelated to fentanyl production (including industrial uses) in order to assess the potential economic impact of controlling phenethyl bromide as a list I chemical. DEA seeks to document any unpublicized use(s) and other proprietary use(s) of phenethyl bromide, and related halides and sulfonates, that are not in the public domain. Therefore, DEA is soliciting comment on the uses of phenethyl bromide, and related halides and sulfonates, in the legitimate marketplace.

DEA is soliciting input from all potentially affected parties regarding: (1) the types of legitimate industries using phenethyl bromide, and related halides and sulfonates; (2) the legitimate uses, legitimate needs, and quantities produced, used, and distributed of phenethyl bromide, and related halides and sulfonates; (3) the size of the domestic market for phenethyl bromide, and related halides and sulfonates, if any; (4) the number of manufacturers of phenethyl bromide, and related halides and sulfonates; (5) the number of distributors of phenethyl bromide, and related halides and sulfonates; (6) the level of import and export of phenethyl bromide, and related halides and sulfonates; (7) the potential burden that controlling phenethyl bromide, and related halides and sulfonates, as a list I chemical may have on any legitimate industry and trade; (8) the potential number of individuals/firms that may be adversely affected by such regulatory controls (particularly with respect to the impact on small businesses); and (9) any other information on the manner of manufacturing, distribution, consumption, storage, disposal, and uses of phenethyl bromide, and related halides and sulfonates, by industry and others. DEA invites all interested parties to provide any information on any legitimate uses of phenethyl bromide, and related halides and sulfonates, in industry, commerce, academia, research and development, or other applications. DEA seeks both quantitative and qualitative data.

Such information may be submitted electronically to the address listed above and is requested by November 27, 2024. This information will be used to properly determine the effect that

¹² Control of a Chemical Precursor Used in the Illicit Manufacture of Fentanyl as a List I Chemical, 72 FR 20039 (Apr. 23, 2007).

¹³ Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals, 85 FR 20822 (Apr. 15, 2020).

¹⁴ Designation of 4-Piperidone as a List I Chemical, 88 FR 21902 (Apr. 12, 2023).

¹⁵ Control of Immediate Precursor Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance, 75 FR 37295 (June 29, 2010).

¹⁶ Control of the Immediate Precursor Norfentanyl Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance, 85 FR 21320 (Apr. 17, 2020).

¹⁷ <https://www.dea.gov/press-releases/2018/01/05/china-announces-scheduling-controls-two-fentanyl-precursor-chemicals>. Accessed March 9, 2022.

¹⁸ Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals, 85 FR 20822 (April 15, 2020).

¹⁹ Control of the Immediate Precursor Norfentanyl Used in the Illicit Manufacture of Fentanyl as a

Schedule II Controlled Substance, 85 FR 21320 (April 17, 2020).

²⁰ Control of Immediate Precursor Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance, 75 FR 37295 (June 29, 2010).

²¹ Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals, 85 FR 20822 (April 15, 2020).

proposed regulations to make phenethyl bromide a list I chemical under the CSA would have on industry.

Handling of Confidential or Proprietary Information

Confidential or proprietary information may be submitted as part of a comment regarding this advanced notice of proposed rulemaking. Please see the “POSTING OF PUBLIC COMMENTS” section above for a discussion of the identification and redaction of confidential business information and personally identifying information.

Regulatory Analyses

This ANPRM was developed in accordance with the principles of Executive Order (E.O.) 12866, “Regulatory Planning and Review,” E.O. 13563, “Improving Regulation and Regulatory Review,” and E.O. 14094, “Modernizing Regulatory Review.” Because this action is an ANPRM, the requirement of E.O. 12866 to assess the costs and benefits of this action does not apply.

Furthermore, the requirements of the Regulatory Flexibility Act do not apply to this action because, at this stage, it is an ANPRM and not a “rule” as defined in 5 U.S.C. 601. Following review of the comments received in response to this ANPRM, if DEA proceeds with a notice of proposed rulemaking regarding this matter, DEA will conduct all relevant analyses as required by statute or E.O.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 10, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–24616 Filed 10–25–24; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 236

[Docket No. FRA–2023–0064]

RIN 2130–AC95

Positive Train Control Systems

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: FRA is proposing to amend certain regulations governing positive train control (PTC) systems. Since December 31, 2020, by law, PTC systems have generally governed rail operations on PTC-mandated main lines, which encompass nearly 59,000 route miles today. Through FRA’s oversight and continued engagement with the industry, FRA has found that its existing PTC regulations do not adequately address temporary situations during which PTC technology is not enabled, including after certain initialization failures or in cases where a PTC system needs to be temporarily disabled to facilitate repair, maintenance, infrastructure upgrades, or capital projects. FRA expects PTC systems to be reliable and robust, further reducing the occurrence of initialization failures and outages. This NPRM proposes to establish strict parameters and operating restrictions under which railroads may continue to operate safely in certain necessary scenarios when PTC technology is temporarily not governing rail operations. The purpose of this NPRM is to enable continued, safe operations and improve rail safety by facilitating prompt repairs, upgrades, and restoration of PTC system service.

DATES: Written comments must be received by December 27, 2024. FRA believes a 60-day comment period is appropriate to allow the public to comment on this proposed rule. FRA will consider comments received after that date to the extent practicable.

ADDRESSES:

Comments: Comments related to Docket No. FRA–2023–0064 may be submitted by going to <https://www.regulations.gov> and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name, docket number (FRA–2023–0064), and Regulation Identifier Number (RIN) for this rulemaking (2130–AC95). All

comments received will be posted without change to <https://www.regulations.gov>; this includes any personal information. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT:

Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: Gabe.Neal@dot.gov; or Stephanie Anderson, Attorney Adviser, telephone: 202–834–0609, email: Stephanie.Anderson@dot.gov.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

Section 20157 of title 49 of the United States Code (U.S.C.) mandates each Class I railroad, and each entity providing regularly scheduled intercity or commuter rail passenger transportation, to implement an FRA-certified PTC system on: (1) its main lines over which poison- or toxic-by-inhalation hazardous materials are transported, if the line carries five million or more gross tons of any annual traffic; (2) its main lines over which intercity or commuter rail passenger transportation is regularly provided; and (3) any other tracks the Secretary of Transportation (Secretary) prescribes by

regulation or order.¹ By law, PTC systems must be designed to prevent certain accidents or incidents, including train-to-train collisions, over-speed derailments, incursions into established work zones, and movements of trains through switches left in the wrong position.²

Currently, 37 host railroads³—including 7 Class I railroads,⁴ 24 entities that provide regularly scheduled intercity or commuter rail passenger transportation (hereinafter referred to as “intercity passenger railroads or commuter railroads,” respectively), and 6 Class II or III, short line, or terminal railroads—are directly subject to the statutory mandate. On December 29, 2020, FRA announced that railroads had fully implemented FRA-certified and interoperable PTC systems on all PTC-mandated main lines.⁵ 49 U.S.C. 20157(a); 49 CFR 236.1005(b)(7).

Today, PTC technology is governing rail operations on nearly 59,000 route miles. Based on FRA’s oversight of PTC technology since FRA last amended its PTC regulations in 2021, FRA identified three aspects of its existing PTC regulations that warrant revision to address ongoing challenges. Overall, the proposed amendments would benefit the railroad industry, the public, and FRA by facilitating repairs, maintenance, upgrades, and capital improvements; expanding certain railroad informational requirements; reducing costs; and enabling the safe,

reliable, and resilient movement of people and goods, while preserving rail safety.

This NPRM proposes to establish strict parameters and operating restrictions under which railroads may continue to operate safely in three specific scenarios when PTC technology is temporarily not governing rail operations:

1. When non-revenue passenger equipment needs to operate to a maintenance facility or yard, for the sole purpose of repairing or exchanging PTC technology;

2. When a PTC system needs to be temporarily disabled to facilitate repair, maintenance, an infrastructure upgrade, or a capital project; and

3. When a system-level or widescale problem occurs resulting in multiple trains’ PTC systems failing to initialize.

FRA’s objective in this rulemaking is to establish clear, uniform processes, rather than addressing issues that arise in a reactive and piecemeal manner. FRA expects that establishing predictable, prescriptive processes will both enable continued operations and improve railroad safety by facilitating prompt repairs, upgrades, and restoration of PTC system service and eliminating uncertainty and inconsistent application of FRA’s regulations. FRA’s proposed parameters and operating restrictions in this NPRM are intended to be sufficiently strict to ensure that railroads and PTC system suppliers and vendors proactively identify and remedy problems before they arise and immediately correct any problems that may surface despite proactive measures.

First, FRA is proposing to establish an exception, under 49 CFR 236.1006(b)(6), to permit, under certain conditions, non-revenue passenger equipment to operate to maintenance facilities or yards, without being governed by PTC technology. This NPRM proposes to extend the exception currently afforded to certain freight movements to movements of non-revenue passenger equipment, including equipment that is owned or controlled by an intercity passenger railroad or commuter railroad.

This proposed exception would enable non-revenue passenger equipment, including a locomotive, locomotive consist, or train without passengers onboard, to operate to a maintenance facility or yard for the sole purpose of repairing or exchanging⁶ a

PTC system or component. Commuter railroads have informed FRA this proposed exception would be beneficial and necessary, as it would enable them, for example, to operate a PTC-equipped locomotive, where the onboard PTC technology is not functioning and requires repair, to a maintenance facility or yard to repair or exchange the PTC system. To ensure rail safety, FRA is proposing to impose six conditions on each movement of non-revenue passenger equipment subject to this exception, including speed and distance restrictions, the requirement to establish an absolute block (meaning no other traffic may be present in the area), and other protections of the route.

Second, FRA proposes to improve the existing process, under 49 CFR 236.1021(m), that railroads currently utilize to request and obtain FRA’s approval to disable their PTC systems temporarily when necessary to facilitate repair, maintenance, infrastructure upgrades, and capital projects. This NPRM proposes to add paragraph (m)(4) to existing § 236.1021 to focus on this specific type of request for amendment (RFA) to PTC systems (*i.e.*, where a temporary PTC system outage is proposed), as it is different from the other types of RFAs that railroads submit under § 236.1021 and requires additional FRA oversight.

FRA proposes to require railroads to provide additional, essential information in an RFA that seeks to temporarily disable a PTC system to enable FRA to evaluate more fully the scope, circumstances, and necessity of a proposed temporary outage and properly determine whether granting the request is in the public interest and consistent with railroad safety. For example, this NPRM proposes to impose nine additional content requirements for this specific type of RFA, including certain justifications, safety analyses, mitigations, and other documentation to demonstrate the proposed outage is as narrow in scope, impact, and duration, as possible.

Third, FRA proposes to reintroduce as a permanent provision a version of a temporary provision regarding PTC system initialization failures, which expired on December 31, 2022.⁷ The expired regulatory provision previously permitted any train, including an individual train, to keep operating subject to certain restrictions, if the train failed to initialize for any reason prior to the train’s departure from its initial terminal. In FRA’s 2014 final rule, FRA

¹ See Rail Safety Improvement Act of 2008, Public Law 110–432, section 104, 122 Stat. 4848 (Oct. 16, 2008), as amended by the Positive Train Control Enforcement and Implementation Act of 2015, Public Law 114–73, 129 Stat. 568 (Oct. 29, 2015); the Fixing America’s Surface Transportation Act, Public Law 114–94, section 11315(d), 129 Stat. 1312 (Dec. 4, 2015); and the Passenger Rail Expansion and Rail Safety Act of 2021, Public Law 117–58, section 22414, 135 Stat. 429 (Nov. 15, 2021), codified as amended at 49 U.S.C. 20157. See also 49 CFR part 236, subpart I.

² See, e.g., 49 U.S.C. 20157(g)(1), (i)(5); 49 CFR 236.1005 (setting forth the technical specifications).

³ As this proposed rule primarily focuses on host railroads, FRA references the current number of PTC-mandated *host* railroads (37). A host railroad is “a railroad that has effective operating control over a segment of track,” and a tenant railroad is “a railroad, other than a host railroad, operating on track upon which a PTC system is required.” See 49 CFR 236.1003(b).

⁴ FRA acknowledges that one Class I railroad (Canadian Pacific Railway) recently acquired a second Class I railroad (Kansas City Southern Railway). However, for purposes of FRA’s PTC regulations and related oversight, FRA is currently counting these railroads separately, as they presently submit separate PTC filings and have indicated they will do so unless and until they fully integrate their PTC systems.

⁵ Federal Railroad Administration, FRA Announces Landmark Achievement with Full Implementation of Positive Train Control (Dec. 29, 2020), available at <https://railroads.dot.gov/sites/fra.dot.gov/files/2020-12/fra1920.pdf>.

⁶ FRA’s existing regulations, including 49 CFR 236.1029(b)(6), refer to repairing or exchanging a PTC system or component. To clarify, FRA notes that “exchange” is intended to refer to the

industry’s practice of, for example, swapping out a defective component for a functioning component.

⁷ See 49 CFR 236.1029(g)(2).

authorized this provision temporarily, recognizing that “there may be issues that could be identified and resolved in the early days following PTC system implementation and revenue service operation.”⁸ In 2014, FRA also observed that “[e]xperience over these intervening years will provide more empirical data on PTC system reliability, and may be a basis for FRA to revisit this issue at a later date should circumstances warrant.”⁹

FRA’s intention in this NPRM, by proposing to reintroduce an updated version of this provision, is to address only system-level outages or failures that result in multiple trains’ PTC systems failing to initialize, impacting the trains of the host railroad and often most, if not all, of its tenant railroads. Currently, if a PTC system fails to initialize, trains are generally prohibited from operating, which has resulted in situations where passengers could be stranded, and vital freight shipments halted.

Although PTC technology is generally reliable and robust, it is a complex technology, composed of many subsystems and dependent on external networks, and it continues to experience

unplanned outages. For example, railroads’ Quarterly Reports of PTC System Performance¹⁰ show that PTC technology failed to initialize on approximately 236 intercity passenger or commuter trains and 894 freight trains in 2023.¹¹ Additionally, based on voluntary reporting by railroads, FRA is aware of eight (8) system-level outages that occurred in 2023 that caused multiple trains to fail to initialize.

FRA is proposing to impose two tiers of operating restrictions that would become increasingly restrictive as time passes, to ensure both that railroads utilize any operating flexibility only when necessary and that railroads and their vendors and suppliers identify and resolve issues promptly. FRA expects this will help strike the appropriate balance between enabling continued operations subject to speed restrictions, pending resolution of a PTC failure, and restoring PTC systems as quickly as possible. In short, if a PTC system fails to initialize, impacting multiple trains, FRA proposes to permit railroads to continue operating for 24 hours, subject to the operating restrictions, including speed limits, that previously applied to initialization failures and that currently

apply to *en route* failures.¹² After the first 24 hours, FRA proposes to impose a significant speed limit of restricted speed, among other restrictions, both to help ensure rail safety and to propel the industry to act quickly to restore PTC system service.

FRA analyzed the economic impact of this proposed rule over a 10-year period and estimated its benefits and costs, which are shown in the table below. The total estimated 10-year net benefits would be \$81.8 million (discounted at 2 percent), and the annualized net benefits would be \$9.1 million (discounted at 2 percent). The industry benefits associated with FRA’s proposal to amend three provisions—*i.e.*, to introduce a new exception for certain non-revenue passenger equipment movements, improve the RFA process regarding temporary PTC system outages, and permit continued operations following certain initialization failures, subject to operating restrictions—would outweigh the industry costs and government administrative costs associated with FRA’s proposal to expand the content requirements for RFAs related to temporary outages.

TABLE A—TOTAL 10-YEAR DISCOUNTED BENEFITS, COSTS, AND NET BENEFITS
[2023 Dollars]¹

Category	Present value 2% (\$)	Present value 3% (\$)	Present value 7% (\$)	Annualized 2% (\$)	Annualized 3% (\$)	Annualized 7% (\$)
Industry Benefits	83,534,444	80,105,191	68,518,285	9,299,600	9,390,772	9,755,462
Total Costs	1,760,775	1,688,492	1,444,258	196,021	197,943	205,630
Industry Costs	1,514,075	1,451,919	1,241,905	168,557	170,209	176,819
Government Administrative Costs	246,700	236,573	202,353	27,464	27,734	28,811
Net Benefits ²	81,773,669	78,416,699	67,074,027	9,103,579	9,192,829	9,549,832

¹ Numbers in this table and subsequent tables may not sum due to rounding. The present value of costs and benefits are calculated in this analysis. Present value provides a way of converting future benefits into equivalent dollars today. The formula used to calculate the present value at the particular discount rate is: $1/(1+r)^t$, where “r” is the discount rate, and “t” is the year. Discount rates of 2%, 3%, and 7% are used in this analysis.

² Net Benefits = Industry Benefits – (Industry Costs + Government Administrative Costs). FRA notes that the net industry benefits of this proposed rule may help reduce the overall industry costs for implementing and operating PTC systems.

II. Background

A. Legal Authority To Prescribe PTC Regulations

Section 104(a) of the Rail Safety Improvement Act of 2008 required the Secretary to prescribe PTC regulations

necessary to implement the statutory mandate, including regulations specifying the essential technical functionalities of PTC systems and how FRA certifies PTC systems.¹³ The Secretary delegated to the Administrator of the Federal Railroad Administration

the authority to carry out the functions and exercise the authority vested in the Secretary by the Rail Safety Improvement Act of 2008. 49 CFR 1.89(b).

In accordance with its authority under 49 U.S.C. 20157(g) and 49 CFR 1.89(b),

⁸ 79 FR 49693, 49706 (Aug. 22, 2014).

⁹ *Id.*

¹⁰ Form FRA F 6180.152, Office of Management and Budget (OMB) Control No. 2130–0553; 49 U.S.C. 20157(m) (as amended by the Passenger Rail Expansion and Rail Safety Act of 2021, Public Law 117–58, section 22414, 135 Stat. 429 (Nov. 15, 2021)).

¹¹ The referenced initialization failures exclude any initialization failures where the source or cause was the onboard subsystem, as proposed

§ 236.1029(g)(3) excludes such initialization failures from receiving the flexibility afforded under proposed § 236.1029(g), as they typically impact one train. FRA is citing to the relevant initialization failures where the source or cause was, for example, the back office, wayside, or communications subsystems because those types of issues would generally impact more than one train and would be within the scope of this proposed provision.

¹² An *en route* failure is a situation where a controlling locomotive experiences a “PTC system

failure or the PTC system is otherwise cut out while *en route* (*i.e.*, after the train has departed its initial terminal).” 49 CFR 236.1029(b) (emphasis added). FRA’s current regulations provide that when an *en route* failure occurs, a train may continue operating in accordance with certain restrictions, including speed limits that are based on the underlying signal or train control system still in effect, outlined under 49 CFR 236.1029(b)(1) through (6).

¹³ Public Law 110–432, 122 Stat. 4848 (Oct. 16, 2008), codified as amended at 49 U.S.C. 20157(g).

FRA published its first final PTC rule on January 15, 2010, which is set forth, as amended, under 49 CFR part 236, subpart I.¹⁴ FRA's PTC regulations under 49 CFR part 236, subpart I, prescribe "minimum, performance-based safety standards for PTC systems . . . including requirements to ensure that the development, functionality, architecture, installation, implementation, inspection, testing, operation, maintenance, repair, and modification of those PTC systems will achieve and maintain an acceptable level of safety." 49 CFR 236.1001(a). FRA subsequently amended its PTC regulations via final rules published in 2010, 2012, 2014, 2016, and 2021.¹⁵

Most recently, on July 27, 2021, FRA amended its PTC regulations to improve the process by which railroads submit, and FRA reviews, RFAs to railroads' FRA-certified PTC systems and their associated PTC Safety Plans (PTCSPs), and to establish more robust reporting requirements to enable FRA to oversee the reliability and performance of railroads' PTC systems effectively. Also, in January 2023, FRA announced that it issued a guidance document addressing requirements related to the submission of requests for waivers, applications to modify or discontinue a signal system, and other special approval requests to FRA, and FRA underscored the importance of ensuring that railroads' filings contain sufficient, non-confidential information for the public to review and on which to comment.¹⁶

In this proposed rule, FRA proposes to revise three sections, 49 CFR 236.1006, 236.1021, and 236.1029, of FRA's existing PTC regulations pursuant to its specific authority under 49 CFR 1.89 and 49 U.S.C. 20157(g), and its general authority under 49 U.S.C. 20103 to prescribe regulations and issue orders for every area of railroad safety.

B. Public Participation Prior to the Issuance of the NPRM

FRA regularly engages with host railroads, tenant railroads, PTC system vendors and suppliers, industry associations, and labor organizations, as part of FRA's oversight of railroads'

operation of PTC systems on the mandated main lines under 49 U.S.C. 20157 and the other lines where railroads are voluntarily implementing PTC technology. The purpose of this section is to summarize FRA's pertinent meetings prior to the issuance of this NPRM, pursuant to 49 CFR 5.5.

From November 2023 to February 2024, FRA met with the following four industry associations and their member railroads to discuss the objectives of this NPRM and solicit their feedback: the American Public Transportation Association (APTA), the American Short Line and Regional Railroad Association (ASLRRA), the Association of American Railroads (AAR), and the Commuter Rail Coalition (CRC).

Representatives from the following 35 Class I railroads, commuter and passenger railroads, and short line and regional railroads, listed alphabetically, attended one or more of the AAR, APTA,¹⁷ ASLRRA, and CRC meetings referenced immediately above: Alaska Railroad; Altamont Corridor Express; BNSF Railway (BNSF); Canadian National Railway (CN); Canadian Pacific Kansas City Limited (CPKC); Capital Metropolitan Transportation Authority (CMTY); Central Florida Rail Corridor (CFRC); CSX Transportation, Inc. (CSX); Denton County Transportation Authority; Genesee & Wyoming Inc. (G&W); Long Island Rail Road (LIRR); Maryland Area Rail Commuter (MARC); Massachusetts Bay Transportation Authority (MBTA); Metro-North Railroad (Metro-North); National Railroad Passenger Corporation (Amtrak); New Jersey Transit (NJT); New Mexico Rail Runner Express; Norfolk Southern Railway (NS); North County Transit District (NCTD); Northeast Illinois Regional Commuter Railroad Corporation (Metra); Northern Indiana Commuter Transportation District (NICD); Northstar Commuter Rail; Peninsula Corridor Joint Powers Board (Caltrain); Regional Transportation District (Denver RTDC); Sonoma-Marin Area Rail Transit (SMART); Sound Transit; South Florida Regional Transportation Authority (SFRTA); Southeastern Pennsylvania Transportation Authority (SEPTA); Southern California Regional Rail Authority (Metrolink); TEXRail; Tri-County Metropolitan Transportation District of Oregon (TriMet); Trinity Railway Express (TRE); Union Pacific Railroad (UP); Utah Transit Authority

(UTA FrontRunner); and Virginia Railway Express (VRE).

In addition, for the same purpose, FRA met with the following 10 labor organizations in February 2024: the American Train Dispatchers Association (ATDA); the Brotherhood of Locomotive Engineers and Trainmen, a Division of the Rail Conference of the International Brotherhood of Teamsters (BLET); the Brotherhood of Maintenance of Way Employes Division of the International Brotherhood of Teamsters (BMWED); the Brotherhood of Railroad Signalmen (BRS); the Brotherhood of Railway Carmen Division, Transportation Communications International Union (BRC); the International Association of Machinists and Aerospace Workers (IAM); the International Association of Sheet Metal, Air, Rail, and Transportation Workers—Transportation Division (SMART-TD); the International Brotherhood of Electrical Workers (IBEW); the Transport Workers Union of America (TWU); and the Transportation Trades Department, AFL-CIO (TTD).

In general, the four industry associations and 35 railroads strongly supported the three objectives of this NPRM. The labor organizations FRA met with supported FRA's objective of enabling operations while maintaining rail safety, but they expressed concern that regulatory flexibility might have the unintended consequence of degrading safety or delaying repairs to PTC technology. Accordingly, with all feedback in mind, FRA drafted its proposed requirements and restrictions in 49 CFR 236.1006(b)(6), 236.1021(m)(4), and 236.1029(g) to prioritize rail safety, address limited circumstances for facilitating repairs, maintenance, and infrastructure upgrades, and enable the safe, reliable, and resilient movement of passengers, commuters, and freight.

As the detailed feedback the associations, railroads, and labor organizations provided during the meetings was directed at a specific proposal in this NPRM, FRA discusses the feedback in the appropriate portions of Section III (*Section-by-Section Analysis*) of this NPRM.

The proposals in this NPRM are based on FRA's own review and analysis and, in part, on the feedback provided during the meetings in 2023 and 2024, specified above. FRA seeks comments on all proposals made in this NPRM.

¹⁴ 75 FR 2598 (Jan. 15, 2010).

¹⁵ See 75 FR 59108 (Sept. 27, 2010); 77 FR 28285 (May 14, 2012); 79 FR 49693 (Aug. 22, 2014); 81 FR 10126 (Feb. 29, 2016); and 86 FR 40154 (July 27, 2021).

¹⁶ 88 FR 1448 (Jan. 10, 2023); Federal Railroad Administration, Guidance on Submitting Requests for Waivers, Block Signal Applications, and Other Approval Requests to FRA (Dec. 2022), available at <https://railroads.dot.gov/sites/fra.dot.gov/files/2022-12/Guidance%20on%20Submitting%20Waiver%20Special%20Approval%20Other%20Requests%20for%20Approval%20to%20FRA%20%28Dec%202022%29%20final.pdf>.

¹⁷ In addition to FRA's meeting with APTA, FRA met with the following two user groups in February 2024, as coordinated through APTA: the Enhanced Automatic Train Control (E-ATC) User Group and the Interoperable Electronic Train Management System (I-ETMS) User Group.

III. Section-by-Section Analysis

Section 236.1006 Equipping Locomotives Operating in PTC Territory

Existing paragraph (b) in § 236.1006 contains a list of exceptions to the general requirement under paragraph (a) that each locomotive, locomotive consist, or train that operates on any PTC-governed track segment “be controlled by a locomotive equipped with an onboard PTC apparatus that is fully operative and functioning in accordance with the applicable PTCSP approved under this subpart.” 49 CFR 236.1006(a), (b)(1) through (5).

FRA proposes to add a new exception, under proposed paragraph (b)(6), to permit non-revenue passenger equipment to operate to maintenance facilities or yards, without being governed by PTC technology, under certain conditions. Currently, a similar exception is available only to freight railroads under existing paragraph (b)(5) of this section. The purpose of new proposed paragraph (b)(6) is to extend that type of exception to movements of certain non-revenue passenger equipment, which would include equipment owned or controlled by an intercity passenger railroad or commuter railroad.

The sole purpose of new proposed paragraph (b)(6) is to enable non-revenue passenger equipment, including a locomotive, locomotive consist, or train, to operate to a maintenance facility or yard for the purpose of repairing or exchanging a PTC system. During FRA’s APTA and CRC meetings in February 2024, several commuter railroads, including CMTY, MARC, Metro-North, NICD, and NJT, commented that this proposed exception would be beneficial and necessary, as it would enable them, for example, to operate a PTC-equipped locomotive, where the onboard PTC technology is not functioning and requires repair, to a maintenance facility or yard to repair or exchange the PTC system or component. Without this proposed provision, intercity passenger railroads and commuter railroads would need to utilize rescue trains or, in other words, use an operative, PTC-equipped locomotive, locomotive consist, or train to move the non-operative, PTC-equipped equipment to a maintenance facility or yard. This proposed provision will enable a railroad to repair the equipment more efficiently, thus helping improve rail safety.

During FRA’s meetings in February 2024, commuter railroads cited often experiencing issues with transporting equipment requiring repair to their maintenance facilities, including

unavailability of equipment and cascading schedule delays, and they supported this proposed exception, even though it would potentially constrain some operations. For example, the introductory text of proposed paragraph (b)(6) makes it clear that this proposed exception would apply only to non-revenue movements, meaning no intercity passenger or commuter rail service could be provided while moving this equipment not governed by a PTC system.

Proposed paragraphs (b)(6)(i) through (v) and (vii) outline the six additional conditions FRA proposes an intercity passenger railroad or commuter railroad must satisfy while utilizing this proposed exception. First, proposed paragraph (b)(6)(i) would limit the speed of the locomotive, locomotive consist, or train to a maximum of 49 miles per hour (mph), which is significantly slower than the normal maximum authorized speed for passenger equipment, which generally ranges between 79 mph and 150 mph.

Second, proposed paragraph (b)(6)(ii) would require an absolute block¹⁸ to be established in front of the locomotive, locomotive consist, or train. This would help ensure safety by essentially eliminating the possibility of a train-to-train collision. During FRA’s February 2024 meetings, CMTY, SMART, and UTA FrontRunner commented that they currently use absolute blocks in similar circumstances and supported the proposal of this condition.

Third, proposed paragraph (b)(6)(iii) specifies that there cannot be any working limits established under part 214 of this chapter on any part of the route. FRA proposes to eliminate the risk of an incursion into an established work zone by not permitting work zones or any roadway workers at all on the route the non-revenue passenger equipment uses to reach the maintenance facility or yard to repair or exchange its PTC technology. To be clear, roadway workers may not perform any work on the route where the non-revenue passenger equipment operates subject to this proposed exception, until after the equipment arrives at its destination, the maintenance facility or yard.

Fourth, proposed paragraph (b)(6)(iv) specifies that the locomotive, locomotive consist, or train could operate in non-revenue service no farther than the next forward location designated in the railroad’s PTCSP for

the repair or exchange¹⁹ of PTC technology. During FRA’s meeting with labor organizations in February 2024, BLET and BRS commented that they were concerned a railroad might utilize this proposed exception to avoid repairing the PTC system or to delay repairing the PTC system by operating the equipment to a more distant repair location than available.

Relatedly, during a meeting in February 2024, NICD observed that the structure of commuter rail operations would inherently prevent railroads from overusing any exception or provision that involves speed restrictions because of the negative impact that has on their operations. For example, even a single train operating at a slower speed can create scheduling issues and cascading delays for commuter trains. In addition, FRA expects that its proposed conditions, including the imposition of a speed restriction, the prohibition against work zones, and an absolute block requirement, would prevent overuse of this exception. Also, FRA crafted proposed paragraph (b)(6)(iv) with BLET and BRS’s comments in mind, and this proposed condition would explicitly prohibit the non-revenue passenger equipment from operating farther than the next forward designated location in the railroad’s FRA-approved PTCSP.

Fifth, similar to a condition in the existing freight version of this exception in paragraph (b)(5) of this section, proposed (b)(6)(v) would require the railroad to protect the route against conflicting operations and establish and comply with sufficient operating rules to protect against a train-to-train collision and the movement of a train through a switch left in the wrong or improper position. This condition would further reduce the possibility of a train-to-train collision as it would address traffic on intersecting tracks. Furthermore, to protect against the movement of a train through a switch left in the wrong or improper position, a railroad’s operating rules could, for example, explain that the railroad utilizes a system or technology capable of monitoring switches. If a railroad does not have such a system or technology, a switch’s position must be manually verified before any movement over the switch points. To accomplish this, a switch tender must check the switch, or the train crew must stop and then confirm the switch position before operating over the switch.

¹⁸ Under 49 CFR 236.709, an absolute block is defined as a “block in which no train is permitted to enter while it is occupied by another train.”

¹⁹ To clarify, FRA notes that “exchange” is intended to refer to the industry’s practice of, for example, swapping out a defective component for a functioning component.

During an FRA meeting in February 2024, SFRTA inquired whether FRA intends to limit the distance of the movement of non-revenue passenger equipment in this proposed exception, as it does in the freight railroad exception in existing paragraph (b)(5). FRA notes that the purpose of the two exceptions is different: the purpose of the freight exception in paragraph (b)(5) is to facilitate freight switching and freight transfer train service, including in revenue service, in or near yards, whereas the purpose of the proposed paragraph (b)(6) exception would be to enable non-revenue passenger equipment to reach maintenance facilities or yards, without being governed by PTC technology, for the specific purpose of repairing or exchanging a PTC system. The commuter railroad SMART commented that it would not be possible to identify a specific distance that applies to all cases because the distance to each intercity passenger or commuter railroad's maintenance facilities and yards, based on the starting point, is unique. FRA agrees, as the applicable distance varies greatly based on case-by-case circumstances. Accordingly, rather than imposing an exact distance limit, FRA expects that the five conditions in proposed paragraphs (b)(6)(i) through (v) would sufficiently define the scope of this exception.

Proposed paragraph (b)(6)(vi) provides that FRA may, in its discretion, approve alternative criteria and conditions, in a PTCSP or an RFA to a PTCSP, if the railroad demonstrates that the alternative criteria and conditions would provide an equivalent or greater level of safety than the default criteria and conditions. FRA is proposing to add this paragraph to mirror that discretionary element of the freight yard movements exception in existing paragraph (b)(5)(vii). Proposed paragraph (b)(6)(vi) provides the opportunity for railroads to propose alternative applications of this exception to FRA for review and approval. An intercity passenger railroad or commuter railroad must obtain FRA's approval only if it seeks to use alternative exception criteria or conditions under proposed paragraph (b)(6)(vi), whereas the standard exception for non-revenue passenger equipment movements would be immediately available for use for any movement that meets all default criteria and conditions in proposed paragraphs (b)(6)(i) through (v).²⁰

²⁰ FRA notes that railroads would report any use of the proposed exception under 49 CFR 236.1006(b)(6) in their Quarterly Reports of PTC

Finally, proposed paragraph (b)(6)(vii) imposes a notification requirement that a railroad must satisfy before moving non-revenue passenger equipment pursuant to this exception. Specifically, this paragraph proposes that before utilizing the default exception under paragraphs (b)(6)(i) through (v) or the discretionary exception under paragraph (b)(6)(vi), the railroad must notify each person involved with the movement of the non-revenue passenger equipment, including any dispatchers and train crews, in addition to any roadway workers who may no longer work on that segment during the movement subject to this exception.

Section 236.1021 Discontinuances, Material Modifications, and Amendments

On December 31, 2022, the regulatory provision under 49 CFR 236.1029(g)(3) expired, which previously permitted a railroad to temporarily disable its PTC system when necessary to perform PTC system repair or maintenance, after notifying an FRA regional office. As § 236.1029(g)(3) has expired, a simple notification to FRA no longer suffices, and a railroad must obtain FRA's approval through an RFA pursuant to 49 CFR 236.1021(m) before a railroad temporarily disables its PTC system and continues rail operations.

The purpose of existing § 236.1021, in relevant part, is to prohibit a railroad from making certain changes to its PTC system or disabling or discontinuing its PTC system, unless the railroad first submits an RFA to its PTC system with certain information and obtains FRA's approval.

This NPRM proposes to add a new paragraph (m)(4) to § 236.1021 to clarify that the RFA process under existing paragraph (m) applies to a case where a railroad seeks to temporarily disable its PTC system, and to continue operations during that time, to facilitate repair, maintenance, infrastructure upgrades, or capital projects. During FRA's meetings with AAR, APTA, ASLRRRA, CRC, and their member railroads in November 2023 and February 2024 to discuss this NPRM, these four associations and several railroads, including all Class I railroads, Alaska Railroad, Amtrak, G&W, Metra, Metro-North, Metrolink, and SFRTA, expressed general support for FRA's proposal to revise existing paragraph (m) to acknowledge explicitly that it covers RFAs to PTC systems involving temporary outages.

System Performance (Form FRA F 6180.152, OMB Control No. 2130-0553), as either a "cut out" or "initialization failure" depending on the circumstances and based on the definitions under 49 CFR 236.1003.

Specifically, proposed paragraph (m)(4) clarifies that a host railroad must utilize the RFA process under paragraph (m) to request and obtain FRA's approval of a temporary PTC system outage, during which train movements may continue, including a short-term outage related to repair, maintenance, an infrastructure upgrade, or a capital project.²¹ To provide non-exhaustive examples of what a temporary PTC system outage includes, proposed paragraph (m)(4) clarifies that the term includes, but is not limited to, any scenario when the onboard PTC apparatus or subsystem, wayside subsystem, communications subsystem, or back office subsystem would be disabled. FRA interprets the term "disabled" broadly and acknowledges the industry also uses the verb "disengage" interchangeably in this context.

Consistent with the current process under existing paragraph (m), proposed paragraph (m)(4)(i) provides that a railroad may temporarily disable PTC technology pursuant to this paragraph only after it obtains approval from the Director of FRA's Office of Railroad Systems and Technology.

Based on FRA's experience reviewing RFAs involving temporary outages throughout 2023 and 2024 to date, FRA found that the current content requirements for RFAs to PTC systems under existing paragraph (m)(2) do not yield sufficient information for FRA to assess the full scope and circumstances of each proposed temporary outage. Accordingly, proposed paragraphs (m)(4)(ii)(A) through (I) identify nine additional content elements this type of RFA must include, in addition to the standard content requirements under paragraph (m)(2), which apply to a broader cross-section of RFAs to PTC systems and PTCSPs.

Proposed paragraph (m)(4)(ii)(A) would require this specific type of RFA to describe the necessity for the proposed temporary outage. For example, in 2023 and 2024, railroads have filed RFAs seeking to temporarily disable a PTC system to facilitate the installation of automatic train control or a new interlocking, or to execute an upgrade of a computer-aided dispatch system, a back office server migration or replacement, or an electrical infrastructure upgrade. This section of the RFA would explain why temporarily

²¹ Several railroads have expressed that their chief concern is a path forward for undertaking non-PTC-related capital projects that necessitate temporarily disabling the PTC system, and FRA is using the general term "capital projects" in this NPRM to avoid any ambiguity and clarify that this process applies to such projects.

disabling a PTC system is technically necessary to perform that type of repair, maintenance, infrastructure upgrade, or capital project.

Proposed paragraph (m)(4)(ii)(B) would require the RFA to describe the physical limits and PTC system functions that would be affected by the proposed temporary outage. This section of the RFA would require an analysis that demonstrates the affected physical limits and affected functions pose the least risk to railroad safety, compared to other options. To assess the RFA, FRA needs to understand the exact location(s) that will be impacted, including milepost limits and other descriptors. Identifying the precise PTC system functions that would be impacted is also essential for FRA to understand the scope of the temporary outage, as an outage might impact only a narrow set of PTC system capabilities.

Proposed paragraph (m)(4)(ii)(C) would require the RFA to include an explanation about how the proposed temporary outage is in the public interest and consistent with railroad safety. Existing § 236.1021(f) requires FRA to determine whether granting a request is in the public interest and consistent with railroad safety, and it is important for an RFA to provide such information.

Proposed paragraph (m)(4)(ii)(D) would require the railroad to provide the proposed timeframe of the temporary outage and an analysis that demonstrates the proposed period poses the least risk to railroad safety, compared to other times. This proposal mirrors a similar requirement under former § 236.1029(g)(3)(ii), which expired in December 2022. FRA has seen railroads prudently identify the timeslot of a specific day of the week with the least traffic, which is what FRA expects this content requirement will help ensure in future RFAs.

As a note, FRA has also seen cases where a railroad avoids needing to submit and obtain FRA's approval of an RFA involving a temporary outage, as the railroad either ceases all operations until it finishes the relevant work, or the railroad selects a time when no trains will operate. FRA commends railroads for structuring their projects that way and expects railroads to submit an RFA, seeking to disable its PTC system temporarily with continued rail service, under proposed paragraph (m)(4) only when ceasing operations would not be feasible.

Relatedly, proposed paragraph (m)(4)(ii)(E) would require the RFA to include both a justification and an analysis that show how the proposed duration of the temporary outage is the

minimum time necessary to complete the pertinent work, test the PTC system, and place the PTC system back into service without undue delay. FRA highlights that proposed paragraph (m)(4) is intended to address short-term outages only, and FRA will deny an RFA that seeks to disable a PTC system for an unreasonable, extensive period. In general, PTC-mandated main lines must be governed by PTC technology, given the presence of intercity passenger rail, commuter rail, or certain freight transportation. *See, e.g.*, 49 U.S.C. 20157(a); 49 CFR 236.1005(b), 236.1006(a). Railroads must show how the length of the proposed temporary outage is the minimum amount of time needed based on the circumstances, which could include outlining a precise schedule and the number of hours involved in each phase and justifications for each timeframe.

Proposed paragraph (m)(4)(ii)(F) would require the RFA to outline the type and frequency of rail operations that would continue during the proposed temporary outage, including those of the host railroad and each tenant railroad.

Proposed paragraph (m)(4)(ii)(G) would require the RFA to identify the applicable speed limit of any train that would operate during the proposed temporary outage, and any other operating restrictions in place to ensure rail safety. For example, a properly drafted RFA will outline the railroad's proposed reduced speed for each type of freight train, based on the commodity transported, and each intercity passenger or commuter train, compared to the normal authorized speeds.

Proposed paragraph (m)(4)(ii)(H) would require the railroad to specify in its RFA the additional safety measures that the host railroad and each tenant railroad must comply with during the proposed temporary outage, to ensure each type of PTC-preventable accident or incident does not occur. Specifically, such safety measures must be designed to prevent a train-to-train collision, an over-speed derailment, an incursion into an established work zone, and a movement of a train through a switch left in the wrong position. It is integral that FRA understands exactly how the railroad will mitigate and eliminate the risk of each type of PTC-preventable accident and incident during the short-term PTC system outage. For example, a railroad might propose to utilize an absolute block to mitigate and eliminate the risk of a train-to-train collision, enforce speed limits through the use of other technology, suspend the establishment of work zones, and

protect switches through other specific means.

Finally, proposed paragraph (m)(4)(ii)(I) would require the railroad to confirm in its RFA that each impacted railroad (including the host railroad and any applicable tenant railroads) will notify all applicable dispatchers, train crews, and roadway workers about the temporary PTC system outage (if FRA authorizes it), including the specific location and duration of the temporary outage, the additional safety measures with which the railroad must comply, and any actions the individual must take during the temporary outage. FRA expects that the proposed specific information an RFA must contain under proposed paragraphs (m)(4)(ii)(A) through (H) would aid the railroad in these notifications. The railroad may make these notifications in accordance with the railroad's operating rules and practices, which may require, for example, such information to be provided via track bulletins, dispatcher bulletins, or special instructions.

Also, FRA notes that its 45-day review-and-decision period under existing paragraph (m) begins when a railroad properly files a complete RFA with all information required under paragraph (m). To be clear, the 45-day clock will not begin on that initial filing date, if an RFA to a PTC system, involving a temporary outage, fails to include any of the contents explicitly required under existing paragraphs (m)(2)(i) through (iv) or the additional content requirements FRA is proposing in paragraphs (m)(4)(ii)(A) through (I).²² Instead, consistent with the current § 236.1021(m) process, the 45-day clock begins on the date the railroad or railroads properly submit any remaining information required under existing paragraph (m)(2)(i) through (iv) and proposed paragraphs (m)(4)(ii)(A) through (I). FRA expects this will help ensure a railroad submits a complete RFA, with all required information, in its initial filing.

In addition, FRA acknowledges that it currently publishes a notice in the **Federal Register** when a railroad submits an RFA to its PTC system under existing § 236.1021(m) and invites public comment on the RFA. *See* 49 CFR 236.1021(e). During FRA's meeting with labor organizations in February 2024, TTD requested confirmation that FRA will not eliminate the opportunity for the public to comment on these RFAs. FRA confirmed during that

²² Consistent with FRA's current practice, if an RFA is missing required information, an FRA PTC specialist will contact the railroad via email to inform the railroad of the missing, required content(s).

meeting that RFAs submitted pursuant to proposed paragraph (m)(4), like all RFAs submitted pursuant to paragraph (m), will be announced in the **Federal Register**, and the public will be afforded an opportunity to review and comment on such RFAs. That notice and comment requirement under § 236.1021(e) is outside the scope of this NPRM and will remain part of FRA's regulations. As a reminder, FRA's December 2022 guidance document underscores the importance of ensuring that railroads' filings contain sufficient, non-confidential information for the public to review and on which to comment.²³

Section 236.1029 PTC System Use and Failures

Currently, paragraphs (g)(1) through (3), entitled "Temporary exceptions," of this section set forth expired regulations. Specifically, existing paragraph (g) indicates that paragraphs (g)(1) through (3) were in effect from October 21, 2014, through December 31, 2022. FRA proposes to replace existing paragraphs (g)(1) through (3) with new provisions that deal directly with initialization failures. FRA's existing regulations, at 49 CFR 236.1003, define "initialization failure" as "any instance when a PTC system fails to activate on a locomotive or train, unless the PTC system successfully activates during a subsequent attempt in the same location or before entering PTC-governed territory."²⁴ In relevant part, now-expired paragraph (g)(2) previously permitted any train to continue operating subject to certain speed limits, potentially indefinitely, if a PTC system failed to initialize for any reason.

FRA recognizes that unplanned outages and other technical issues continue to occur, causing PTC systems to fail to initialize, based on FRA's oversight and railroads' Quarterly Reports of PTC System Performance.²⁵ Railroads' Quarterly Reports of PTC

System Performance show, for example, that PTC technology failed to initialize on approximately 236 intercity passenger or commuter trains and 894 freight trains in 2023.²⁶ Additionally, FRA, based on voluntary reporting by railroads, is aware of eight (8) system-level outages that occurred in 2023 that caused trains to fail to initialize.

During FRA's meetings in November 2023 and February 2024, AAR, APTA, ASLRRRA, CRC, and many railroads²⁷ conveyed strong support for FRA's proposal to reintroduce requirements analogous to the provision that expired in 2022. Consistent with FRA's own observations, AAR, APTA, ASLRRRA, CRC, and their member railroads underscored the need for FRA to establish a process to enable railroads to continue operating safely, following certain initialization failures, because otherwise freight, intercity passenger, and commuter trains will be unable to depart from their initial terminals or other locations and provide necessary transportation.

Specifically, FRA's intention in this NPRM is to address only system-level outages or failures that result in multiple trains' PTC systems failing to initialize, like when a back office server goes down, impacting the trains of the host railroad and most, if not all, of its tenant railroads. Accordingly, FRA proposes to provide a caveat in proposed paragraph (g)(4), which would specify that the relief under paragraph (g)(1), discussed below, does not apply to a single train that experiences an onboard PTC system failure when attempting to initialize. The purpose of proposed paragraph (g) is to address issues affecting multiple trains.

During FRA's meeting with labor organizations in February 2024, BLET, BRS, and TTD acknowledged that FRA's objective in proposed paragraph (g) is to enable operations while maintaining rail safety, but they expressed concern for the potential unintended consequence of degrading safety or delaying repairs to PTC technology. FRA agrees that it is important to structure proposed

paragraph (g) to ensure railroads, vendors, and suppliers identify and fix any issues causing initialization failures immediately.

To ensure this provision is utilized only when necessary and railroads and their vendors and suppliers identify and promptly resolve the root cause of initialization failures, FRA is proposing to impose two tiers of operating requirements that would become increasingly restrictive over time. FRA expects this will help strike the appropriate balance between enabling continued operations, subject to restrictions, and restoring PTC systems as quickly as possible.

First, proposed paragraph (g)(1)(i) provides that when a PTC system fails to initialize as defined in § 236.1003, a train may proceed, during the first 24 hours, only as prescribed under existing paragraphs (b)(1) through (6) of § 236.1029. FRA is proposing to require railroads to utilize the current operating restrictions set forth in existing paragraphs (b)(1) through (6) because railroads, including train crews, are accustomed to complying with those speed limits and other restrictions when they experience *en route* failures, and those restrictions are based on the underlying signal or train control system still in effect. During FRA's meetings, the following railroads explicitly recommended this approach, based on industry's longstanding use of these operating restrictions when PTC technology fails or is otherwise cut out *en route*: Alaska Railroad, Amtrak, BNSF, CN, CPKC, CSX, G&W, MARC, Metra, Metrolink, NICD, NS, and UP.

Second, proposed paragraph (g)(1)(ii) states that after the first 24 hours, the train may proceed only as prescribed under paragraphs (b)(4) through (6) of this section and must not exceed restricted speed as defined in § 236.1003. FRA proposes to require compliance with existing paragraphs (b)(4) through (6) as they contain other applicable restrictions and communication requirements.²⁸ However, instead of the standard speed restrictions under existing paragraph (b), this stricter tier of operating restrictions would limit any train that utilizes this provision beyond 24 hours to restricted speed, which is defined as a "speed that will permit stopping

²³ 88 FR 1448 (Jan. 10, 2023); Federal Railroad Administration, Guidance on Submitting Requests for Waivers, Block Signal Applications, and Other Approval Requests to FRA (Dec. 2022), available at <https://railroads.dot.gov/sites/fra.dot.gov/files/2022-12/Guidance%20on%20Submitting%20Waiver%20Special%20Approval%20Other%20Requests%20for%20Approval%20to%20FRA%20%28Dec%202022%29%20final.pdf>.

²⁴ The definition under 49 CFR 236.1003 also clarifies, "For the types of PTC systems that do not initialize by design, a failed departure test is considered an initialization failure for purposes of the reporting requirement under § 236.1029(h), unless the PTC system successfully passes the departure test during a subsequent attempt in the same location or before entering PTC-governed territory."

²⁵ Form FRA F 6180.152, OMB Control No. 2130-0553; 49 U.S.C. 20157(m).

²⁶ The referenced initialization failures exclude any initialization failures where the source or cause was the onboard subsystem, as proposed paragraph (g)(3) excludes such initialization failures from receiving the flexibility afforded under proposed paragraph (g). FRA is citing to the relevant initialization failures where the source or cause was, for example, the back office, wayside, or communications subsystems because those types of issues would generally impact more than one train and would be within the scope of this proposed provision.

²⁷ Including, for example, Alaska Railroad, Amtrak, BNSF, Caltrain, CN, CPKC, CSX, Denver RTDC, G&W, MARC, MBTA, Metra, Metrolink, NICD, NJT, NS, OmniTRAX, TExRail, TRE, UP, UTA FrontRunner, VRE, and Watco.

²⁸ Specifically, 49 CFR 236.1029(b)(4) through (6) require notifying the designated railroad officer of the failure or cut out as soon as safe and practicable, impose further operating restrictions if the PTC system is the exclusive method of delivering mandatory directives, and prohibit operating farther than the next forward designated location for the repair or exchange of onboard PTC apparatuses, if the failure or cut out was the result of a defective onboard PTC apparatus.

within one-half the range of vision, but not exceeding 20 miles per hour.”²⁹

During FRA’s meetings with APTA, CRC, and their member railroads in February 2024, several commuter railroads, including Denver RTD, MARC, Metra, NICD, NJT, TEXRail, TRE, and UTA FrontRunner supported FRA’s intention to propose a two-tiered framework. For example, MARC and NICD noted that the unplanned outages they recently experienced were resolved in approximately two hours, which means those trains, in a similar scenario under this proposed framework, would be subject to the standard operating restrictions under existing paragraph (b). Furthermore, these commuter railroads expressed appreciation that this proposed framework—with more flexibility on day one—would enable them to transport commuters to their destination if PTC technology fails midday and trains are unable to initialize the PTC system for the remainder of the day. Without this proposed provision, if a train’s PTC system fails midday and is not restored by the evening rush hour, commuters attempting to return home would be forced to rely on alternative modes of transportation, with little to no notice.

These eight commuter railroads also recognized that a clear, tiered approach—which introduces additional restrictions, including restricted speed, 24 hours after the onset of the technical issue—would enable railroads to communicate effectively with their customers if the railroad finds that an issue cannot be remedied within the first 24 hours. Commuter railroads emphasized the importance of being able to provide advance notice to their customers about the speed restrictions that would apply the following day, as that could result in service reductions.

Several stakeholders, including ASLRRRA, ATD, NJT, and UTA FrontRunner, stressed that the operating restrictions FRA proposes in paragraph (g) should be as simple, straightforward, and objective as possible given the complexity of other PTC regulations. Furthermore, FRA recognizes that predictability and transparency are vital when it comes to a process that will govern whether and how intercity passenger, commuter, and freight rail transportation may continue.

Proposed paragraph (g)(2) imposes a notification requirement that a railroad must, as early as is possible, ensure workers are aware of PTC system-level outages and corresponding operating restrictions. Specifically, proposed

paragraph (g)(2) requires each railroad operating in accordance with (g)(1) to notify, as early as is possible, all dispatchers, train crews, and roadway workers about PTC system-level outages or failures that result in multiple trains’ PTC systems failing to initialize, which result in trains proceeding in accordance with operating restrictions. Railroads must ensure job safety briefings reflect such operations.

Proposed paragraph (g)(3) proposes to require railroads to attempt to initialize the PTC system again, when the reason it is not initializing is loss of communications or lack of navigational information, like temporary lack of access to the Global Positioning System (GPS)TM. FRA is aware of multiple PTC systems that rely on GPS, like I-ETMS and the Incremental Train Control System. Specifically, proposed paragraph (g)(3) would require, notwithstanding the relief under paragraph (g)(1), that when a PTC system fails to initialize due to loss of communications or lack of navigational information, the train must attempt to initialize the PTC system again at the next forward, available location. The next forward, available location, depending on the circumstances, could be a segment of a main line, a siding, a yard, or a station, whichever is closest.

In addition, FRA acknowledges that PTC systems are comprised of many subsystems and are often interfaced with other technology. For example, at an AAR meeting in November 2023, CN emphasized that the nature of a system of subsystems, like PTC technology, means there is always the possibility of an outage, as a PTC system relies or depends on the proper functioning of many subsystems. Similarly, FRA is also aware that PTC systems have failed to initialize due to a failure of an interfaced system, like a dispatching system or an electronic storage system. Accordingly, FRA wants to clarify that proposed paragraphs (g)(1) through (5) of this section likewise apply to cases in which a PTC system fails to initialize due to an issue or failure arising from a subsystem or an interfaced system.

In addition, FRA wants to offer a clarification about the application of proposed paragraphs (g)(1) to (5) to the Advanced Civil Speed Enforcement System II (ACSES II). An initialization failure is defined in existing § 236.1003 as “any instance when a PTC system fails to activate on a locomotive or train, unless the PTC system successfully activates during a subsequent attempt in the same location or before entering PTC-governed territory.” Section 236.1003 specifies that for the types of PTC systems that do not initialize by

design, like ACSES II, a failed departure test is considered an initialization failure, unless the PTC system successfully passes the departure test during a subsequent attempt in the same location or before entering PTC-governed territory. ACSES II typically encompasses automatic train control (ATC), and FRA wants to emphasize that the FRA-certified PTC system, however, is ACSES II.³⁰ If ACSES II fails to initialize (*i.e.*, fails its departure test), an ACSES II-equipped train may utilize the relief outlined in proposed paragraph (g) of § 236.1029. By contrast, however, if ATC fails its departure test, a railroad must comply with all applicable signal and train control prohibitions and restrictions in other subparts of part 236. FRA wants to address this nuance to clarify that proposed paragraph (g) does not supersede other existing signal and train control regulations that directly govern ATC.

Finally, proposed paragraph (g)(5) recognizes that FRA may impose additional operating restrictions and other conditions to address recurring issues that result in multiple trains’ PTC systems failing to initialize. For example, under proposed paragraph (g)(5), FRA could require the applicable railroads and PTC system vendors and suppliers to take certain actions or satisfy additional reporting requirements, as they resolve the recurring issues. In addition, proposed paragraph (g)(4) would clarify that FRA reserves the right to deny the relief under proposed paragraph (g)(1) for recurring issues that result in multiple trains’ PTC systems failing to initialize. Although the relief under proposed paragraph (g)(1) is generally self-executing, FRA may choose to intervene under proposed paragraph (g)(5) and deny such relief if, for example, a railroad and/or its applicable PTC system vendor and supplier are not sufficiently correcting a recurrent problem.

IV. Regulatory Impact and Notices

A. Executive Order 12866 as Amended by Executive Order 14094

This proposed rule is a nonsignificant regulatory action under Executive Order 12866, as amended by Executive Order 14094, Modernizing Regulatory Review,³¹ and DOT Order 2100.6A (“Rulemaking and Guidance Procedures”). FRA made this

³⁰ Or in NJT’s case, the Advanced Speed Enforcement System II (ASES II).

³¹ 88 FR 21879 (Apr. 11, 2023), available at <https://www.federalregister.gov/documents/2023/04/11/2023-07760/modernizing-regulatory-review>.

²⁹ 49 CFR 236.1003 (citing to the definition in subpart G, at 49 CFR 236.812).

determination by finding that the economic effects of this proposed regulatory action would not exceed the \$100 million annual threshold defined by Executive Order 12866.

FRA complied with OMB Circular A-4 when accounting for benefits, costs, and cost savings relative to a baseline condition. Typically, a baseline represents a best judgement about what the world would be like in the absence of the regulatory interventions.³²

In this analysis, discount rates are used to account for differences in the timing of the estimated benefits and costs. Benefits and costs that accrue further in the future are more heavily discounted than those impacts that occur today. Discounting reflects individuals' general preference to receive benefits sooner rather than later (and defer costs) and recognizes that costs incurred today are more expensive

than future costs because businesses must forgo an expected rate of return on investment of that capital.³³ OMB recommends using a discount rate of 2 percent.³⁴ This represents the real (inflation-adjusted) rate of return on long-term Federal Government debt over the last 30 years, calculated between 1993 and 2022, and is considered a reasonable approximation of the social rate of time preference.

FRA analyzed the economic impact of this proposed rule over a 10-year period and estimated its costs and benefits, as shown in the table below. The total estimated 10-year net benefits of this proposed rule would be \$81.8 million (discounted at 2 percent), and the annualized net benefits would be \$9.1 million (discounted at 2 percent). The industry benefits associated with FRA's proposal to amend three provisions—*i.e.*, to introduce a new exception for

certain non-revenue passenger equipment movements, improve the RFA process regarding temporary PTC system outages, and permit continued operations following certain initialization failures, subject to operating restrictions—would outweigh the industry costs and government administrative costs associated with FRA's proposal to expand the content requirements for RFAs related to temporary outages.

The following table shows the estimated 10-year benefits, net benefits, and costs of the proposed rule. The total 10-year estimated benefits would be \$83.5 million (discounted at 2 percent), with annualized benefits at \$9.3 million (discounted at 2 percent). The total 10-year estimated costs would be \$1.8 million (discounted at 2 percent), with annualized costs at \$0.2 million (discounted at 2 percent).

TABLE B—TOTAL 10-YEAR DISCOUNTED BENEFITS, COSTS, AND NET BENEFITS

[2023 Dollars]¹

Category	Present value 2% (\$)	Present value 3% (\$)	Present value 7% (\$)	Annualized 2% (\$)	Annualized 3% (\$)	Annualized 7% (\$)
Industry Benefits	83,534,444	80,105,191	68,518,285	9,299,600	9,390,772	9,755,462
Total Costs ²	1,760,775	1,688,492	1,444,258	196,021	197,943	205,630
Industry Costs	1,514,075	1,451,919	1,241,905	168,557	170,209	176,819
Government Administrative Costs	246,700	236,573	202,353	27,464	27,734	28,811
Net Benefits ³	81,773,669	78,416,699	67,074,027	9,103,579	9,192,829	9,549,832

¹ Numbers in this table and subsequent tables may not sum due to rounding. The present value of costs and benefits are calculated in this analysis. Present value provides a way of converting future benefits into equivalent dollars today. The formula used to calculate the present value at the particular discount rate is: $1/(1+r)^t$, where "r" is the discount rate, and "t" is the year. Discount rates of 2%, 3%, and 7% are used in this analysis.

² Total Costs = Industry Costs + Government Administrative Costs.

³ Net Benefits = Industry Benefits—(Industry Costs + Government Administrative Costs). FRA notes that the net industry benefits of this proposed rule may help reduce the overall industry costs for implementing and operating PTC systems.

1. Ten-Year Benefits

Proposed 49 CFR 236.1006(b)(6)

FRA analyzed the potential industry benefits of the three proposed amendments. Overall, the three proposed amendments would benefit the railroad industry, the public, and FRA by facilitating repairs, maintenance, upgrades, and capital improvements; expanding certain railroad informational requirements; reducing costs; and enabling the safe, reliable, and resilient movement of people and goods, while preserving rail safety.

The proposed exception under § 236.1006(b)(6) would enable non-revenue passenger equipment, including a locomotive, locomotive consist, or train without passengers onboard, to operate to a maintenance facility or yard for the sole purpose of repairing or exchanging a PTC system. To ensure rail safety, FRA is proposing to impose five conditions on each movement of non-revenue passenger equipment subject to this exception, including speed and distance restrictions, the requirement to establish an absolute block, and other protections of the route.

In assessing the potential benefits of the proposed provision, FRA focused on

the impact on train operations in the absence of this proposed rule. The methodology employed involved estimating the transportation costs associated with relocating non-operative, PTC-equipped passenger equipment to a maintenance facility or yard to repair or exchange the PTC technology. For example, without this proposed provision, intercity passenger railroads and commuter railroads would need to use an operative, PTC-equipped locomotive, locomotive consist, or train to move the non-operative, PTC-equipped equipment to a maintenance facility or yard.

³² U.S. Office of Management and Budget, Circular A-4 (Nov. 9, 2023), available at <https://www.whitehouse.gov/wp-content/uploads/2023/11/>

CircularA-4.pdf. See Section 4, Developing an Analytic Baseline, pages 11–14.

³³ U.S. Office of Management and Budget, Circular A-4 (Nov. 9, 2023). See Section 12, Discount Rates, pages 75–82.

³⁴ *Id.*

Based on consultation with FRA subject matter experts, FRA calculated the potential benefits for train operations, under proposed § 236.1006(b)(6), by multiplying the expected number of impacted passenger equipment by the transportation cost of moving that equipment to a maintenance facility or yard. FRA estimated a range of \$3,000 to \$4,000 to transport this type of equipment, or an average cost of \$3,500 per piece of equipment, similar to the amount utilized in another FRA NPRM³⁵ to

estimate the transportation cost of moving an empty car. FRA estimates that the transportation cost savings of moving this equipment is the estimated number of non-revenue passenger equipment that may use this proposed exception (*i.e.*, 30 per year or 1 per intercity passenger or commuter railroad³⁶), multiplied by the expected transportation cost of \$3,500, resulting in an overall transportation cost savings of \$105,000 annually. Given the uncertainty about the amount of affected equipment and the five safety

conditions or restrictions that FRA is proposing a railroad must comply with while utilizing this exception, FRA is seeking input from the public on whether the cost of these five safety conditions, which FRA did not calculate due to insufficient data, might reduce the calculated net benefits.

Over a 10-year period, FRA estimates that this proposed provision would result in potential benefits of \$1 million, at the 2-percent discount, or on an annual basis, \$107,100, at the 2 percent discount.

TABLE C—POTENTIAL BENEFITS FROM PERMITTING NON-REVENUE PASSENGER EQUIPMENT TO OPERATE TO MAINTENANCE FACILITIES OR YARDS WITHOUT PTC—10-YEAR BENEFIT

Year	Undiscounted benefit (\$)	Present value 2% (\$)	Present value 3% (\$)	Present value 7% (\$)
1	105,000	105,000	105,000	105,000
2	105,000	102,941	101,942	98,131
3	105,000	100,923	98,973	91,711
4	105,000	98,944	96,090	85,711
5	105,000	97,004	93,291	80,104
6	105,000	95,102	90,574	74,864
7	105,000	93,237	87,936	69,966
8	105,000	91,409	85,375	65,389
9	105,000	89,616	82,888	61,111
10	105,000	87,859	80,474	57,113
Total	1,050,000	962,035	922,541	789,099
Annualized		107,100	108,150	112,350

Proposed 49 CFR 236.1021(m)(4)

Under proposed § 236.1021(m)(4), a railroad seeking to temporarily disable its PTC system, for certain purposes, can request FRA’s approval through the standard RFA process under existing § 236.1021(m). There have been no accidents or incidents associated with railroads’ RFAs for temporary PTC system outages from 2022 to early 2024, the relevant period during which FRA began approving such outages by regulation.

Based on past RFA filings from 2022 to early 2024 involving temporary PTC system outages, FRA estimates that railroads will file approximately 15 RFAs, on average on an annual basis, under proposed § 236.1021(m)(4) in the future. FRA estimates that two-thirds of railroads’ RFAs would involve a PTC system outage lasting for a few hours, while one-third would seek to disable PTC technology for a period of days, given the different nature of underlying capital improvement or maintenance projects. FRA used the Bureau of

Transportation Statistics’ (BTS) 2021 fare rates for intercity passenger and commuter rail transportation—*i.e.*, a \$72.10 average rate for Amtrak and a \$6.30 average rate for commuter railroads. FRA estimated weighted fare rates by using those average 2021 BTS fare rates and analyzing past, pertinent RFAs to estimate that the average fare rate would be approximately \$11 for each intercity passenger railroad or commuter railroad that submits an RFA pursuant to § 236.1021(m)(4) in the future.³⁷

Similarly, FRA analyzed the average number of passengers or commuters per train movement³⁸ during a temporary PTC system outage by analyzing past RFAs and found that each train carries, on average, approximately 200 passengers or commuters. Likewise, FRA analyzed the average number of train movements during a temporary PTC system outage by analyzing past RFAs and estimating the expected number of filings by type of railroad. Based on past RFAs, FRA estimates that

on average, 5 trains operate during a freight railroad’s temporary PTC system outage; 12 trains operate during an intercity passenger or commuter railroad’s PTC system outage that lasts 24 hours or less; and 1,700 trains operate during an intercity passenger or commuter railroad’s PTC system outage that lasts longer (days). For freight railroads, the average cost per train movement is \$250, based on previous FRA estimates.

Then, the expected annual number of RFAs, involving temporary PTC system outages, is multiplied by: (1) the average number of train movements during the temporary outage; (2) the average cost per fare or train movement; and (3) the average number of passengers or commuters per train (for intercity passenger or commuter railroads), and is then adjusted for reduced speed.³⁹ As shown in the tables below, the 15 relevant RFAs that FRA expects to receive annually would result in \$8,578,734 in total benefits, undiscounted, per year. FRA notes this

³⁵ 87 FR 43467 (July 21, 2022).

³⁶ Here, FRA is counting any intercity passenger railroad or commuter railroad, including tenant railroads that provide such service, as the proposed exception is not limited to host railroads.

³⁷ U.S. Department of Transportation, Bureau of Transportation Statistics, Transportation Economic Trends (2022), available at <https://data.bts.gov/stories/s/5h3f-jnbe#transportation-fares>.

³⁸ By “train movement,” FRA is referring to the movement or operation of a train.

³⁹ In its decision letters approving such RFAs, FRA typically requires railroads to comply with the operating restrictions under 49 CFR 236.1029(b), which limit the speed of trains depending on the underlying signal or train control system.

calculation did not include variable operating costs such as fuel expenses and other operational costs. Determining these costs is challenging when assessing benefits. Therefore, the

estimated benefits could be reduced by these variable operating costs, although the exact amount is unclear.⁴⁰ Additionally, FRA is seeking comments on this economic analysis, its

underlying assumptions, and any additional benefits that could be quantified, like the potential impact to ridership from avoiding related train delays or cancellations.

TABLE D—RFA FILINGS INVOLVING TEMPORARY PTC SYSTEM OUTAGES—BENEFITS

	Estimated number of RFAs per year	Average number of train movements during outage	Average cost per fare or train movement (\$)	Average number of passengers per train	RFA average benefit (adjusted for reduced speed) (\$)
PTC System Outages (Hours)—Freight Railroads	2	5	250	N/A	2,076
PTC System Outages (Hours)—Passenger or Commuter Railroads	10	12	11	200	197,165
PTC System Outages (Days)—Passenger or Commuter Railroads	3	1,700	11	200	8,379,494
Total	15	8,578,734

Over a 10-year period, FRA estimates railroads will submit approximately 150 RFAs under proposed § 236.1021(m)(4)

with potential benefits of \$78.6 million, at the 2-percent discount, or \$8.8

million, at the 2-percent discount, on an annual basis.

TABLE E—POTENTIAL BENEFITS FROM CONTINUOUS TRAIN OPERATIONS ASSOCIATED WITH RFAs FOR TEMPORARY PTC SYSTEM OUTAGES—10-YEAR BENEFIT

Year	Undiscounted (\$)	Present value 2% (\$)	Present value 3% (\$)	Present value 7% (\$)
1	8,578,734	8,578,734	8,578,734	8,578,734
2	8,578,734	8,410,524	8,328,868	8,017,509
3	8,578,734	8,245,612	8,086,280	7,492,999
4	8,578,734	8,083,933	7,850,757	7,002,803
5	8,578,734	7,925,425	7,622,094	6,544,675
6	8,578,734	7,770,024	7,400,092	6,116,519
7	8,578,734	7,617,671	7,184,555	5,716,373
8	8,578,734	7,468,305	6,975,296	5,342,405
9	8,578,734	7,321,867	6,772,132	4,992,902
10	8,578,734	7,178,301	6,574,886	4,666,263
Total	85,787,345	78,600,396	75,373,696	64,471,182
Annualized	8,750,309	8,836,097	9,179,246

Proposed 49 CFR 236.1029(g)

The proposed exception under § 236.1029(g) would reintroduce a revised version of a provision regarding PTC system initialization failures that expired on December 31, 2022. This proposed exception would be beneficial even with the conditions and restrictions outlined under this proposed provision.

In assessing the potential benefits of this proposed provision, FRA focused on the impact on train operations in the

absence of this proposed rule. Currently, if a PTC system fails to initialize, trains are generally prohibited from operating, which could result in situations where passengers are stranded and vital freight shipments halted, as the prior regulatory process expired on December 31, 2022. Based on consultation with FRA subject matter experts, FRA estimates the number of future PTC system initialization failures by analyzing railroads' initialization failures in calendar year 2023, as reported to FRA

in railroads' Quarterly Reports of PTC System Performance⁴¹ and projecting to the future. In total, based on past data, FRA expects freight railroads to experience approximately 900 initialization failures per year and intercity passenger or commuter railroads to experience approximately 200 initialization failures per year in the future.⁴² Then, the expected annual number of initialization failures is multiplied by: (1) the average cost of \$11 per fare for intercity passenger or

⁴⁰ Another method for assessing the benefits regarding this proposed provision is to calculate the revenue per ton-mile, provided that information regarding the number of miles that would be utilized is available for the affected railroads. Since FRA does not currently possess that level of information, the methodology described above was employed.

⁴¹ Form FRA F 6180.152 (OMB Control No. 2130-0553), under 49 U.S.C. 20157(m) and 49 CFR 236.1029(h). These reports include information about railroads' initialization failures.

⁴² The estimated 1,100 initialization failures exclude any initialization failures where the source or cause is the onboard subsystem, as proposed § 236.1029(g)(3) excludes such initialization failures from receiving the flexibility afforded under

proposed § 236.1029(g), as they typically impact one train. FRA's estimate refers to the number of initialization failures where the source or cause is, for example, the back office, wayside, or communications subsystems because those types of issues would generally impact more than one train and would be within the scope of this proposed provision.

commuter railroads and \$250 per train movement for freight railroads; and (2) the average number of passengers or commuters per train of 200 (for intercity passenger or commuter railroads), and is then adjusted for the reduced speed, based on the proposed speed restrictions under 49 CFR 236.1029(g).

As shown in the table below, FRA’s proposal to permit the operation of

approximately 1,100 trains that FRA expects might experience PTC system initialization failures would result in \$433,520 in total benefits, undiscounted, per year. FRA notes this calculation did not include variable operating costs such as fuel expenses and other operational costs. Therefore, the estimated benefit could be reduced

by these variable operating costs, although the exact amount is unclear. Additionally, FRA is seeking comments on this economic analysis, its underlying assumptions, and any additional benefits that could be quantified, like the potential impact on ridership from avoiding related train delays or cancellations.

TABLE F—ENABLING THE OPERATION OF TRAINS IMPACTED BY INITIALIZATION FAILURES—BENEFITS

Railroad type	Estimated trains impacted annually	Average cost per fare or train movement	Average number of passengers per train	Average benefit (adjusted for reduced speed) (\$)
Freight	900	250	N/A	\$159,220
Intercity Passenger or Commuter	200	11	200	274,300
Total	1,100	433,520

Over a 10-year period, FRA estimates that proposed § 236.1029(g) would result in potential benefits of \$4.0

million, or on an annualized basis, \$442,190, discounted at 2 percent.

TABLE G—POTENTIAL BENEFITS FROM CONTINUOUS TRAIN OPERATIONS DUE TO PROCESS REGARDING CERTAIN INITIALIZATION FAILURES—10-YEAR BENEFIT

Year	Freight railroads (\$)	Passenger railroads (\$)	Undiscounted benefit (\$)	Present value 2% (\$)	Present value 3% (\$)	Present value 7% (\$)
	a	b	c = a + b			
1	159,220	274,300	433,520	433,520	433,520	433,520
2	159,220	274,300	433,520	425,020	420,893	405,159
3	159,220	274,300	433,520	416,686	408,634	378,653
4	159,220	274,300	433,520	408,516	396,732	353,881
5	159,220	274,300	433,520	400,505	385,177	330,730
6	159,220	274,300	433,520	392,652	373,958	309,094
7	159,220	274,300	433,520	384,953	363,066	288,873
8	159,220	274,300	433,520	377,405	352,491	269,974
9	159,220	274,300	433,520	370,005	342,225	252,313
10	159,220	274,300	433,520	362,750	332,257	235,806
Total	1,592,200	2,743,000	4,335,200	3,972,013	3,808,954	3,258,003
Annualized	442,190	446,526	463,866

In addition to these direct benefits, there are potential societal benefits to the proposals in the NPRM. For example, there are possible fuel and emission savings from people not using alternative transportation modes like traditional buses or cars that use fuel or non-carbon technologies like batteries, which would be necessary if the proposals in this NPRM did not exist, and railroads were not allowed to operate trains in certain circumstances. Freight trains are generally known for their fuel efficiency compared to fuel-powered trucks, and intercity passenger or commuter trains are more efficient than driving fuel-powered vehicles, potentially resulting in lower carbon

emissions. Specifically, a single freight train can be up to 75% more fuel-efficient than a fuel-powered truck.⁴³ Similarly, passenger trains are up to 46% more efficient than driving fuel-powered vehicles.⁴⁴ However, policies promoting electric vehicle use may lead to increased adoption of electric vehicles, which could reduce the anticipated emission benefits.

⁴³ Federal Railroad Administration, FRA Announces Climate Challenge to Meet Net-Zero Greenhouse Gas Emissions by 2050 (Apr. 22, 2022), available at <https://railroads.dot.gov/newsroom/press-releases/federal-railroad-administration-announces-climate-challenge-meet-net-zero-0>.

⁴⁴ *Id.*

2. Ten-Year Costs

FRA analyzed the potential industry costs of the proposed amendments, which would: (1) permit non-revenue passenger equipment to operate to maintenance facilities or yards, without being governed by PTC technology and with no passengers onboard, for the sole purpose of repairing or exchanging a PTC system, under certain conditions; (2) improve the existing process railroads utilize to request and obtain FRA’s approval to disable their PTC systems temporarily—when necessary to facilitate repair, maintenance, infrastructure upgrades, and capital projects—by requiring railroads to provide additional, essential

information in their requests to amend their PTC systems; and (3) reintroduce a limited version of a provision regarding PTC system initialization failures, which expired on December 31, 2022, under certain conditions.

Of the three proposed amendments, FRA analyzed the cost of railroads filing RFAs regarding temporary PTC system outages under proposed § 236.1021(m)(4), which contains additional content requirements to enable FRA to assess the full scope and circumstances of each proposed temporary outage. Since the other two proposed provisions, under §§ 236.1006(b)(6) and 236.1029(g), would establish an exception or process with certain conditions, there may be

minimal potential costs tied to these proposed provisions. However, FRA expects the potential benefits of these proposed provisions to outweigh any potential costs they might present. FRA welcomes comments on the potential impact.

Also, FRA acknowledges that a proposal to establish a new exception for non-revenue passenger equipment and reintroduce a limited version of an expired process might appear to present safety risks, if not properly addressed. Accordingly, FRA’s proposed rule contains multiple operating restrictions and other protections to help mitigate or eliminate any associated risks and help preserve or improve rail safety.

Based on consultation with FRA subject matter experts, FRA calculated the total cost for filing an RFA by multiplying the number of submissions by its associated hourly burden. The hourly burden is then multiplied by the wage rate of an Executive, Official, & Staff Assistant employee. For this analysis, FRA used the fully burdened wage rate of \$118.46 to calculate both costs (*i.e.*, the cost of submitting a new RFA and the cost of submitting a revised RFA).⁴⁵ This wage rate includes factors such as salary, benefits, and overhead costs associated with employing staff members involved in the RFA filing process.

TABLE H—COSTS OF RFAS TO PTC SYSTEMS INVOLVING TEMPORARY OUTAGES

	Hourly wage rate (\$)	Number of RFAs per year	Number of hours per RFA	Total cost of RFAs per year (\$)
	a	b	c	d = a * b * c
New RFAs	118.46	15	90	159,921
Revised RFAs	118.46	1	45	5,331
Total				165,252

The following table provides the 10-year cost to the railroad industry associated with the filing of an RFA

involving a temporary PTC system outage under proposed § 236.1021(m)(4). FRA estimates that the

total cost to the railroad industry would be \$1.5 million, or \$168,557 annualized, discounted at 2 percent.

TABLE I—TOTAL COSTS OF RFAS ABOUT TEMPORARY PTC SYSTEM OUTAGES

Year	Cost of new RFAs per year	Cost of revised RFAs per year (\$)	Undiscounted cost of RFAs (\$)	Present value 2% (\$)	Present value 3% (\$)	Present value 7% (\$)
1	159,921	5,331	165,252	165,252	165,252	165,252
2	159,921	5,331	165,252	162,011	160,439	154,441
3	159,921	5,331	165,252	158,835	155,766	144,337
4	159,921	5,331	165,252	155,720	151,229	134,895
5	159,921	5,331	165,252	152,667	146,824	126,070
6	159,921	5,331	165,252	149,674	142,548	117,822
7	159,921	5,331	165,252	146,739	138,396	110,114
8	159,921	5,331	165,252	143,862	134,365	102,910
9	159,921	5,331	165,252	141,041	130,451	96,178
10	159,921	5,331	165,252	138,275	126,652	89,886
Total	159,921	5,331	1,652,517	1,514,075	1,451,919	1,241,905
Annualized				168,557	170,209	176,819

Additionally, alongside the railroad industry’s cost of filing RFAs under proposed § 236.1021(m)(4), there are governmental costs associated with the

filing of these RFAs. The following table shows the annual estimated government costs for reviewing railroads’ RFAs pertaining to temporary PTC system

outages and issuing related decision letters.

⁴⁵ Throughout this document, the dollar equivalent cost or benefit for the industry is derived from the Surface Transportation Board’s 2023 Full

Year Wage A&B data series using the appropriate employee group hourly wage rate, which includes an additional 75 percent for fringe benefits and

overhead. For instance, the 2023 hourly wage rate of \$67.69 is burdened by 75 percent ($\$67.69 \times 1.75 = \118.46).

TABLE J—GOVERNMENT ADMINISTRATIVE COSTS FROM RFA REVIEW AND APPROVAL—ANNUAL COSTS

	Average number of employees	Hourly wage rate (\$) ⁴⁶	Number of hours per RFA	Estimated RFAs per year	Total cost (\$)
		a	b	c	d = a * b * c
Railroad Safety Specialist (GS-13)—All locations	1	98.77	6	15	8,889
Railroad Safety Specialist (GS-14)—All locations	1	116.71	3	15	5,252
Railroad Safety Specialist (GS-14)—All locations	1	116.71	2	15	3,501
Railroad Safety Specialist Supervisor (GS-15)—DC Metro	1	147.96	1	15	2,219
Railroad Safety Specialist Senior Executive—DC Metro	1	175.00	1	15	2,625
Attorney (GS-15)—DC Metro	1	147.96	2	15	4,439
Annual Total Cost			15	15	26,926

The following table shows the 10-year estimated government costs for reviewing RFAs pertaining to temporary PTC system outages and issuing related

decision letters. FRA expects it would cost approximately \$246,700 over the 10-year period, or \$27,464 annualized, discounted at 2 percent, to review and

approve or deny these RFAs, as shown in the following table.

TABLE K—GOVERNMENT ADMINISTRATIVE COSTS FROM RFA REVIEW AND APPROVAL—10-YEAR COSTS

Year	Undiscounted government administrative cost (\$)	Present value 2% (\$)	Present value 3% (\$)	Present value 7% (\$)
1	26,926	26,926	26,926	26,926
2	26,926	26,398	26,142	25,164
3	26,926	25,880	25,380	23,518
4	26,926	25,373	24,641	21,979
5	26,926	24,875	23,923	20,542
6	26,926	24,387	23,226	19,198
7	26,926	23,909	22,550	17,942
8	26,926	23,440	21,893	16,768
9	26,926	22,981	21,255	15,671
10	26,926	22,530	20,636	14,646
Total	269,258	246,700	236,573	202,353
Annualized		27,464	27,734	28,811

3. Results

The industry benefits associated with FRA’s proposal to amend three provisions—*i.e.*, to introduce a new exception for certain non-revenue passenger equipment movements, improve the RFA process regarding temporary PTC system outages, and

permit continued operations following certain initialization failures, subject to operating restrictions—would outweigh the industry costs and government administrative costs associated with FRA’s proposal to expand the content requirements for RFAs related to temporary outages.

The following table shows the estimated 10-year costs, benefits, and net benefits of the proposed rule. The total estimated 10-year net benefits would be \$81.8 million (discounted at 2 percent) and annualized net benefits would be \$9.1 million (discounted at 2 percent).

TABLE L—TOTAL 10-YEAR DISCOUNTED BENEFITS, COSTS, AND NET BENEFITS [2023 Dollars]

Category	Present value 2% (\$)	Present value 3% (\$)	Present value 7% (\$)	Annualized 2% (\$)	Annualized 3% (\$)	Annualized 7% (\$)
Industry Benefits	83,534,444	80,105,191	68,518,285	9,299,600	9,390,772	9,755,462
Total Costs	1,760,775	1,688,492	1,444,258	196,021	197,943	205,630
Industry Costs	1,514,075	1,451,919	1,241,905	168,557	170,209	176,819
Government Administrative Costs	246,700	236,573	202,353	27,464	27,734	28,811
Net Benefits	81,773,669	78,416,699	67,074,027	9,103,579	9,192,829	9,549,832

⁴⁶ U.S. Office of Personnel Management, “2023 General Schedule (GS) Locality Pay Tables,” available at [https://www.opm.gov/policy-data-](https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2023/general-schedule/)

[oversight/pay-leave/salaries-wages/2023/general-schedule/](https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2023/general-schedule/). The base salary is burdened with an

additional 75 percent to account for fringe benefits and overhead.

B. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601, *et seq.*) and Executive Order 13272, “Proper Consideration of Small Entities in Agency Rulemaking,” (67 FR 53461 (Aug. 16, 2002)) require agency review of proposed and final rules to assess their impacts on small entities. An agency must prepare an Initial Regulatory Flexibility Analysis (IRFA) unless it determines and certifies that a rule, if promulgated, would not have a significant economic impact on a substantial number of small entities. FRA has not determined whether this proposed rule would have a significant economic impact on a substantial number of small entities.

FRA invites all interested parties to submit comments, data, and information demonstrating the potential economic impact on small entities that will result from the adoption of this proposed rule. FRA particularly encourages small entities potentially impacted by the proposed amendments to participate in the public comment process. FRA will consider all comments received during the public comment period for this NPRM when making a final determination of the rule’s economic impact on small entities. FRA prepared an IRFA, which is included below, to aid the public in commenting on the potential small business impacts of the proposed requirements in this NPRM.

1. Reasons for Considering Agency Action

Through FRA’s oversight and continued engagement with the industry, FRA has found that its existing PTC regulations do not adequately address temporary situations during which PTC technology is not enabled, including after certain initialization failures or in cases where a PTC system needs to be temporarily disabled to facilitate repair, maintenance, infrastructure upgrades, or capital projects. This NPRM proposes to establish parameters and operating restrictions under which railroads may continue to operate safely in certain scenarios when PTC technology is temporarily not governing rail operations. Overall, the proposed amendments would benefit the railroad industry, the public, and FRA by facilitating repairs, maintenance, upgrades, and capital improvements; expanding certain railroad informational requirements; reducing costs; and enabling the safe, reliable, and efficient movement of people and goods, while preserving rail safety.

2. A Succinct Statement of the Objectives of, and the Legal Basis for, the Proposed Rule

FRA is proposing to revise three PTC regulations based on the statutory general authority of the Secretary. The Secretary has broad statutory authority to “prescribe regulations and issue orders for every area of railroad safety” under 49 U.S.C. 20103 and regarding PTC technology under 49 U.S.C. 20157(g). The Secretary delegated this authority to the Federal Railroad Administrator. 49 CFR 1.89(b).

This proposed rule would provide flexibility to certain train movements and improve existing processes, which would result in net benefits to railroads. The industry benefits associated with FRA’s proposal to amend §§ 236.1006(b), 236.1021(m) and 236.1029(g)—*i.e.*, to introduce a new exception for certain non-revenue passenger equipment movements, improve the RFA process regarding temporary PTC system outages, and permit continued operations following certain initialization failures, subject to operating restrictions—would outweigh the industry costs and government administrative costs associated with FRA’s proposal to expand the content requirements for RFAs related to temporary outages under § 236.1021(m), while also maintaining rail safety.

FRA’s objective in this rulemaking is to establish clear, uniform processes, rather than addressing issues that arise in a reactive and piecemeal manner. FRA expects that establishing predictable, prescriptive processes will both enable continued operations and improve railroad safety by eliminating uncertainty and inconsistent application of FRA’s regulations and facilitating prompt repairs, upgrades, and restoration of PTC system service. FRA’s proposed parameters and operating restrictions in this NPRM are intended to be sufficiently strict to ensure that railroads and PTC system suppliers and vendors proactively identify and remedy problems before they arise and immediately correct any problems that may surface despite proactive measures.

3. A Description of and, Where Feasible, an Estimate of the Number of Small Entities to Which the Proposed Rule Would Apply

The Regulatory Flexibility Act of 1980 requires a review of proposed and final rules to assess their impact on small entities, unless the Secretary certifies that the rule would not have a significant economic impact on a substantial number of small entities. “Small entity” is defined in 5 U.S.C.

601 as a small business concern that is independently owned and operated and is not dominant in its field of operation. The U.S. Small Business Administration (SBA) has authority to regulate issues related to small businesses, and stipulates in its size standards that a “small entity” in the railroad industry is a for-profit “line-haul railroad” that has fewer than 1,500 employees, a “short line railroad” with fewer than 500 employees, or a “commuter rail system” with annual receipts of less than seven million dollars. See “Size Eligibility Provisions and Standards,” 13 CFR part 121, subpart A.

The proposed rule would directly apply to all 37 host railroads subject to 49 U.S.C. 20157—including 7 Class I railroads, 24 intercity passenger railroads or commuter railroads, and 6 Class II or III, short line, or terminal railroads. Only 5 of the current PTC-mandated host railroads are small entities.

4. A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule, Including an Estimate of the Class of Small Entities That Will be Subject to the Requirements and the Type of Professional Skill Necessary for Preparation of the Report or Record

The proposed amendments would improve the process railroads use to file an RFA involving a temporary PTC system outage. Those entities would be subject to the requirements of this proposed rule and would also benefit from the additional flexibility associated with this proposed rule.

FRA expects that a railroad’s RFA pursuant to proposed § 236.1021(m)(4) would be completed by an executive or senior manager and require analytical and writing skills.

To calculate the individual costs for small entities, FRA divided the total annualized cost by the number of estimated host railroads. FRA assumes that the hourly burden to submit an RFA is independent of an entity’s size because the RFA depends upon the PTC system and not the individual railroad making the submission. The total annualized cost for all host railroads would be \$168,557, discounted at 2 percent. FRA estimates that the annualized cost to each host railroad would be approximately \$4,556, discounted at 2 percent. Although the proposed rule would impose costs on those host railroads that are small entities, benefits would also accrue.

To calculate the individual benefit for small entities, FRA divided the total annualized benefits by the number of estimated host railroads. The total

annualized benefits for all host railroads would be \$9.3 million, discounted at 2 percent. FRA estimates that the annualized benefit for each host railroad would be \$251,341, discounted at 2 percent. FRA requests comments on the economic impact that small entities would face under this proposed rule.

5. Identification, to the Extent Practicable, of All Relevant Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

FRA is not aware of any relevant Federal rule that duplicates, overlaps with, or conflicts with the proposed rule. This proposed rule intends to improve the process associated with RFAs for temporary PTC system outages, establish a new exception for certain non-revenue passenger equipment, and reintroduce a limited

version of a provision that previously expired.

6. A Description of Significant Alternatives to the Rule

The proposed amendments in this rulemaking would benefit the railroad industry, the public, and FRA by facilitating repairs, maintenance, upgrades, and capital improvements; expanding certain railroad informational requirements; reducing costs; and enabling the safe, reliable, and resilient movement of people and goods, while preserving rail safety.

The main alternative to this rulemaking would be to maintain the status quo. The alternative of not issuing the proposed rule would forgo improving the process under § 236.1021(m) that host railroads use to submit RFAs for temporary PTC system outages. In the absence of this proposed rule, non-revenue passenger equipment

would not be afforded the same type of exception currently available to freight railroads under § 236.1006(b). In addition, without this rule, railroads would not be able to operate in certain scenarios when PTC technology is temporarily not governing rail operations under proposed § 236.1029(g).

C. Paperwork Reduction Act

FRA is submitting the information collection requirements in this proposed rule to OMB⁴⁷ under the Paperwork Reduction Act of 1995.⁴⁸ Please note that any new or revised requirements, as proposed in this NPRM, are marked by asterisks (*) in the table below. The sections that contain the proposed and current information collection requirements under OMB Control No. 2130-0553 and the estimated time to fulfill each requirement are as follows:

CFR section	Respondent universe	Total annual responses (A)	Average time per response (B)	Total annual burden hours (C = A * B)	Total cost equivalent in USD (D = C * wage rates)
235.6(c)—Expedited application for approval of certain changes described in this section.	42 railroads	10 expedited applications.	5.00 hours	50.00 hours	\$4,456.50
—Copy of expedited application to labor union.	42 railroads	10 copies	30.00 minutes	5.00 hours	445.65
—Railroad letter rescinding its request for expedited application of certain signal system changes.	42 railroads	1 letter	6.00 hours	6.00 hours	534.78
—Revised application for certain signal system changes.	42 railroads	1 application	5.00 hours	5.00 hours	445.65
—Copy of railroad revised application to labor union.	42 railroads	1 copy	30.00 minutes	0.50 hours	44.57
236.1—Railroad maintained signal plans at all interlockings, automatic signal locations, and controlled points, and updates to ensure accuracy.	700 railroads	25 plan changes ...	15.00 minutes	6.25 hours	557.06
236.15—Designation of automatic block, traffic control, train stop, train control, cab signal, and PTC territory in timetable instructions.	700 railroads	10 timetable instructions.	30.00 minutes	5.00 hours	445.65
236.18—Software management control plan—New railroads.	2 railroads	2 plans	160.00 hours	320.00 hours	28,521.60
236.23(e)—The names, indications, and aspects of roadway and cab signals shall be defined in the carrier’s Operating Rule Book or Special Instructions. Modifications shall be filed with FRA within 30 days after such modifications become effective.	700 railroads	2 modifications	1.00 hour	2.00 hours	178.26
236.587(d)—Certification and departure test results.	742 railroads	4,562,500 train departures.	5.00 seconds	6,336.81 hours	564,799.88
236.905(a)—Railroad Safety Program Plan (RSPP)—New railroads.	2 railroads	2 RSPPs	40.00 hours	80.00 hours	7,130.40
236.913(a)—Filing and approval of a joint Product Safety Plan (PSP).	742 railroads	1 joint plan	2,000.00 hours	2,000.00 hours	236,920.00
—(c)(1) Informational filing/petition for special approval.	742 railroads	0.5 filings/approval petitions.	50.00 hours	25.00 hours	2,228.25

⁴⁷ FRA will be using the OMB control number 2130-0553 for this information collection.

⁴⁸ 44 U.S.C. 3501, *et seq.*

CFR section	Respondent universe	Total annual responses (A)	Average time per response (B)	Total annual burden hours (C = A * B)	Total cost equivalent in USD (D = C * wage rates)
—(c)(2) Response to FRA’s request for further data after informational filing.	742 railroads	0.25 data calls/documents.	5.00 hours	1.25 hour	111.41
—(d)(1)(ii) Response to FRA’s request for further information within 15 days after receipt of the Notice of Product Development (NOPD).	742 railroads	0.25 data calls/documents.	1.00 hour	0.25 hours	22.28
—(d)(1)(iii) Technical consultation by FRA with the railroad on the design and planned development of the product.	742 railroads	0.25 technical consultations.	5.00 hours	1.25 hour	111.41
—(d)(1)(v) Railroad petition to FRA for final approval of NOPD.	742 railroads	0.25 petitions	1.00 hour	0.25 hours	22.28
—(d)(2)(ii) Response to FRA’s request for additional information associated with a petition for approval of PSP or PSP amendment.	742 railroads	1 request	50.00 hours	50.00 hours	4,456.50
—(e) Comments to FRA on railroad informational filing or special approval petition.	742 railroads	0.5 comments/letters.	10.00 hours	5.00 hours	445.65
—(h)(3)(i) Railroad amendment to PSP	742 railroads	2 amendments	20.00 hours	40.00 hours	3,565.20
—(j) Railroad field testing/information filing document.	742 railroads	1 field test/document.	100.00 hours	100.00 hours	8,913.00
236.917(a)—Railroad retention of records: results of tests and inspections specified in the PSP.	13 railroads with PSP.	13 PSP safety results.	160.00 hours	2,080.00 hours	185,390.40
—(b) Railroad report that frequency of safety-relevant hazards exceeds threshold set forth in PSP.	13 railroads	1 report	40.00 hours	40.00 hours	3,565.20
—(b)(3) Railroad final report to FRA on the results of the analysis and countermeasures taken to reduce the frequency of safety-relevant hazards.	13 railroads	1 report	10.00 hours	10.00 hours	891.30
236.919(a)—Railroad Operations and Maintenance Manual (OMM).	13 railroads	1 OMM update	40.00 hours	40.00 hours	3,565.20
—(b) Plans for proper maintenance, repair, inspection, and testing of safety-critical products.	13 railroads	1 plan update	40.00 hours	40.00 hours	3,565.20
—(c) Documented hardware, software, and firmware revisions in OMM.	13 railroads	1 revision	40.00 hours	40.00 hours	3,565.20
236.921 and 923(a)—Railroad Training and Qualification Program.	13 railroads	1 program	40.00 hours	40.00 hours	3,565.20
236.923(b)—Training records retained in a designated location and available to FRA upon request.	13 railroads	350 records	10.00 minutes	58.33 hours	5,198.95
236.1001(b)—A railroad’s additional or more stringent rules than prescribed under 49 CFR part 236, subpart I.	38 railroads	1 rule or instruction	40.00 hours	40.00 hours	4,738.40
236.1005(b)(4)(i)–(ii)—A railroad’s submission of estimated traffic projections for the next 5 years, to support a request, in a PTCIP or an RFA, not to implement a PTC system based on reductions in rail traffic.	The burden for this requirement is included under §§ 236.1009(a) and 236.1021.				
236.1005(b)(4)(iii)—A railroad’s request for a de minimis exception, in a PTCIP or an RFA, based on a minimal quantity of PIH materials traffic.	7 Class I railroads	1 exception request.	40.00 hours	40.00 hours	3,565.20
—(b)(5) A railroad’s request to remove a line from its PTCIP based on the sale of the line to another railroad and any related request for FRA review from the acquiring railroad.	The burden for this requirement is included under §§ 236.1009(a) and 236.1021.				

CFR section	Respondent universe	Total annual responses (A)	Average time per response (B)	Total annual burden hours (C = A * B)	Total cost equivalent in USD (D = C * wage rates)
—(g)(1)(i) A railroad’s request to temporarily reroute trains not equipped with a PTC system onto PTC-equipped tracks and vice versa during certain emergencies.	38 railroads	45 routing extension requests.	8.00 hours	360.00 hours	32,086.80
—(g)(1)(ii) A railroad’s written or telephonic notice to FRA of the conditions necessitating emergency rerouting and other required information under 236.1005(i).	38 railroads	45 written or telephonic notices.	2.00 hours	90.00 hours	8,021.70
—(g)(2) A railroad’s temporary rerouting request due to planned maintenance not exceeding 30 days.	38 railroads	720 requests	8.00 hours	5,760.00 hours	513,388.80
—(h)(1) A response to any request for additional information from FRA, prior to commencing rerouting due to planned maintenance.	38 railroads	10 responses	2.00 hours	20.00 hours	1,782.60
—(h)(2) A railroad’s request to temporarily reroute trains due to planned maintenance exceeding 30 days.	38 railroads	160 requests	8.00 hours	1,280.00 hours	114,086.40
236.1006(b)(4)(iii)(B)—A progress report due by December 31, 2020, and by December 31, 2022, from any Class II or III railroad utilizing a temporary exception under this section.	The paperwork requirement is no longer applicable.				
—(b)(5)(vii) A railroad’s request to utilize different yard movement procedures, as part of a freight yard movements exception—.	The burden for this requirement is included under §§ 236.1015 and 236.1021.				
—(b)(6) Establishing a new exception to permit non-revenue passenger equipment to operate to maintenance facilities or yards, without being governed by PTC technology, under certain conditions (*New proposed provision*).	There is no paperwork requirement associated with this proposed provision.				
236.1007(b)(1)—For any high-speed service over 90 miles per hour (mph), a railroad’s PTC Safety Plan (PTCSP) must additionally establish that the PTC system was designed and will be operated to meet the fail-safe operation criteria in appendix C.	The burden for this requirement is included under §§ 236.1015 and 236.1021.				
—(c) An HSR–125 document accompanying a host railroad’s PTCSP, for operations over 125 mph.	38 railroads	1 HSR–125 document.	3,200.00 hours	3,200.00 hours	379,072.00
—(c)(1) A railroad’s request for approval to use foreign service data, prior to submission of a PTCSP.	38 railroads	0.33 requests	8,000.00 hours	2,640.00 hours	235,303.20
—(d) A railroad’s request in a PTCSP that FRA excuse compliance with one or more of this section’s requirements.	38 railroads	1 request	1,000.00 hours	1,000.00 hours	118,460.00
236.1009(a)(2)—A PTCIP if a railroad becomes a host railroad of a main line requiring the implementation of a PTC system, including the information under 49 U.S.C. 20157(a)(2) and 49 CFR 236.1011.	264 railroads	1 PTCIP	535.00 hours	535.00 hours	63,376.10
—(a)(3) Any new PTCIPs jointly filed by a host railroad and a tenant railroad.	264 railroads	1 joint PTCIP	267.00 hours	267.00 hours	31,628.82
—(b)(1) A host railroad’s submission, individually or jointly with a tenant railroad or PTC system supplier, of an unmodified Type Approval.	264 railroads	1 document	8.00 hours	8.00 hours	713.04

CFR section	Respondent universe	Total annual responses (A)	Average time per response (B)	Total annual burden hours (C = A * B)	Total cost equivalent in USD (D = C * wage rates)
—(b)(2) A host railroad’s submission of a PTCDP with the information required under 49 CFR 236.1013, requesting a Type Approval for a PTC system that either does not have a Type Approval or has a Type Approval that requires one or more variances.	264 railroads	1 PTCDP	2,000.00 hours	2,000.00 hours	178,260.00
—(d) A host railroad’s submission of a PTCSP.	The burden for this requirement is included under § 236.1015.				
—(e)(3) Any request for full or partial confidentiality of a PTCIP, Notice of Product Intent (NPI), PTCDP, or PTCSP.	38 railroads	10 confidentiality requests.	8.00 hours	80.00 hours	7,130.40
—(h) Any responses or documents submitted in connection with FRA’s use of its authority to monitor, test, and inspect processes, procedures, facilities, documents, records, design and testing materials, artifacts, training materials and programs, and any other information used in the design, development, manufacture, test, implementation, and operation of the PTC system, including interviews with railroad personnel.	38 railroads	36 interviews and documents.	4.00 hours	144.00 hours	12,834.72
—(j)(2)(iii) Any additional information provided in response to FRA’s consultations or inquiries about a PTCDP or PTCSP.	38 railroads	1 set of additional information.	400.00 hours	400.00 hours	35,652.00
236.1011(a) through (b)—PTCIP content requirements.	The burden for this requirement is included under §§ 236.1009(a) and (e) and 236.1021.				
—(e) Any public comment on PTCIPs, NPIs, PTCDPs, and PTCSPs.	38 railroads	2 public comments	8.00 hours	16.00 hours	1,426.08
236.1013—PTCDP and NPI content requirements.	The burden for this requirement is included under §§ 236.1009(b), (c), and (e) and 236.1021.				
236.1015—Any new host railroad’s PTCSP meeting all content requirements under 49 CFR 236.1015.	264 railroads	1 PTCSP	8,000.00 hours	8,000.00 hours	713,040
—(g) A PTCSP for a PTC system replacing an existing certified PTC system.	38 railroads	0.33 PTCSPs	3,200.00 hours	1,056.00 hours	94,121.28
—(h) A quantitative risk assessment, if FRA requires one to be submitted.	38 railroads	0.33 assessments	800.00 hours	264.00 hours	23,530.32
236.1017(a)—An independent third-party assessment, if FRA requires one to be conducted and submitted.	38 railroads	0.33 assessments	1,600.00 hours	528.00 hours	62,546.88
—(b) A railroad’s written request to confirm whether a specific entity qualifies as an independent third party.	38 railroads	0.33 written requests.	8.00 hours	2.64 hours	235.30
—Further information provided to FRA upon request.	38 railroads	0.33 sets of additional information.	20.00 hours	6.60 hours	588.26
—(d) A request not to provide certain documents otherwise required under appendix F for an independent, third-party assessment.	38 railroads	0.33 requests	20.00 hours	6.60 hours	588.26
—(e) A request for FRA to accept information certified by a foreign regulatory entity for purposes of 49 CFR 236.1017 and/or 236.1009(i).	38 railroads	0.33 requests	32.00 hours	10.56 hours	941.21
236.1019(b)—A request for a passenger terminal main line track exception (MTEA).	38 railroads	1 MTEA	160.00 hours	160.00 hours	14,260.80

CFR section	Respondent universe	Total annual responses (A)	Average time per response (B)	Total annual burden hours (C = A * B)	Total cost equivalent in USD (D = C * wage rates)
—(c)(1) A request for a limited operations exception (based on restricted speed, temporal separation, or a risk mitigation plan).	38 railroads	1 request and/or plan.	160.00 hours	160.00 hours	14,260.80
—(c)(2) A request for a limited operations exception for a non-Class I, freight railroad's track.	10 railroads	1 request	160.00 hours	160.00 hours	14,260.80
—(c)(3) A request for a limited operations exception for a Class I railroad's track.	7 railroads	1 request	160.00 hours	160.00 hours	14,260.80
—(d) A railroad's collision hazard analysis in support of an MTEA, if FRA requires one to be conducted and submitted.	38 railroads	0.33 collision hazard analyses.	50.00 hours	16.50 hours	1,470.65
—(e) Any temporal separation procedures utilized under the 49 CFR 236.1019(c)(1)(ii) exception.	The burden for this requirement is included under § 236.1019(c)(1).				
236.1021(a) through (d)—An RFA to a railroad's PTCIP or PTCDP.	38 railroads	10 RFAs	160.00 hours	1,600.00 hours	142,608.00
—(e) Any public comments, if an RFA includes a request for approval of a discontinuance or material modification of a signal or train control system and a Federal Register notice is published.	5 Interested parties	10 RFA public comments.	16.00 hours	160.00 hours	14,260.80
—(l) Any jointly filed RFA to a PTCDP or PTCSP.	The burden for this requirement is included under § 236.1021(a) through (d) and (m).				
—(m) Any RFA to a railroad's PTCSP ..	38 railroads	15 RFAs	80.00 hours	1,200.0 hours	106,956.00
—(m)(4) Any RFA to a railroad's PTC system that involves a proposed temporary PTC system outage (*New proposed provision*).	38 railroads	15 RFAs	90.00 hours	1,350.0 hours	159,921.00
—(m) A railroad's revised RFA, if needed.	38 railroads	1 revised RFA	45.00 hours	45.00 hours	5,330.70
236.1023(a)—A railroad's PTC Product Vendor List, which must be continually updated.	38 railroads	2 updated lists	8.00 hours	16.00 hours	1,426.08
—(b)(1) The railroad shall specify within its PTCSP all contractual arrangements between a railroad and its hardware and software suppliers or vendors for certain immediate notifications.	The burden for this requirement is included under §§ 236.1015 and 236.1021.				
—(b)(2) through (3) A vendor's or supplier's notification, upon receipt of a report of any safety-critical failure of its product, to any railroads using the product.	10 vendors or suppliers.	10 notifications	8.00 hours	80.00 hours	7,130.40
—(c)(1) through (2) A railroad's process and procedures for taking action upon being notified of a safety-critical failure or a safety-critical upgrade, patch, revision, repair, replacement, or modification, and a railroad's configuration/revision control measures, set forth in its PTCSP.	The burden for this requirement is included under §§ 236.1015 and 236.1021.				

CFR section	Respondent universe	Total annual responses (A)	Average time per response (B)	Total annual burden hours (C = A * B)	Total cost equivalent in USD (D = C * wage rates)
—(d) A railroad's submission, to the applicable vendor or supplier, of the railroad's procedures for action upon notification of a safety-critical failure, upgrade, patch, or revision to the PTC system and actions to be taken until it is adjusted, repaired, or replaced.	38 railroads	2.50 notifications ...	16.00 hours	40.00 hours	3,565.20
—(e) A railroad's database of all safety-relevant hazards, which must be maintained after the PTC system is placed in service.	38 railroads	38 database updates.	16.00 hours	608.00 hours	54,191.04
—(e)(1) A railroad's notification to the vendor or supplier and FRA if the frequency of a safety-relevant hazard exceeds the threshold set forth in the PTCDP and PTCSP, and about the failure, malfunction, or defective condition that decreased or eliminated the safety functionality—Form FRA F 6180.179—Errors and Malfunctions Notification.	38 railroads	8 notifications	7.50 hours	60.00 hours	5,347.80
—(e)(2) Continual updates about any and all subsequent failures.	38 railroads	1 update	8.00 hours	8.00 hours	713.04
—(f) Any notifications that must be submitted to FRA under 49 CFR 236.1023.	The burden for this requirement is included under § 236.1023(e)(1), (g), and (h)(1)(2).				
—(g) A railroad's and vendor's or supplier's report, upon FRA request, about an investigation of an accident or service difficulty due to a manufacturing or design defect and their corrective actions.	38 railroads	0.50 reports	40.00 hours	20.00 hours	1,782.60
—(h) A PTC system vendor's or supplier's reports of any safety-relevant failures, defective conditions, previously unidentified hazards, recommended mitigation actions, and any affected railroads—Form FRA F 6180.179—Errors and Malfunctions Notification.	10 vendors	20 reports	7.50 hours	150.00 hours	13,370
—(k) A report of a failure of a PTC system resulting in a more favorable aspect than intended or other condition hazardous to the movement of a train, including the reports required under part 233.	The burden for this requirement is included under § 236.1023(e)(1), (g), and (h)(1)(2) and 49 CFR 233.7.				
—236.1029(b)(4)—A report of an en route failure, other failure, or cut out to a designated railroad officer of the host railroad.	150 host and tenant railroads.	1,000 reports	30.00 minutes	500.00 hours	44,565
—(g) Reintroducing a provision regarding initialization failures that previously expired in December 2022, and establishing operating restrictions under which railroads may continue to operate safely when a PTC system fails to initialize (*New proposed requirement*).	In this proposed provision, there is no paperwork requirement. However, under an existing regulation, FRA requires host railroads operating FRA-certified PTC systems to submit Quarterly Reports of PTC System Performance, using Form FRA F 6180.152, under 49 U.S.C. 20157(m) and 49 CFR 236.1029(h). These reports include information about railroads' initialization failures.				
—(h) Form FRA F 6180.152—Report of PTC System Performance.	38 railroads	148 reports	32.00 hours	4,736.00 hours	422,119.68

CFR section	Respondent universe	Total annual responses (A)	Average time per response (B)	Total annual burden hours (C = A * B)	Total cost equivalent in USD (D = C * wage rates)
236.1031(a)–(d)—A railroad’s Request for Expedited Certification.	FRA anticipates that there will be zero requests for expedited certification during this 3-year ICR.				
236.1033—Communications and security requirements.	The burden for this requirement is included under §§ 236.1009 and 236.1015.				
236.1035(a) through (b)—A railroad’s request for authorization to field test an uncertified PTC system and any responses to FRA’s testing conditions.	38 railroads	10 requests	40.00 hours	400.00 hours	35,652.00
236.1037(a)(1) through (2)—Records retention.	The burden for this requirement is included under §§ 236.1009 and 236.1015.				
—(a)(3) through (4) Records retention ..	The burden for this requirement is included under §§ 236.1039 and 236.1043(b).				
—(b) Results of inspections and tests specified in a railroad’s PTCS and PTCDP.	38 railroads	800 records	1.00 hour	800.00 hours	71,304.00
—(c) A contractor’s records related to the testing, maintenance, or operation of a PTC system maintained at a designated office.	20 contractors	1,600 records	10.00 minutes	266.67 hours	23,768.30
—(d)(3) A railroad’s final report of the results of the analysis and countermeasures taken to reduce the frequency of safety-related hazards below the threshold set forth in the PTCS.	38 railroads	8 final reports	160.00 hours	1,280 hours	114,086.40
236.1039(a) through (c), (e)—A railroad’s PTC Operations and Maintenance Manual (OMM), which must be maintained and available to FRA upon request.	38 railroads	2 OMM updates	10.00 hours	20.00 hours	1,782.60
—(d) A railroad’s identification of a PTC system’s safety-critical components, including spare equipment.	38 railroads	1 identified new component.	1.00 hour	1.00 hour	89.13
236.1041(a) through (b) and 236.1043(a)—A railroad’s PTC Training and Qualification Program (i.e., a written plan).	38 railroads	2 programs	10.00 hours	20.00 hours	1,782.60
236.1043(b)—Training records retained in a designated location and available to FRA upon request.	150 host and tenant railroads.	150 PTC training records.	1.00 hour	150.00 hours	13,369.50
Total	742 railroads and 10 vendors.	4,567,839 responses.	N/A	53,309 hours	5,014,416

All estimates include the time for reviewing instructions; searching existing data sources; gathering or maintaining the needed data; and reviewing the information. Pursuant to 44 U.S.C. 3506(c)(2)(B), FRA solicits comments concerning: whether these information collection requirements are necessary for the proper performance of the functions of FRA, including whether the information has practical utility; the accuracy of FRA’s estimates of the burden of the information collection requirements; the quality, utility, and clarity of the information to be collected; and whether the burden of collection of information on those who

are to respond, including through the use of automated collection techniques or other forms of information technology, may be minimized. Organizations and individuals desiring to submit comments on the collection of information requirements or to request a copy of the paperwork package submitted to OMB should contact Ms. Arlette Mussington, Information Collection Clearance Officer, at email: arlette.mussington@dot.gov or telephone: (571) 609–1285, or Ms. Joanne Swafford, Information Collection Clearance Officer, at email: joanne.swafford@dot.gov or telephone: (757) 897–9908.

OMB is required to make a decision concerning the collection of information requirements contained in this proposed rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal. FRA is not authorized to impose a penalty on persons for violating information collection requirements that do not display a current OMB control number, if required.

D. Federalism Implications

Executive Order 13132, “Federalism,” requires FRA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” See 64 FR 43255 (Aug. 10, 1999). “Policies that have federalism implications” are defined in Executive Order 13132 to include regulations having “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” *Id.* Under Executive Order 13132, the agency may not issue a regulation with federalism implications that imposes substantial direct compliance costs and that is not required by statute, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by State and local governments or the agency consults with State and local government officials early in the process of developing the regulation. Where a regulation has federalism implications and preempts State law, the agency seeks to consult with State and local officials in the process of developing the regulation.

FRA has analyzed this proposed rule under the principles and criteria contained in Executive Order 13132. FRA has determined this proposed rule would not have a substantial direct effect on the States or their political subdivisions; on the relationship between the Federal Government and the States or their political subdivisions; or on the distribution of power and responsibilities among the various levels of government. In addition, FRA has determined this proposed rule does not impose substantial direct compliance costs on State and local governments. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

This proposed rule could have preemptive effect by the operation of law under a provision of the former Federal Railroad Safety Act of 1970, repealed and recodified at 49 U.S.C. 20106. Section 20106 provides that States may not adopt or continue in effect any law, regulation, or order related to railroad safety or security that covers the subject matter of a regulation prescribed or order issued by the Secretary of Transportation (with respect to railroad safety matters) or the Secretary of Homeland Security (with respect to railroad security matters), except when the State law, regulation,

or order qualifies under the “essentially local safety or security hazard” exception to section 20106.

FRA has analyzed this proposed rule in accordance with the principles and criteria contained in Executive Order 13132. As explained above, FRA has determined that this proposed rule has no federalism implications, other than the possible preemption of State laws under Federal railroad safety statutes, specifically 49 U.S.C. 20106. Accordingly, FRA has determined that preparation of a federalism summary impact statement for this proposed rule is not required.

E. International Trade Impact Assessment

The Trade Agreements Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and where appropriate, that they be the basis for U.S. standards. This proposed rule is not expected to affect trade opportunities for U.S. firms doing business overseas or for foreign firms doing business in the United States.

F. Environmental Impact

FRA has evaluated this proposed rule consistent with the National Environmental Policy Act (NEPA; 42 U.S.C. 4321, *et seq.*), the Council of Environmental Quality’s NEPA implementing regulations at 40 CFR parts 1500 through 1508, and FRA’s NEPA implementing regulations at 23 CFR part 771, and determined that it is categorically excluded from environmental review and therefore does not require the preparation of an environmental assessment (EA) or environmental impact statement (EIS). Categorical exclusions (CEs) are actions identified in an agency’s NEPA implementing regulations that do not normally have a significant impact on the environment and therefore do not require either an EA or EIS. See 40 CFR 1508.4. Specifically, FRA has determined that this proposed rule is categorically excluded from detailed environmental review pursuant to 23 CFR 771.116(c)(15), “Promulgation of rules, the issuance of policy statements, the waiver or modification of existing regulatory requirements, or discretionary approvals that do not result in significantly increased emissions of air or water pollutants or noise.”

This proposed rule does not directly or indirectly impact any environmental resources and would not result in significantly increased emissions of air or water pollutants or noise. Instead, the proposed rule is likely to result in safety benefits. In analyzing the applicability of a CE, FRA must also consider whether unusual circumstances are present that would warrant a more detailed environmental review. See 23 CFR 771.116(b). FRA has concluded that no such unusual circumstances exist with respect to this proposed rule and the proposal meets the requirements for categorical exclusion under 23 CFR 771.116(c)(15).

Pursuant to Section 106 of the National Historic Preservation Act and its implementing regulations, FRA has determined this undertaking has no potential to affect historic properties. See 16 U.S.C. 470. FRA has also determined that this rulemaking does not approve a project resulting in a use of a resource protected by section 4(f). See Department of Transportation Act of 1966, as amended (Pub. L. 89–670, 80 Stat. 931); 49 U.S.C. 303.

G. Environmental Justice

Executive Order 12898, “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” requires DOT agencies to achieve environmental justice as part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects, including interrelated social and economic effects, of their programs, policies, and activities on minority populations and low-income populations. DOT Order 5610.2C (“U.S. Department of Transportation Actions to Address Environmental Justice in Minority Populations and Low-Income Populations”) instructs DOT agencies to address compliance with Executive Order 12898 and requirements within DOT Order 5610.2C in rulemaking activities, as appropriate, and also requires consideration of the benefits of transportation programs, policies, and other activities where minority populations and low-income populations benefit, at a minimum, to the same level as the general population as a whole when determining impacts on minority and low-income populations.⁴⁹ FRA has evaluated this

⁴⁹ Executive Order 14096 “Revitalizing Our Nation’s Commitment to Environmental Justice,” issued on April 26, 2023, supplements Executive Order 12898, but is not currently referenced in DOT Order 5610.2C.

proposed rule under Executive Orders 12898 and 14096 and DOT Order 5610.2C and has determined it would not cause disproportionate and adverse human health and environmental effects on communities with environmental justice concerns.

H. Unfunded Mandates Reform Act of 1995

Under section 201 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 2 U.S.C. 1531), each Federal agency “shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law).” Section 202 of the Act (2 U.S.C. 1532) further requires that “before promulgating any general notice of proposed rulemaking that is likely to result in promulgation of any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement” detailing the effect on State, local, and Tribal governments and the private sector. This proposed rule would not result in the expenditure, in the aggregate, of \$100,000,000 or more (as adjusted annually for inflation) in any one year, and thus preparation of such a statement is not required.

I. Energy Impact

Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,” requires Federal agencies to prepare a Statement of Energy Effects for any “significant energy action.” 66 FR 28355 (May 22, 2001). As FRA acknowledged in section IV, there are societal benefits to the proposals in this NPRM. For example, there are possible fuel savings and carbon emission savings⁵⁰ from people not using alternative transportation modes like buses or cars, which would be necessary if the proposed flexibilities in this NPRM did not exist and railroads were not allowed to operate trains in certain circumstances. FRA evaluated this proposed rule under Executive Order 13211 and determined that this

⁵⁰ As noted above, passenger trains are up to 46% more efficient than driving and 34% more efficient than flying. Also, a single freight train can be up to 75% more fuel-efficient than a truck.

proposed rule is not a “significant energy action” within the meaning of Executive Order 13211, based on currently available information. However, FRA welcomes comments on the extent to which this proposed rule would result in fuel and emission savings.

J. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL–14 FDMS, accessible through <https://www.transportation.gov/privacy>. To facilitate comment tracking and response, DOT encourages commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

K. Tribal Consultation

FRA has evaluated this NPRM in accordance with the principles and criteria contained in Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments.”⁵¹ The proposed rule would not have a substantial direct effect on one or more Indian tribes, would not impose substantial direct compliance costs on Indian Tribal governments, and would not preempt Tribal laws. Therefore, the funding and consultation requirements of Executive Order 13175 do not apply, and a Tribal summary impact statement is not required.

L. Rulemaking Summary, 5 U.S.C. 553(b)(4)

As required by 5 U.S.C. 553(b)(4), a summary of this rulemaking can be found in the Abstract section of the Department’s Unified Agenda entry for this rulemaking at: <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202310&RIN=2130-AC95>.

List of Subjects in 49 CFR Part 236

Penalties, Positive train control, Railroad safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, FRA proposes to amend 49 CFR part 236 as follows:

⁵¹ 65 FR 67249 (Nov. 9, 2000).

PART 236—RULES, STANDARDS, AND INSTRUCTIONS GOVERNING THE INSTALLATION, INSPECTION, MAINTENANCE, AND REPAIR OF SIGNAL AND TRAIN CONTROL SYSTEMS, DEVICES, AND APPLIANCES

■ 1. The authority citation for part 236 continues to read as follows:

Authority: 49 U.S.C. 20102–20103, 20107, 20133, 20141, 20157, 20301–20303, 20306, 20501–20505, 20701–20703, 21301–21302, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 2. Amend § 236.1006 by adding paragraph (b)(6) to read as follows:

§ 236.1006 Equipping locomotives operating in PTC territory.

* * * * *

(b) * * *

(6) *Exception for certain non-revenue passenger equipment movements.* This exception is available to enable only non-revenue passenger equipment, including a locomotive, locomotive consist, or train without passengers, to operate to a maintenance facility or yard for the purpose of repairing or exchanging a PTC system. Such non-revenue equipment may operate to a maintenance facility or yard without being governed by PTC technology, as otherwise required under this part, only if it meets the criteria in this paragraph (b)(6) and the following conditions:

(i) The speed of the locomotive, locomotive consist, or train must not exceed 49 miles per hour;

(ii) An absolute block must be established in front of the locomotive, locomotive consist, or train;

(iii) There cannot be any working limits established under part 214 of this chapter or any roadway workers on any part of the route;

(iv) The locomotive, locomotive consist, or train must operate no farther than the next forward location designated in the railroad’s PTCSP for the repair or exchange of PTC technology; and

(v) The railroad must protect the route of the locomotive, locomotive consist, or train against conflicting operations and establish and comply with sufficient operating rules to protect against a train-to-train collision and the movement of a train through a switch left in the improper position.

(vi) FRA may, in its discretion, approve exception criteria and conditions other than those outlined in paragraphs (b)(6) and (b)(6)(i) through (v) of this section, in a PTCSP or an RFA, if the proposed criteria and conditions provide an equivalent or

greater level of safety than these default criteria and conditions.

(vii) Before utilizing the default exception under paragraphs (b)(6)(i) through (v) of this section or the discretionary exception under paragraph (b)(6)(vi) of this section, the railroad must notify each person involved with the movement of the non-revenue passenger equipment, including any dispatchers and train crews, and any roadway workers who may no longer work on that segment during the movement subject to this exception.

* * * * *
■ 3. Amend § 236.1021 by adding paragraph (m)(4) to read as follows:

§ 236.1021 Discontinuances, material modifications, and amendments.

* * * * *
(m) * * *

(4) A host railroad must utilize the RFA process under this paragraph (m) to request and obtain FRA's approval of a temporary PTC system outage, during which train movements may continue, including a short-term outage related to repair, maintenance, an infrastructure upgrade, or a capital project. A temporary PTC system outage includes, but is not limited to, any scenario when the onboard PTC apparatus or subsystem, wayside subsystem, communications subsystem, or back office subsystem would be disabled to perform a repair, maintenance, an infrastructure upgrade, or a capital project.

(i) A railroad may temporarily disable PTC technology pursuant to paragraph (m)(4) of this section only after it obtains approval from the Director of FRA's Office of Railroad Systems and Technology.

(ii) In addition to the content requirements outlined in paragraph (m)(2) of this section, an RFA that seeks to disable a PTC system temporarily must also contain the following information:

(A) The technical necessity for the proposed temporary outage to perform the repair, maintenance, infrastructure upgrade, or capital project;

(B) The physical limits and PTC system functions that would be affected by the proposed temporary outage, and an analysis that demonstrates the

affected physical limits and affected functions pose the least risk to railroad safety, compared to other options;

(C) An explanation about how the proposed temporary outage is in the public interest and consistent with railroad safety;

(D) The proposed timeframe of the temporary outage, and an analysis that demonstrates the proposed period of time poses the least risk to railroad safety, compared to other times;

(E) A justification and an analysis that show how the proposed duration of the temporary outage is the minimum time necessary to complete the pertinent work, test the PTC system, and place the PTC system back into service without undue delay;

(F) The type and frequency of rail operations that would continue during the proposed temporary outage, including those of the host railroad and each tenant railroad;

(G) The applicable speed limit of any train that would operate during the proposed temporary outage and the speed limit prior to any proposed temporary outage, and any other operating restrictions;

(H) The additional safety measures the host railroad and each tenant railroad must comply with during the proposed temporary outage, to ensure each type of PTC-preventable accident or incident does not occur. Specifically, such safety measures must be designed to prevent a train-to-train collision, an over-speed derailment, an incursion into an established work zone, and a movement of a train through a switch left in the wrong position; and

(I) A confirmation that before initiating the proposed temporary outage (if FRA authorizes it), each impacted railroad will notify all applicable dispatchers, train crews, and roadway workers about the temporary PTC system outage, including the specific location and duration of the temporary outage, the additional safety measures with which the railroad must comply, and any actions the individual must take during the temporary outage.

■ 4. Amend § 236.1029 by revising paragraph (g) to read as follows:

§ 236.1029 PTC system use and failures.

* * * * *

(g) *Initialization failures.* (1) Except as stated under paragraph (g)(3) or (4) of this section, when a PTC system fails to initialize as defined in § 236.1003, a train may proceed only according to the following operating restrictions:

(i) For the first 24 hours, the train may proceed only as prescribed under paragraphs (b)(1) through (6) of this section; and

(ii) After the first 24 hours, the train may proceed only as prescribed under paragraphs (b)(4) through (6) of this section, and must not exceed restricted speed as defined in § 236.1003.

(2) Each railroad operating in accordance with paragraph (g)(1) of this section will notify, as early as is possible, all dispatchers, train crews, and roadway workers about PTC system-level outages or failures that result in multiple trains' PTC systems failing to initialize, thus resulting in trains proceeding in accordance with operating restrictions. Railroads must ensure that job safety briefings reflect such operations.

(3) Notwithstanding the relief under paragraph (g)(1) of this section, when a PTC system fails to initialize due to loss of communications or lack of navigational information, the train must attempt to initialize the PTC system at the next forward, available location, including a main line, siding, yard, or station, whichever is closest.

(4) The relief under paragraph (g)(1) of this section does not apply to a single train that experiences an onboard PTC system failure at the initial terminal. The purpose of this paragraph (g) is to address issues affecting multiple trains.

(5) FRA reserves the right to impose additional operating restrictions and other conditions to address recurring issues that result in multiple trains' PTC systems failing to initialize and to deny the relief under paragraph (g)(1) of this section for recurring issues that result in multiple trains' PTC systems failing to initialize.

* * * * *

Issued in Washington, DC.

Amitabha Bose,
Administrator.

[FR Doc. 2024-24559 Filed 10-25-24; 8:45 am]

BILLING CODE 4910-06-P

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: WIC & FMNP Outreach, Innovation, and Modernization Evaluation

AGENCY: Food and Nutrition Service (FNS), Department of Agriculture (USDA).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is a new collection. The purpose of this information collection is to provide information on the implementation and effectiveness of modernization projects across all 88 Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) State agencies to help identify successes, opportunities for improvement, and areas for additional support from FNS to strengthen project implementation.

DATES: Written comments must be received on or before December 27, 2024.

ADDRESSES: Comments may be emailed to Carol.Dreibelbis@usda.gov. Comments will also be accepted through the Federal eRulemaking Portal. Go to <http://www.regulations.gov>, and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or requests for copies of this information collection should be directed to Carol Dreibelbis at Carol.Dreibelbis@usda.gov or 703-305-2161.

SUPPLEMENTARY INFORMATION: The American Rescue Plan Act of 2021 (ARPA), which was signed into law in March 2021, provided USDA with \$390 million and waiver authority for outreach, innovation, and program modernization in WIC and the WIC Farmers' Market Nutrition Program (FMNP). FNS is interested in understanding the implementation and outcomes related to these modernization efforts.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: WIC & FMNP Outreach, Innovation, and Modernization Evaluation.

Form Number: N/A.

OMB Number: 0584-NEW.

Expiration Date: Not Yet Determined.

Type of Request: New collection.

Abstract: The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) provides supplemental food, nutrition education, and referrals to health and social services to pregnant and postpartum women, infants, and children up to age 5 who are living in households with low incomes and are at nutritional risk. The WIC Farmers' Market Nutrition Program (FMNP) provides eligible WIC participants with FMNP benefits, in addition to their regular WIC benefits, which can be used to buy eligible foods from farmers, farmers' markets, or roadside stands that have been approved by the WIC State agency. While the benefits of participating in WIC have been well documented, WIC continues to reach only about half of those eligible to participate.¹ WIC has

relied on a traditional service delivery model that includes potentially challenging requirements for participants—such as regular in-person-only appointments to determine eligibility and to continue receiving services; limited or no online or digital services; and in-person shopping only. In an effort to improve service delivery and permanently modernize WIC, the American Rescue Plan Act (ARPA) of 2021 provided FNS with \$390 million and waiver authority to support WIC modernization. Under ARPA, FNS supports WIC modernization efforts by providing grants to all State agencies, offering waivers that support modernization efforts, collaborating with partners via cooperative agreements and contracts, and conducting projects. WIC modernization efforts seek to improve the WIC participant experience, reduce disparities in WIC service delivery, and increase WIC participation and retention.

The WIC & FMNP Outreach, Innovation, and Modernization Evaluation (WIC modernization evaluation) will help FNS understand the implementation and impacts of ARPA-funded projects and waivers to inform current and future modernization efforts. The WIC modernization evaluation has three components: an implementation study, a waiver study, and an impact study. The implementation study will provide a comprehensive understanding of project implementation while accommodating variations in the timing of projects within different program areas, implementation within and between State agencies, and innovative approaches. The implementation study component will collect a broad range of data from WIC State agencies, local agencies, clinics, vendors and authorized outlets (including farmers, farmers' markets, and roadside stands), and WIC participants. These data will provide current and ongoing information about modernization efforts in all 88 WIC State agencies.

Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Eligibility and WIC Program Reach in 2022. Prepared by Insight Policy Research, Contract No. 12319819A0005. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support, Project Officer: Grant Lovellette. Available online at: www.fns.usda.gov/research-analysis.

¹ Kessler C., Bryant A., Munkacsy K., and Gray K. (2024). *National- and State-Level Estimates of the*

The waiver study component will provide an understanding of waiver issuance and how State agencies used waivers. The waiver study will rely on many of the same data sources as the implementation study, especially the interviews with WIC State agencies. The study will also collect information on whether and how unique waivers were implemented by WIC State agencies to conduct the modernization projects.

The impact study component of the evaluation will measure the impact of the WIC and FMNP modernization projects on participants through key short-term and intermediate-term outcome measures, including enrollment, participation, retention, benefit redemption, participant experience (e.g., satisfaction), and disparities in program delivery. It will address whether the modernization projects improved these key outcome measures and how changes in these outcomes were related to the number and type of modernization projects. While most outcomes will be measured with administrative data (collected under existing projects), the impact study will also use surveys to learn about the experiences and satisfaction of WIC program staff, vendor/authorized outlet staff, and participants with the changes to the WIC program because of the modernization activities. In addition, the impact study will rely on information from the implementation and waiver studies regarding where and when projects and waivers were implemented.

Affected Public: Identified respondent groups include the following:

1. State, local, and tribal governments: WIC State agency staff in all 88 State agencies and local agency and clinic staff in every State agency jurisdiction.

2. Business (profit, non-profit, or farm) respondents: WIC and FMNP vendors and authorized outlet staff in every State agency jurisdiction.

3. Individual/household respondents: WIC participants in every State agency jurisdiction.

Estimated Number of Respondents: The total estimated number of respondents is 186,608. Of the 186,608 respondents to be contacted, 24,564 are expected to be responsive and 162,044 are expected to be nonresponsive. The breakout is as follows:

1. *5,938 State, local, and tribal government staff:* Of the 132 State agency staff contacted for an interview, 132 are expected to be responsive. Of the 222 local agency and clinic staff contacted for a case study interview, 160 are expected to be responsive. Of the 5,200 State agency, local agency, and clinic staff contacted for a survey, 4,160 are expected to be responsive. Of the 88 State agency staff invited for a webinar, 88 are expected to be responsive. Of the 176 State agency staff invited for a data collection planning meeting, 176 are expected to be responsive. Of the 88 State agency staff asked to support data collection, 88 are expected to be responsive. Of the 32 local agency staff invited for a data collection planning meeting and support data collection, 32 are expected to be responsive.

2. *4,200 business respondents:* Of the 100 WIC vendor/outlet staff contacted for a case study interview, 68 are expected to be responsive. Of the 4,100 WIC vendor/outlet staff contacted for a survey, 3,280 are expected to be responsive.

3. *176,470 individual respondents:* Of the 920 WIC participants contacted for a case study focus group, 580 are expected to be responsive. Of the 175,550 WIC participants contacted for a survey, 15,800 are expected to be responsive.

Estimated Number of Responses per Respondent: 9.2 across the entire collection, including respondents who receive communications but do not provide data for the study. The breakout is as follows:

1. *State agency staff:* 6.3 responses per respondent. 132 State agency staff will be asked to complete a virtual interview (each year, for three years) and 1,300 State agency staff will be asked to complete a survey. Prior to data collection, they will receive advanced communications about the study. 88 State agency staff will be invited to attend a webinar. 176 State agency staff will be invited to attend a planning meeting. 88 State agency staff will be asked to support data collection.

2. *Local agency and clinic staff:* 6.6 responses per respondent. 222 local agency and clinic staff will be asked to complete an in-person interview and 3,900 will be asked to complete a

survey. Prior to data collection, they will receive advanced communications about the study. 32 local agency staff will be asked to attend a planning meeting and support data collection.

3. *WIC vendor/outlet staff:* 10.8 responses per respondent. 100 vendor/outlet staff will be asked to complete an in-person case study interview and 4,100 will be asked to complete a survey. Prior to data collection, they will receive advanced communications about the study.

4. *Individual respondents:* 9.3 responses per respondent. 920 WIC participants will be asked to participate in a case study focus group and 175,550 will be asked to complete a survey. Prior to data collection, they will receive advanced communications about the study.

Estimated Total Annual Responses: Including respondents who receive communications but do not provide data for the study, there are an estimated 1,717,385 total responses and 572,462 annual responses. This is an estimated annual average, as data collection activities will take place over the course of three years: 2025, 2026, and 2027.

Estimated Time per Response: The estimated time of responses varies from 1 minute (0.0167 hours) for receipt of a text or email to 3.0167 hours for local agency staff planning and supporting data collection for case studies. Including respondents who receive communications but do not provide data for the study, the estimated average response time is about 1.2 minutes (0.02 hours).

Estimated Total Annual Burden on Respondents: Including burden on respondents who receive communications but do not provide data for the study, there is an estimated 32,108 hours of total burden and 10,703 hours of annual burden on respondents. This is an estimated annual average, as data collection activities will take place over the course of three years: 2025, 2026, and 2027. Please see the table below for estimated total annual burden for each type of respondent.

BILLING CODE 3410-30-P

Respondent Category	Type of respondents	Instruments	Appendix	Sample Size	Number of respondents	Frequency of response	Total responses	Hours per response	Total burden (hours)	Number of Non-respondents	Frequency of response	Total responses	Hours per response	Total burden (hours)	Grand Total Burden Estimate (hours)
Individual/ Household	WIC participants participating in case study focus groups	WIC Participant Case Study Focus Group Recruitment Email from State/Local Agency	Appendix N.2	920	920	1	920	0.0167	15	0	0	-	0.0167	-	15
		WIC Participant Case Study Focus Group Scheduling Email	Appendix N.3	920	644	1	644	0.0167	11	276	1	276	0.0167	4.609	15
		WIC Participant Case Study Focus Group Confirmation Email	Appendix N.5	644	644	1	644	0.0167	11	0	0	-	0.0000	-	11
		WIC Participant Case Study Focus Group Confirmation Text	Appendix N.6	644	644	1	644	0.0167	11	0	0	-	0.0000	-	11
		WIC Participant Case Study Focus Group Reminder Email	Appendix N.7	644	644	1	644	0.0167	11	0	0	-	0.0000	-	11
		WIC Participant Case Study Focus Group Reminder Text	Appendix N.8	644	644	1	644	0.0167	11	0	0	-	0.0000	-	11
		WIC Participant Case Study Focus Group Guide	Appendix F.4	644	580	1	580	1.5000	870	64	1	64	0.0000	-	870
		WIC Participant Case Study Focus Group Thank You Email	Appendix N.9	580	580	1	580	0.0167	10	0	0	-	0.0000	-	10
		WIC Participant Case Study Focus Group Thank You Text	Appendix N.10	580	580	1	580	0.0167	10	0	0	-	0.0000	-	10
	WIC Participant Case Study Focus Group Recruitment Flyer	Appendix N.1	1,600	1,600	1	1,600	0.0167	27	0	0	-	0.0167	-	27	
	WIC participants participating in experience surveys	WIC Participant Experience Survey Recruitment Email from WIC State Agency	Appendix T.2	175,550	175,550	1	175,550	0.0167	2,932	0	0	-	0.0167	-	2,932
		WIC Participant Experience Survey Invitation Email from WIC State Agency	Appendix T.3	175,550	175,550	1	175,550	0.0167	2,932	0	0	-	0.0167	-	2,932
		WIC Participant Experience Survey Invitation Text	Appendix T.4	175,550	175,550	1	175,550	0.0167	2,932	0	0	-	0.0167	-	2,932
		WIC Participant Experience Survey Reminder Email	Appendix T.5	175,550	175,550	2	351,100	0.0167	5,863	0	0	-	0.0167	-	5,863
		WIC Participant Experience Survey Reminder Text	Appendix T.6	175,550	175,550	2	351,100	0.0167	5,863	0	0	-	0.0167	-	5,863
		WIC Participant Experience Survey Reminder Phone Call	Appendix T.5	175,550	8,778	1	8,778	0.0334	293	0	0	-	0.0334	-	293
		WIC Participant Experience Survey Reminder Postcard	Appendix T.5	175,550	5,267	1	5,267	0.0167	88	0	0	-	0.0167	-	88
		WIC Participant Experience Survey	Appendix Q	175,550	15,800	1	15,800	0.1670	2,639	159,750	1	159,750	0.0000	-	2,639
		WIC Participant Experience Survey Thank You Email	Appendix T.7	15,800	15,800	1	15,800	0.0167	264	0	0	-	0.0000	-	264
WIC Participant Experience Survey Thank You Text	Appendix T.8	15,800	15,800	1	15,800	0.0167	264	0	0	-	0.0000	-	264		
Study Description for WIC Participants	Appendix N.4	175,550	175,550	1	175,550	0.0167	2,932	0	0	-	0.0167	-	2,932		
Individual/ Household Sub-Total				176,470	16,380	8.33	1,473,324	0.0190	27,966	160,090	1.00	160,090	0.000	4.6	27,991
Business (Profit, Non-Profit, or Farm)	WIC & FMNP vendor/outlet staff participating in case study interviews	WIC & FMNP Vendor/Outlet Staff Case Study Interview Recruitment Email from State or Local Agency	Appendix M.1	100	100	1	100	0.0167	2	0	0	-	0.0167	-	2
		WIC & FMNP Vendor/Outlet Staff Case Study Interview Recruitment Email from the Mathematica Study Team	Appendix M.2	100	75	1	75	0.0167	1	25	1	25	0.0167	0.418	2
		WIC & FMNP Vendor/Outlet Staff Case Study Interview Confirmation Email	Appendix M.4	75	75	1	75	0.0167	1	0	0	-	0.0000	-	1
		WIC & FMNP Vendor/Outlet Staff Case Study Interview Confirmation Text	Appendix M.5	75	75	1	75	0.0167	1	0	0	-	0.0000	-	1
		WIC & FMNP Vendor/Outlet Staff Case Study Interview Reminder Email	Appendix M.6	75	75	1	75	0.0167	1	0	0	-	0.0000	-	1
		WIC & FMNP Vendor/Outlet Staff Case Study Interview Reminder Text	Appendix M.7	75	75	1	75	0.0167	1	0	0	-	0.0000	-	1
		WIC & FMNP Vendor/Outlet Staff Case Study Interview Protocol	Appendix F.2	75	68	1	68	1.0000	68	7	7	1	0.0000	-	68
		WIC & FMNP Vendor/Outlet Staff Case Study Interview Thank You Email	Appendix M.8	68	68	1	68	0.0167	1	0	0	-	0.0000	-	1
	WIC & FMNP vendor/outlet staff participating in experience surveys	WIC & FMNP Vendor/Outlet Staff Case Study Interview Thank You Text	Appendix M.9	68	68	1	68	0.0167	1	0	0	-	0.0000	-	1
		WIC & FMNP Vendor/Outlet Staff Experience Survey Recruitment Email from WIC State Agency	Appendix S.2	4,100	4,100	1	4,100	0.0167	68	0	0	-	0.0167	-	68
		WIC & FMNP Vendor/Outlet Staff Experience Survey Invitation Email from the Mathematica Study Team	Appendix S.3	4,100	4,100	1	4,100	0.0167	68	0	0	-	0.0167	-	68
		WIC & FMNP Vendor/Outlet Staff Experience Survey Invitation Text	Appendix S.4	4,100	4,100	1	4,100	0.0167	68	0	0	-	0.0167	-	68
		WIC & FMNP Vendor/Outlet Staff Experience Survey Reminder Email	Appendix S.5	4,100	4,100	2	8,200	0.0167	137	0	0	-	0.0167	-	137
		WIC & FMNP Vendor/Outlet Staff Experience Survey Reminder Text	Appendix S.6	4,100	4,100	2	8,200	0.0167	137	0	0	-	0.0167	-	137
		WIC & FMNP Vendor/Outlet Staff Experience Survey Reminder Phone Call	Appendix S.5	4,100	1,230	1	1,230	0.0334	41	0	0	-	0.0334	-	41
		WIC & FMNP Vendor/Outlet Staff Experience Survey	Appendix P	4,100	3,280	1	3,280	0.1670	548	820	1	820	0.0000	-	548
WIC & FMNP Vendor/Outlet Staff Experience Survey Thank You Email	Appendix S.7	3,280	3,280	1	3,280	0.0167	55	0	0	-	0.0000	-	55		
WIC & FMNP Vendor/Outlet Staff Experience Survey Thank You Text	Appendix S.8	3,280	3,280	1	3,280	0.0167	55	0	0	-	0.0000	-	55		

Respondent Category	Type of respondents	Instruments	Appendix	Sample Size	Number of respondents	Frequency of response	Total responses	Hours per response	Total burden (hours)	Number of Non-respondents	Frequency of response	Total responses	Hours per response	Total burden (hours)	Grand Total Burden Estimate (hours)
		Study Description for WIC & FMNP Vendors/Outlets	Appendix M.3	4,100	4,100	1	4,100	0.0167	68	0	0	-	0.0167	-	68
Business (Profit, Non-Profit, or Farm) Sub-Total				4,200	3,348	10.61	44,549	0.0297	1,324	852	1.00	852	0.0005	0.4	1,325
State, Local, or Tribal Government	WIC local agency/clinic staff participating in case study interviews	WIC Local Agency Case Study Recruitment Email from State Agency	Appendix L.1	32	32	1	32	0.0167	0.5344	0	0	-	0.0167	-	1
		WIC Local Agency Case Study Planning Call Recruitment Email from the Mathematica Study Team and Planning Call	Appendix L.2	32	32	1	32	3.0167	96.5344	0	0	-	3.0167	-	97
		WIC Local Agency Staff Case Study Interview Scheduling Email	Appendix L.3	222	178	1	178	0.0167	2.9726	44	1	44	0.0167	0.735	4
		WIC Local Agency Staff Case Study Interview Reminder Email	Appendix L.5	178	178	1	178	0.0167	2.9726	0	0	-	0.0000	-	3
		WIC Local Agency Staff Case Study Interview Protocol	Appendix F.3	178	160	1	160	1.0000	160.0000	18	1	18	0.0000	-	160
		WIC Local Agency Staff Case Study Interview Thank You Email	Appendix L.6	160	160	1	160	0.0167	2.6720	0	0	-	0.0000	-	3
		Study Description for WIC Local Agencies	Appendix L.4	32	32	1	32	0.0167	0.5344	0	0	-	0.0167	-	1
	WIC local agency/clinic staff participating in experience surveys	WIC Program Staff Experience Survey Invitation Email from the Mathematica Study Team	Appendix R.2	3,900	3,900	1	3900	0.0167	65.1300	0	0	-	0.0167	-	65
		WIC Program Staff Experience Survey Reminder Email	Appendix R.3	3,900	3,900	4	15600	0.0167	260.5200	0	0	-	0.0167	-	261
		WIC Program Staff Experience Survey	Appendix O	3,900	3,120	1	3120	0.1670	521.0400	760	1	760	0.0000	-	521
		WIC Program Staff Experience Survey Thank You Email	Appendix R.4	3,120	3,120	1	3120	0.0167	52.1040	0	0	-	0.0000	-	52
	WIC State agency staff participating in interviews	WIC State Agency Study Recruitment Email from the Mathematica Study Team and Planning Call	Appendix K.1	176	176	1	176	0.5167	90.9392	0	0	-	0.5167	-	91
		WIC State Agency Staff Interview Scheduling Email and Preparation Time	Appendix K.2	132	132	3	396	0.2667	105.6132	0	0	-	0.2667	-	106
		WIC State Agency Staff Interview Reminder Email	Appendix K.3	132	132	3	396	0.0167	6.6132	0	0	-	0.0167	-	7
		WIC State Agency Staff Interview Protocol	Appendix F.1	132	132	3	396	1.0000	396.0000	0	0	-	1.0000	-	396
		WIC State Agency Staff Interview Thank You Email and Follow-up Questions	Appendix K.4	132	132	3	396	0.2667	105.6132	0	0	-	0.2667	-	106
		Study Description for WIC State Agencies	Appendix J	176	176	1	176	0.0167	2.9392	0	0	-	0.0167	-	3
	WIC State agency staff participating in experience surveys	WIC Program Staff Experience Survey Invitation Email from the Mathematica Study Team	Appendix R.2	1,300	1,300	1	1300	0.0167	21.7100	0	0	-	0.0167	-	22
		WIC Program Staff Experience Survey Reminder Email	Appendix R.3	1,300	1,300	4	5200	0.0167	86.8400	0	0	-	0.0167	-	87
		WIC Program Staff Experience Survey	Appendix O	1,300	1,040	1	1040	0.1670	173.6800	260	1	260	0.0000	-	174
		WIC Program Staff Experience Survey Thank You Email	Appendix R.4	1,040	1,040	1	1040	0.0167	17.3680	0	0	-	0.0000	-	17
	WIC State agency staff coordinating logistics	Mathematica Study Team Request to WIC State Agencies for WIC Program Staff Contact List for Experience Survey	Appendix R.1	88	88	1	88	2.0000	176.0000	0	0	-	2.0000	-	176
		Mathematica Study Team Request to WIC State Agencies for WIC Participant Contact List for Experience Survey	Appendix T.1	88	88	1	88	2.0000	176.0000	0	0	-	2.0000	-	176
		Mathematica Study Team Request to WIC State agencies for WIC & FMNP vendor/outlet staff contact list for experience survey	Appendix S.1	88	88	1	88	2.0000	176.0000	0	0	-	2.0000	-	176
		USDA Endorsement Letter for WIC State Agencies	Appendix I	88	88	1	88	0.0167	1.4696	0	0	-	0.0167	-	1
		WIC State Agency Webinar Invitation Email and Webinar	Appendix H	88	88	1	88	1.0167	89.4696	0	0	-	1.0167	-	89
	State, Local, or Tribal Government Sub-Total				5,938	4,836	6.31	37,468	0.07450	2,791	1,102	1.00	1,102	0.0007	0.7
COMBINED TOTAL				186,608	24,564	8.33	1,555,341	0.02064	32,102	162,044	1.00	162,044	0.0000	5.8	32,108

Tameka Owens,

Acting Administrator and Assistant
Administrator, Food and Nutrition Service.

[FR Doc. 2024-25008 Filed 10-25-24; 8:45 am]

BILLING CODE 3410-30-C

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Significant Cave Nomination Application

AGENCY: Forest Service, Agriculture
(USDA).

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the extension without change to a currently approved collection information collection, *Significant Cave Nominations under the Federal Cave Resources Protection Act*.

DATES: Comments must be received in writing on or before December 27, 2024 to be assured of consideration.

Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Limaris Soto, Lands, Minerals, and Geology, 1617 Cole Boulevard, Building 17, Lakewood CO 80401. Comments also may be submitted via facsimile to 303-275-5122 or by email to limaris.soto@usda.gov.

Comments submitted in response to this notice may be made available to the public through relevant websites and upon request. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

The public may inspect the draft supporting statement and/or comments received at 1617 Cole Boulevard, Building 17, Lakewood, CO 80401, during normal business hours. Visitors are encouraged to call ahead to 720-827-8912 to facilitate entry to the building. The public may request an electronic copy of the draft supporting

statement and/or any comments received be sent via return email. Requests should be emailed to limaris.soto@usda.gov.

FOR FURTHER INFORMATION CONTACT:

Limaris Soto, Lands, Minerals, and Geology, by phone at 720-827-8912 or email to limaris.soto@usda.gov.

Individuals who use telecommunications devices for the deaf and hard of hearing may call 711 to reach the Telecommunications Relay Service, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Significant Cave Nomination Application.

OMB Number: 0596-0244.

Expiration Date of Approval: December 31, 2024.

Type of Request: Extension without change to a currently approved collection.

Abstract: The information covered in this request applies to caves on Federal lands administered by the U.S. Department of Agriculture, Forest Service. The Forest Service proposes to collect the information in this request in accordance with the Federal Cave Resources Protection Act (FCRPA) [Pub. L. 100-691, 107 Stat. 4546] and regulations at 36 CFR 290 (Cave Resources Management) which require the Secretary of Agriculture to identify and protect significant caves on National Forest System lands.

The Forest Service must collect this information to comply with the FCRPA (16 U.S.C. 4301-4310) and its implementing regulations at 36 CFR 290 that contain criteria for the identification of significant caves. The information collection is also responsive to requirements of the 36 CFR part 290—Cave Management regulations that specify the process for nomination of significant caves and assessment of whether the listed criteria for a cave to be considered significant have been met. 36 CFR 290.3(a) states that significant cave nominations will be accepted by the Forest Supervisor where the cave is located.

The Forest Service uses the information in a cave nomination to determine if specified criteria are met for the nominated cave to be listed as significant in accordance with the FCRPA and regulations at 36 CFR 290.3. The information is necessary for full compliance with agencies' responsibilities to identify and protect significant caves and their resources. Nominations are voluntary. The information collected in the Significant Cave Nomination Worksheet includes:

- The name, address, and telephone number of the individual or

organization submitting the nomination. This allows us to confirm the source of the information;

- The name of the cave, which is necessary for the listing of caves and to ensure there are no duplications;

- The location of the cave, which is essential for verification, management, and future planning purposes;

- The name of the agency and the administrative unit, which is necessary to ensure that the application is forwarded to the appropriate agency office;

- A discussion of how the cave meets the criteria, which is the key aspect of the nomination, and is used to determine whether the cave should be designated as significant;

- Studies, maps, research papers, and other supporting documentation, which are important in the significance evaluation;

- The name, address, and telephone number of the individual who is knowledgeable about the resources in the cave, which are necessary in case the information in the nomination is unclear or there is a need for additional information to complete the evaluation;

- The date that the nomination is submitted, which is essential for tracking purposes; and

- The signature and title of the individual submitting the nomination, which is necessary to confirm that it is an official nomination.

The Forest Service collects the information from anyone who wishes to nominate a cave to be considered significant. Caves can be nominated by the public, Forest Service partners, other government agencies, and Forest Service staff. The information collected is used to determine whether a nominated cave meets specified criteria to be considered significant per the FCRPA and 36 CFR 290.

Forest Service Manual 2880.43 states that the Forest Supervisor must ensure that all caves within their jurisdictions are evaluated in accordance with the FCRPA and 36 CFR 290 and make a determination of significant caves nominated for such designation. Under the FCRPA the Secretary shall request that the list of significant caves shall be updated periodically, after consultation with appropriate private sector interest, including cavers. If agencies did not collect cave nominations, they might not become aware of potentially significant caves' existence or might have insufficient information upon which to base a judgment as to their significance. As a result, it is likely that agencies would not be able to comply fully with their statutory responsibilities to identify and protect significant caves

and their resources. The information is collected on occasion, which is the minimum frequency necessary to comply with the statute.

Affected Public: Individuals and Households.

Estimate of Burden per Response: 11 hours.

Estimated Annual Number of Respondents: 10.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 110.

Comment Is Invited

Comment is invited on: (1) whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the agency, including whether the information will have practical or scientific utility; (2) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request for Office of Management and Budget approval.

Christopher French,

Deputy Chief for National Forest System.

[FR Doc. 2024-24996 Filed 10-25-24; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Small Business Timber Sale Set-Aside Program; Appeal Procedures on Recomputation of Shares

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the extension with revision of a currently approved information collection, titled Small

Business Timber Sale Set-Aside Program; Appeal Procedures on Recomputation of Shares.

DATES: Comments must be received in writing on or before December 27, 2024 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Director, Forest Management, Mail Stop 1103, Forest Service, USDA, 1400 Independence Avenue SW, Washington, DC 20024.

Comments also may be submitted by email to: SM.FS.WONFSSBAIC@usda.gov.

Comments submitted in response to this notice may be made available to the public through relevant websites and upon request. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

The public may inspect the draft supporting statement and/or comments received. The public may request an electronic copy of the draft supporting statement and/or any comments received be sent via return email. Requests should be emailed to SM.FS.WONFSSBAIC@usda.gov.

FOR FURTHER INFORMATION CONTACT:

Mike Spisak, Natural Resources Staff, 910-975-0114. Individuals who use telecommunication devices for the hearing impaired may call 711 to reach the Telecommunications Relay Service, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Small Business Timber Sale Set-Aside Program; Appeal Procedures on Recomputation of Shares.

OMB Number: 0596-0141.

Expiration Date of Approval: February 28, 2025.

Type of Request: Extension with revision of a currently approved information collection.

Abstract: The Forest Service adopted the Small Business Timber Sale Set-Aside Program (Set-Aside Program) on July 26, 1990 (55 FR 30485). The agency administers the Set-Aside Program in

cooperation with the Small Business Administration (SBA) under the authorities of the Small Business Act (15 U.S.C. 631), the National Forest Management Act of 1976, and SBA regulations in 13 CFR part 121. The Set-Aside Program is designed to ensure that small business timber purchasers have the opportunity to purchase a fair proportion of National Forest System timber offered for sale. Under the Set-Aside Program, the Forest Service must recompute the shares of timber sales to be set aside for qualifying small businesses every 5 years based on the actual volume of sawtimber that has been purchased by small businesses. Additionally, shares must be recomputed if there is a change in manufacturing capability, if the purchaser size class changes, or if certain purchasers discontinue operations.

In 1992, the agency adopted new administrative appeal procedures (36 CFR part 215), which excluded the Set-Aside Program. Prior to adoption of 36 CFR part 215, the agency accepted appeals of recomputation decisions under 36 CFR part 217 and therefore decided to establish procedures for providing notice to affected purchasers offering an opportunity to comment on the recomputation of shares (61 FR 7468). The Conference Report accompanying the 1997 Omnibus Appropriation Act (Pub. L. 104-208) directed the Forest Service to reinstate an appeals process for decisions concerning recomputation of Small Business Set-Aside shares, structural recomputations of SBA shares, or changes in policies impacting the Set-Aside Program prior to December 31, 1996. The Small Business Timber Sale Set-Aside Program, Appeal Procedures on Recomputation of Shares (36 CFR 223.118; 64 FR 411, January 5, 1999), outlines the types of decisions that are subject to appeal, who may appeal decisions, the procedures for appealing decisions, the timelines for appeal, and the contents of the notice of appeal.

The Forest Service provides qualifying timber sale purchasers with 30-days for pre-decisional review and comment on draft decisions to reallocate shares, including the data used in making the proposed recomputation decision. Within 15 days after the close of the 30-day pre-decisional review period, an agency official makes a decision on the shares to be set aside for small businesses and gives written notice of the decision to all parties on the national forest timber sale bidders list for the affected area. The written notice provides the date by which the

appeal may be filed and how to obtain information on appeal procedures.

Only those timber sale purchasers, or their representatives, who are affected by small business share timber sale set-aside recomputation decisions and who have submitted pre-decisional comments may appeal recomputation decisions. The appellant must file a notice of appeal with the appropriate Forest Service official within 20 days of the date on the notice of decision. The notice of appeal must include:

1. The appellant's name, mailing address, and daytime telephone number;
2. The title or type of recomputation decision involved and date of the decision;
3. The name of the responsible Forest Service official;
4. A brief description and date of the decision being appealed;
5. A statement of how the appellant is adversely affected by the decision being appealed;
6. A statement of facts in dispute regarding the issue(s) raised by the appeal;
7. Specific references to law, regulation, or policy that the appellant believes have been violated (if any) and the basis for such an allegation;
8. A statement as to whether and how the appellant has tried to resolve the appeal issues with the responsible Forest Service official, including evidence of submission of written comments at the pre-decisional stage; and
9. A statement of the relief the appellant seeks.

The Appeal Deciding Officer shall review the decision and appeal record and issue a written appeal decision to the parties as required by 36 CFR 223.118. The data gathered in this information collection is not available from other sources.

Affected Public: Timber sale purchasers, or their representatives, who are affected by recomputations of small business share of timber sales.

Estimate of Burden per Response: 20 hours, inclusive of pre-decisional comments and appeal.

Estimated Annual Number of Respondents: 10.

Estimated Annual Number of Responses per Respondent: 2.

Estimated Total Annual Burden on Respondents: 200 hours.

Comment Is Invited

Comment is invited on: (1) whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the agency, including whether the

information will have practical or scientific utility; (2) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request for Office of Management and Budget approval.

Christopher French,

Deputy Chief, National Forest System.

[FR Doc. 2024-24995 Filed 10-25-24; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF COMMERCE

Economic Development Administration

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application Materials for EDA Investment Assistance

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on August 28, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Economic Development Administration (EDA), Commerce.

Title: Application Materials for EDA Investment Assistance.

OMB Control Number: 0610-0094.

Form Number(s): ED-900, ED-900B, ED-900C, ED-900D, ED-900E, ED-900F.

Type of Request: Extension of a currently approved information collection.

Number of Respondents: For construction projects, 977 estimated respondents, and for non-construction projects, 1,663 estimated respondents, for a total of 2,640 estimated respondents.

Average Hours per Response: For construction projects, 43.0 estimated hours per response, and for non-construction projects, 17.1 estimated hours per response.

Burden Hours: For construction projects, 42,011 estimated annual burden hours, and for non-construction projects, 28,437 estimated annual burden hours, for a total of 70,448 estimated total annual burden hours.

Needs and Uses: EDA must collect specific information from applicants for EDA investment assistance to evaluate whether proposed projects satisfy eligibility and programmatic requirements contained in EDA's authorizing legislation, the Public Works and Economic Development Act of 1965, as amended (42 U.S.C. 3121 *et seq.*); EDA regulations at 13 CFR Chapter III; and applicable Notices of Funding Opportunity.

EDA proposes to extend the following forms under this information collection: Forms ED-900 (General Application for EDA Programs), ED-900B (Beneficiary Information Form), ED-900C (EDA Application Supplement for Construction Programs), ED-900D (Requirements for Design and Engineering Assistance), ED-900E (Calculation of Estimated Relocation and Land Acquisition Expenses), and ED-900F (Additional EDA Assurances for Revolving Loan Fund Investments).

Affected Public: Entities eligible for EDA financial assistance, including Federal, State, and local governments; Indian tribes; institutions of higher education; not-for-profit entities; and business or other for-profit organizations.

Frequency: During application for EDA investment assistance.

Respondent's Obligation: Mandatory.

Legal Authority: The Public Works and Economic Development Act of 1965 (42 U.S.C. 3121 *et seq.*).

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day

Review—Open for Public Comments” or by using the search function and entering either the title of the collection or the OMB Control Number 0610–0094.

Sheleen Dumas,

Departmental PRA Clearance Officer, Office of the Under Secretary of Economic Affairs, Commerce Department.

[FR Doc. 2024–25006 Filed 10–25–24; 8:45 am]

BILLING CODE 3510–34–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2170]

Activation Limit Increase Under Alternative Site Framework; Foreign-Trade Zone 84; Houston, Texas

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones (FTZ) Act provides for “. . . the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,” and authorizes the Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the Port of Houston Authority, grantee of Foreign-Trade Zone 84, submitted an application to the Board (FTZ Docket B–36–2024, docketed June 26, 2024) for authority to increase the activation limit of the zone under the ASF to 3,000 acres;

Whereas, the application has been processed pursuant to the FTZ Act and the Board’s regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner’s report, and finds that the requirements of the FTZ Act and the Board’s regulations are satisfied;

Now, therefore, the Board hereby orders:

The application to increase the activation limit of the zone under the ASF to 3,000 acres is approved, subject to the FTZ Act and the Board’s regulations, including section 400.13.

Dated: October 23, 2024.

Dawn Shackelford,

Executive Director of Trade Agreements Policy & Negotiations, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 2024–25011 Filed 10–25–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–171]

Disposable Aluminum Containers, Pans, Trays, and Lids From the People’s Republic of China: Preliminary Affirmative Countervailing Duty Determination, Preliminary Affirmative Determination of Critical Circumstances, and Alignment of Final Determination With Final Antidumping Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of disposable aluminum containers, pans, trays, and lids (disposable aluminum containers) from the People’s Republic of China (China). The period of investigation (POI) is January 1, 2023, through December 31, 2023. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable October 28, 2024.

FOR FURTHER INFORMATION CONTACT: Brian Warnes, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0028.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this countervailing duty (CVD) investigation on June 12, 2024.¹ On July 25, 2024, Commerce postponed the deadline for the preliminary determination until October 15, 2024, in accordance with section

¹ See *Disposable Aluminum Containers, Pans, Trays, and Lids from the People’s Republic of China: Initiation of Countervailing Duty Investigation*, 89 FR 49833 (June 12, 2024) (*Initiation Notice*).

703(c)(1)(A) of the Act.² On July 26, 2024, Commerce further tolled all deadlines in this proceeding by seven days.³ The deadline for the preliminary determination is now October 21, 2024.

For a complete description of events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.⁴ A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The products covered by this investigation are disposable aluminum containers from China. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In accordance with the *Preamble* to Commerce’s regulations,⁵ the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope).⁶ No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice*.

Methodology

Commerce is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.*, a financial contribution by an “authority” that gives rise to a benefit to the recipient,

² See *Disposable Aluminum Containers, Pans, Trays, and Lids from the People’s Republic of China: Postponement of Preliminary Determination in the Countervailing Duty Investigation*, 89 FR 60355 (July 25, 2024).

³ See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,” dated July 25, 2024.

⁴ See Memorandum, “Decision Memorandum for the Preliminary Affirmative Determination of the Countervailing Duty Investigation of Disposable Aluminum Containers, Pans, Trays, and Lids from the People’s Republic of China,” dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁵ See *Antidumping Duties; Countervailing Duties, Final Rule*, 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

⁶ See *Initiation Notice*, 89 FR at 49834.

and that the subsidy is specific.⁷ For a full description of the methodology underlying our preliminary determination, see the Preliminary Decision Memorandum.

Commerce notes that, in making these findings, it relied, in part, on facts available, and, because it finds that certain respondents and the Government of China did not act to the best of their ability to respond to Commerce’s requests for information, it drew an adverse inference where appropriate in selecting from among the facts otherwise available.⁸ For further information, see the “Use of Facts Otherwise Available and Adverse Inferences” section in the Preliminary Decision Memorandum.

Preliminary Affirmative Determination Critical Circumstances

In accordance with section 703(e)(1) of the Act, we preliminarily find that critical circumstances exist with respect to imports of subject merchandise from Henan Aluminium Corporation (Henan), Zhejiang Acumen Living Technology Co., Ltd. (Zhejiang Acumen), and all other exporters/producers of disposable

aluminum containers from China. For a full discussion of our preliminary critical circumstances determination, see the “Preliminary Affirmative Determination of Critical Circumstances” section of the Preliminary Decision Memorandum.

Alignment

In accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), Commerce is aligning the final CVD determination in this investigation with the final determination in the concurrent antidumping duty (AD) investigation of disposable aluminum containers from China, based on a request made by the Aluminum Foil Container Manufacturers Association (the petitioner).⁹ Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than March 4, 2025, unless postponed.

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that, in the preliminary determination, Commerce shall determine an estimated all-others rate

for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any rates that are zero, *de minimis*, or based entirely under section 776 of the Act.

In this investigation, Commerce preliminarily calculated a total subsidy rate for Henan that is not zero, *de minimis*, or based entirely on the facts otherwise available. The rate determined for the other mandatory respondent, Zhejiang Acumen, is based entirely under section 776 of the Act. Because Commerce calculated a total countervailable subsidy rate for Henan that is not zero, *de minimis*, or based entirely on the facts otherwise available, and because the only other respondent, Zhejiang Acumen, is based entirely on the facts otherwise available, we have preliminarily determined the all-others rate to be Henan’s rate.¹⁰

Preliminary Determination

Commerce preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent <i>ad valorem</i>)
Henan Aluminium Corporation	78.12
Zhejiang Acumen Living Technology Co., Ltd	* 312.91
All Others	78.12

* Rate based on facts available with adverse inferences.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with

issues raised in the case briefs or other written comments.

Suspension of Liquidation

Section 703(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the later of: (a) the date which is 90 days before the date on which the suspension of liquidation was first ordered; or (b) the date on which notice of initiation of the investigation was published. Commerce preliminarily finds that critical circumstances exist for imports of subject merchandise from all exporters/producers. In accordance with section 703(e)(2)(A) of the Act, the suspension of liquidation shall apply to unliquidated entries of merchandise from all exporters/producers that were

entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the publication of this notice. Further, pursuant to 19 CFR 351.205(d), Commerce will instruct U.S. Customs and Border Protection to require a cash deposit to suspended entries equal to the rates indicated above.

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to

⁷ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

⁸ See sections 776(a) and (b) of the Act.

⁹ See Petitioner’s Letter, “Petitioner’s Request to Align Final Antidumping and Countervailing Duty Determinations,” dated October 11, 2024.

¹⁰ See Memorandum, “Calculation of Subsidy Rate for All Others,” dated concurrently with this notice.

issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.¹¹ Interested parties who submit case or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.¹²

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public executive summary for each issue raised in their briefs.¹³ Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹⁴

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, via ACCESS, within 30 days after the date of publication of this notice. Requests should contain (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of the issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing.¹⁵ Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

¹¹ See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

¹² See 19 CFR 351.309(c)(2) and (d)(2).

¹³ We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹⁴ See *APO and Service Final Rule*, 88 FR at 67069.

¹⁵ See 19 CFR 351.310(d).

All submissions, including case and rebuttal briefs, as well as hearing requests, should be filed using ACCESS. An electronically-filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline.

U.S. International Trade Commission (ITC) Notification

In accordance with section 703(f) of the Act, Commerce will notify the ITC of its determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of disposable aluminum containers from China are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 703(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c).

Dated: October 21, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is disposable aluminum containers, pans, trays, and lids produced primarily from flat-rolled aluminum. The subject merchandise includes disposable aluminum containers, pans, trays, and lids regardless of shape or size and whether or not wrinkled or smooth.

The term "disposable" is used to identify an aluminum article that is designed to be used once, or for a limited number of times, and then recycled or otherwise disposed. "Containers, pans, and trays" are receptacles for holding goods.

The subject disposable aluminum lids are intended to be used in combination with disposable containers produced from aluminum or other materials (e.g., paper or plastic). Where a disposable aluminum lid is imported with a non-aluminum container, only the disposable aluminum lid is included in the scope.

Disposable aluminum containers, pans, trays, and lids are also included within the scope regardless of whether the surface has been embossed, printed, coated (including with a non-stick substance), or decorated, and regardless of the style of the edges. The inclusion of a nonaluminum lid or dome sold or packaged with an otherwise in-scope article does not remove the article from the scope, however, only the disposable aluminum container, pan, tray, and lid is covered by the scope definition.

Disposable aluminum containers, pans, trays, and lids are typically used in food-related applications, including but not limited to food preparation, packaging, baking, barbecuing, reheating, takeout, or storage, but also have other uses. Regardless of end use, disposable aluminum containers, pans, trays, and lids that meet the scope definition and are not otherwise excluded are subject merchandise.

Excluded from the scope are disposable aluminum casks, drums, cans, boxes and similar containers (including disposable aluminum cups and bottles) properly classified under Harmonized Tariff Schedule of the United States (HTSUS) subheading 7612.90. However, aluminum containers, pans, trays, and lids that would otherwise be covered by the scope are not excluded based solely on the fact that they are being classified under HTSUS subheading 7612.90.5000 due to the thickness of aluminum being less than 0.04 mm or greater than 0.22 mm.

The flat-rolled aluminum used to produce the subject articles may be made to ASTM specifications ASTM B479 or ASTM B209–14 but can also be made to other specifications. Regardless of the specification, however, all disposable aluminum containers, pans, trays, and lids meeting the scope description are included in the scope.

Disposable aluminum containers, pans, trays, and lids are currently classifiable under HTSUS subheading 7615.10.7125. Further, merchandise that falls within the scope of this proceeding may also be entered into the United States under HTSUS subheadings 7612.90.1090, 7615.10.3015, 7615.10.3025, 7615.10.7130, 7615.10.7155, 7615.10.7180, 7615.10.9100, and 8309.90.0000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this proceeding is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Alignment
- IV. Injury Test
- V. Preliminary Affirmative Determination of Critical Circumstances
- VI. Diversification of China's Economy
- VII. Use of Facts Available and Adverse Inferences
- VIII. Subsidies Valuation
- IX. Benchmarks and Interest Rates
- X. Analysis of Programs
- XI. Recommendation

[FR Doc. 2024–25013 Filed 10–25–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE**International Trade Administration**

[A–560–842]

Frozen Warmwater Shrimp From Indonesia: Final Affirmative Determination of Sales at Less-Than-Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that imports of frozen warmwater shrimp (shrimp) from Indonesia are being, or are likely to be, sold in the United States at less-than-fair value (LTFV) for the period of investigation (POI) October 1, 2022, through September 30, 2023.

DATES: Applicable October 28, 2024.

FOR FURTHER INFORMATION CONTACT: Rachel Jennings or Miranda Bourdeau, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1110 or (202) 482–2021, respectively.

SUPPLEMENTARY INFORMATION:**Background**

On May 30, 2024, Commerce published in the *Federal Register* its preliminary affirmative determination in the LTFV investigation of shrimp from Indonesia.¹ We invited interested parties to comment on the *Preliminary Determination*. On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.² The deadline for the final determination is now October 21, 2024.³

A summary of the events that occurred since Commerce published the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination may be found in the Issues and Decision Memorandum.⁴ The Issues and Decision

¹ See *Frozen Warmwater Shrimp from Indonesia: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures*, 89 FR 46861 (May 30, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,” dated July 22, 2024.

³ *Id.*

⁴ See Memorandum, “Issues and Decision Memorandum for the Final Affirmative

Memorandum is a public document and is on file electronically via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The product covered by this investigation is shrimp from Indonesia. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination*. Therefore, we made no changes to the scope of the investigation.

Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended (the Act), Commerce verified the sales and cost information submitted by PT Bahari Makmur Sejati (BMS),⁵ and PT First Marine Seafoods and PT Khom Foods (collectively, First Marine/Khom Foods)⁶ for use in our final determination. We used standard verification procedures, including an examination of relevant sales and accounting records, and original source

Determination of Sales at Less-Than-Fair-Value of Frozen Warmwater Shrimp from Indonesia,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁵ See Memoranda, “Verification of the Questionnaire Responses of PT Bahari Makmur Sejati in the Less-Than-Fair-Value Investigation of Frozen Warmwater Shrimp from Indonesia,” dated July 22, 2024; and “Verification of the Cost Response of PT Bahari Makmur Sejati in the Antidumping Duty Investigation of Frozen Warmwater Shrimp from Indonesia,” dated August 6, 2024.

⁶ See Memoranda, “Verification of the Questionnaire Responses of PT First Marine Seafoods and PT Khom Foods in the Less-Than-Fair-Value Investigation of Frozen Warmwater Shrimp from Indonesia,” dated August 2, 2024, and “Verification of the Cost Response of PT First Marine Seafoods in the Less Than Fair Value Investigation of Frozen Warm Water Shrimp from Indonesia,” dated September 6, 2024. In the *Preliminary Determination*, Commerce determined that PT First Marine Seafoods and PT Khom Foods are a single entity and no party commented on this finding. Accordingly, we continue to treat these companies as a single entity for this final determination. See *Preliminary Determination* PDM at 5.

documents provided by BMS and First Marine/Khom Foods.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by interested parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached to this notice as Appendix II.

Changes Since the Preliminary Determination

We have made certain changes since the *Preliminary Determination*. See the Issues and Decision Memorandum for a discussion of these changes.

Use of Adverse Facts Available

In making this final determination, Commerce relied, in part, on facts otherwise available with an adverse inference (AFA), pursuant to sections 776(a) and (b) of the Act, in determining BMS’s domestic brokerage and handling expenses. For further discussion of our application of AFA, see the Issues and Decision Memorandum.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

For the final determination of this investigation, Commerce calculated an estimated weighted-average dumping margin of 0.00 percent for BMS, and an estimated weighted-average dumping margin of 3.90 percent for First Marine/Khom Foods. Therefore, the only rate that is not zero, *de minimis*, or based entirely on facts otherwise available is the rate calculated for First Marine/Khom Foods. Consequently, the rate calculated for First Marine/Khom Foods is also assigned as the rate for all other producers and exporters.

Final Determination

Commerce determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Weighted-average dumping margin (percent) ⁷
PT Bahari Makmur Sejati	0.00
PT First Marine Seafoods/PT Khom Foods	3.90
All Others	3.90

Disclosure

Commerce intends to disclose the calculations performed in connection with this final determination to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of subject merchandise, as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption on or after May 30, 2024, the date of publication of the *Preliminary Determination* in the **Federal Register** except for those entries of subject merchandise produced and exported by BMS.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), upon the publication of this notice, we will instruct CBP to require a cash deposit for estimated weighted-average antidumping duties as follows: (1) the cash deposit rate for the companies listed in the table above that exported the subject merchandise will be equal to the company-specific estimated weighted-average dumping margins determined in this final determination; (2) if the exporter is not a company identified in the table above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the estimated weighted-average dumping margin for all other producers and exporters. These suspension of

liquidation instructions will remain in effect until further notice.

Because the estimated weighted-average dumping margin for BMS is zero, entries of shipments of subject merchandise that are produced and exported by BMS will not be subject to suspension of liquidation or cash deposit requirements. In such situations, Commerce also applies the exclusion from the provisional measures to the producer/exporter combination that was examined in the investigation. Accordingly, Commerce will not be directing CBP to suspend liquidation of entries of subject merchandise produced and exported by BMS. However, entries of subject merchandise from this company in any other producer/exporter combination (*i.e.*, where BMS is either the producer or the exporter, but not both), or by third parties that sourced subject merchandise from the excluded producer/exporter combination, will be subject to suspension of liquidation at the all-others rate.

Further, because the estimated weighted-average dumping margin is zero for subject merchandise produced and exported by BMS, entries of such merchandise will be excluded from the potential antidumping duty order. Such an exclusion will not be applicable to merchandise exported to the United States by this respondent in any other producer/exporter combinations or by third parties that sourced subject merchandise from the excluded producer/exporter combination.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (ITC) of our final affirmative determination of sales at LTFV. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of shrimp from Indonesia no later than 45 days after this final determination. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and

all cash deposits will be refunded or canceled, and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the "Continuation of Suspension of Liquidation" section.

Administrative Protective Order

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This final determination and notice are issued and published in accordance with sections 735(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: October 21, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of this investigation includes certain frozen warmwater shrimp and prawns whether wild-caught (ocean harvested) or farm-raised (produced by aquaculture), head-on or head-off, shell-on or peeled, tail-on or tail-off, deveined or not deveined, cooked or raw, or otherwise processed in frozen form. "Tails" in this context means the tail fan, which includes the telson and the uropods.

The frozen warmwater shrimp and prawn products included in the scope, regardless of definitions in the Harmonized Tariff Schedule of the United States (HTSUS), are products which are processed from warmwater shrimp and prawns through freezing and which are sold in any count size.

⁷ Commerce determined that countervailable subsidies are not being provided to producers and exporters of shrimp from Indonesia. See Memorandum, "Decision Memorandum for the Final Negative Determination of the Countervailing Duty Investigation of Frozen Warmwater Shrimp from Indonesia," dated concurrently with this notice.

The products described above may be processed from any species of warmwater shrimp and prawns. Warmwater shrimp and prawns are generally classified in, but are not limited to, the Penaeidae family. Some examples of the farmed and wild-caught warmwater species include, but are not limited to, whiteleg shrimp (*Penaeus vannamei*), banana prawn (*Penaeus merguensis*), fleshy prawn (*Penaeus chinensis*), giant river prawn (*Macrobrachium rosenbergii*), giant tiger prawn (*Penaeus monodon*), redspotted shrimp (*Penaeus brasiliensis*), southern brown shrimp (*Penaeus subtilis*), southern pink shrimp (*Penaeus notialis*), southern rough shrimp (*Trachypenaeus curvirostris*), southern white shrimp (*Penaeus schmitti*), blue shrimp (*Penaeus stylirostris*), western white shrimp (*Penaeus occidentalis*), and Indian white prawn (*Penaeus indicus*).

Frozen shrimp and prawns that are packed with marinade, spices or sauce are included in the scope. In addition, food preparations, which are not “prepared meals,” that contain more than 20 percent by weight of shrimp or prawn are also included in the scope.

Excluded from the scope are: (1) breaded shrimp and prawns (HTSUS subheading 1605.21.10.20); (2) shrimp and prawns generally classified in the Pandalidae family and commonly referred to as coldwater shrimp, in any state of processing; (3) fresh shrimp and prawns whether shell-on or peeled (HTSUS subheadings 0306.36.0020 and 0306.36.0040); (4) shrimp and prawns in prepared meals (HTSUS subheading 1605.21.05.00 and 1605.29.05.00); (5) dried shrimp and prawns; (6) canned warmwater shrimp and prawns (HTSUS subheading 1605.29.10.40); and (7) certain battered shrimp. Battered shrimp is a shrimp-based product: (1) that is produced from fresh (or thawed-from-frozen) and peeled shrimp; (2) to which a “dusting” layer of rice or wheat flour of at least 95 percent purity has been applied; (3) with the entire surface of the shrimp flesh thoroughly and evenly coated with the flour; (4) with the non-shrimp content of the end product constituting between four and ten percent of the product’s total weight after being dusted, but prior to being frozen; and (5) that is subjected to IQF freezing immediately after application of the dusting layer. When dusted in accordance with the definition of dusting above, the battered shrimp product is also coated with a wet viscous layer containing egg and/or milk, and par-fried.

The products covered by the scope are currently classified under the following HTSUS subheadings: 0306.17.0004, 0306.17.0005, 0306.17.0007, 0306.17.0008, 0306.17.0010, 0306.17.0011, 0306.17.0013, 0306.17.0014, 0306.17.0016, 0306.17.0017, 0306.17.0019, 0306.17.0020, 0306.17.0022, 0306.17.0023, 0306.17.0025, 0306.17.0026, 0306.17.0028, 0306.17.0029, 0306.17.0041, 0306.17.0042, 1605.21.1030, and 1605.29.1010. These HTSUS subheadings are provided for convenience and for customs purposes only and are not dispositive, but rather the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Changes Since the *Preliminary Determination*
- IV. Discussion of the Issues
 - Comment 1: Whether BMS’s Cost Reporting Warrants the Application of Total AFA
 - Comment 2: Whether Commerce Should Rely on BMS’s Reported Selling Prices and Expenses for Products Containing Sauce
 - Comment 3: Whether Commerce Should Apply Partial AFA to BMS’s Reported Domestic Brokerage and Handling Expenses (DBROKU)
 - Comment 4: Whether Commerce Should Use BMS’s Quarterly Cost Data
 - Comment 5: Whether Commerce Should Revise BMS’s “Transactions Disregarded” Calculation
 - Comment 6: Whether Commerce Should Reject the Petitioner’s Pre-Verification Comments
 - Comment 7: Whether Commerce Should Reject First Marine/Khom Foods’ Raw Material Cost Reporting
 - Comment 8: Whether Commerce Should Make a Correction to First Marine/Khom Foods’ Final Margin Program
 - Comment 9: Whether Commerce Should Continue to Rely on the Financial Statements of PT Central Poteina Prima Tbk (CP Prima) to Calculate Constructed Value (CV) Profit and Selling Expenses
- V. Recommendation

[FR Doc. 2024–24953 Filed 10–25–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–552–838]

Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Affirmative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of frozen warmwater shrimp (shrimp) from the Socialist Republic of Vietnam (Vietnam). The period of investigation (POI) is January 1, 2022, through December 31, 2022.

DATES: Applicable October 28, 2024.

FOR FURTHER INFORMATION CONTACT: Adam Simons, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401

Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6172.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2024, Commerce published its *Preliminary Determination in the Federal Register* and invited interested parties to comment.¹ On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.² The deadline for the final determination is now October 21, 2024. For a complete discussion of the events that followed the *Preliminary Determination*, see the Issues and Decision Memorandum.³

The Issues and Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The merchandise covered by the scope of this investigation is shrimp from Vietnam. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination*. Therefore, we made no changes to the scope of the investigation.

Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended (the Act), in May and June, 2024, Commerce conducted verification of the subsidy information reported by the Government of Vietnam (GOV), Soc Trang Seafood

¹ See *Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination with Final Antidumping Duty Determination*, 89 FR 22374 (April 1, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,” dated July 22, 2024.

³ See Memorandum, “Issues and Decision Memorandum for the Final Determination of the Countervailing Duty Investigation of Frozen Warmwater Shrimp from the Socialist Republic of Vietnam,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Joint Stock Company (STAPIMEX), and STAPIMEX’s supplier Giang Hong Phuong for use in our final determination. We used standard verification procedures, including an examination of relevant accounting records and original source documents provided by STAPIMEX, Giang Hong Phuong, and the GOV.⁴

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs that were submitted by interested parties in this investigation are discussed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, see Appendix II.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.*, a financial contribution by

an “authority” that gives rise to a benefit to the recipient, and that the subsidy is specific.⁵ For a full description of the methodology underlying our final determination, see the Issues and Decision Memorandum.

In making this final determination, Commerce relied, in part, on facts otherwise available, including with an adverse inference, pursuant to sections 776(a) and (b) of the Act. For a full discussion of our application of adverse facts available (AFA), see the *Preliminary Determination*,⁶ and the Issues and Decision Memorandum at the section entitled “Uses of Facts Available and Application of Adverse Inferences.”

Changes Since the Preliminary Determination

Based on our review and analysis of the information at verification and comments received from interested parties, we made changes to the subsidy rate calculations for Thong Thuan Company Limited to include the subsidy programs included in the Post-Preliminary Analysis Memo.⁷ For a discussion of these changes, see the Issues and Decision Memorandum.

All-Others Rate

Pursuant to section 705(c)(5)(A)(i) of the Act, Commerce will determine an all-others rate equal to the weighted-average countervailable subsidy rates established for exporters and/or producers individually investigated, excluding any zero and *de minimis* countervailable subsidy rates, and any rates determined entirely under section 776 of the Act. We continue to assign a rate based entirely on facts available to Thong Thuan Company Limited. Therefore, the only rate that is not zero, *de minimis*, or based entirely on facts otherwise available is the rate calculated for STAPIMEX. Consequently, we continue to assign the rate calculated for STAPIMEX as the rate for all other producers and exporters, pursuant to section 705(c)(5)(A)(i) of the Act.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist for the period January 1, 2022, through December 31, 2022:

Company	Subsidy rate (percent <i>ad valorem</i>)
Soc Trang Seafood Joint Stock Company	2.84
Thong Thuan Company Limited	* 221.82
All Others	2.84

* Rate based on AFA.

Disclosure

Commerce intends to disclose to interested parties the calculations and analysis performed in this final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination*, and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of entries of subject merchandise from Vietnam that were entered, or withdrawn from warehouse, for consumption, on or after

April 1, 2024, the date of the publication of the *Preliminary Determination* in the **Federal Register**.⁸ In accordance with section 703(d) of the Act, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from warehouse, on or after July 30, 2024, but to continue the suspension of liquidation of all entries of subject merchandise on or before July 29, 2024.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a countervailing duty order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for entries of subject merchandise in the amounts

indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or cancelled.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our final affirmative determination that countervailable subsidies are being provided to producers and exporters of shrimp from Vietnam. Because the final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with

⁴ See Memoranda, “Verification of Soc Trang Seafood Joint Stock Company,” dated August 14, 2024; “Verification of the Government of the Socialist Republic of Vietnam,” dated August 29, 2024; and “Verification of Giang Hong Phuong,” dated July 31, 2024.

⁵ See sections 771(5)(B) and (D) of the Act regarding financial contribution; see also section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

⁶ See *Preliminary Determination* PDM at 6–15.
⁷ See Memorandum, “Post-Preliminary Analysis in the Countervailing Duty Investigation of Frozen

Warmwater Shrimp from the Socialist Republic of Vietnam,” dated May 23, 2024; see also Issues and Decision Memorandum at Appendix for the revised AFA rate calculation.

⁸ See *Preliminary Determination*, 89 FR at 22374.

material injury, by reason of imports of shrimp from Vietnam no later than 45 days after our final determination. In addition, we are making available to the ITC all non-privileged and nonproprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance. If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a countervailing duty order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the "Continuation of Suspension of Liquidation" section.

Administrative Protective Order

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published in accordance with sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: October 21, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of this investigation includes certain frozen warmwater shrimp and prawns whether wild-caught (ocean harvested) or farm-raised (produced by aquaculture), head-on or head-off, shell-on or peeled, tail-on or tail-off, deveined or not deveined, cooked or

raw, or otherwise processed in frozen form. "Tails" in this context means the tail fan, which includes the telson and the uropods.

The frozen warmwater shrimp and prawn products included in the scope, regardless of definitions in the Harmonized Tariff Schedule of the United States (HTSUS), are products which are processed from warmwater shrimp and prawns through freezing and which are sold in any count size.

The products described above may be processed from any species of warmwater shrimp and prawns. Warmwater shrimp and prawns are generally classified in, but are not limited to, the *Penaeidae* family. Some examples of the farmed and wild-caught warmwater species include, but are not limited to, whiteleg shrimp (*Penaeus vannamei*), banana prawn (*Penaeus merguensis*), fleshy prawn (*Penaeus chinensis*), giant river prawn (*Macrobrachium rosenbergii*), giant tiger prawn (*Penaeus monodon*), redspotted shrimp (*Penaeus brasiliensis*), southern brown shrimp (*Penaeus subtilis*), southern pink shrimp (*Penaeus notialis*), southern rough shrimp (*Trachypenaeus curvirostris*), southern white shrimp (*Penaeus schmitti*), blue shrimp (*Penaeus stylirostris*), western white shrimp (*Penaeus occidentalis*), and Indian white prawn (*Penaeus indicus*).

Frozen shrimp and prawns that are packed with marinade, spices or sauce are included in the scope. In addition, food preparations, which are not "prepared meals," that contain more than 20 percent by weight of shrimp or prawn are also included in the scope.

Excluded from the scope are: (1) breaded shrimp and prawns (HTSUS subheading 1605.21.1020); (2) shrimp and prawns generally classified in the *Pandalidae* family and commonly referred to as coldwater shrimp, in any state of processing; (3) fresh shrimp and prawns whether shell-on or peeled (HTSUS subheadings 0306.36.0020 and 0306.36.0040); (4) shrimp and prawns in prepared meals (HTSUS subheadings 1605.21.0500 and 1605.29.0500); (5) dried shrimp and prawns; (6) canned warmwater shrimp and prawns (HTSUS subheading 1605.29.1040); and (7) certain battered shrimp. Battered shrimp is a shrimp-based product: (1) that is produced from fresh (or thawed-from-frozen) and peeled shrimp; (2) to which a "dusting" layer of rice or wheat flour of at least 95 percent purity has been applied; (3) with the entire surface of the shrimp flesh thoroughly and evenly coated with the flour; (4) with the non-shrimp content of the end product constituting between four and ten percent of the product's total weight after being dusted, but prior to being frozen; and (5) that is subjected to individually quick frozen (IQF) freezing immediately after application of the dusting layer. When dusted in accordance with the definition of dusting above, the battered shrimp product is also coated with a wet viscous layer containing egg and/or milk, and par-fried.

The products covered by the scope are currently classified under the following HTSUS subheadings: 0306.17.0004, 0306.17.0005, 0306.17.0007, 0306.17.0008, 0306.17.0010, 0306.17.0011, 0306.17.0013,

0306.17.0014, 0306.17.0016, 0306.17.0017, 0306.17.0019, 0306.17.0020, 0306.17.0022, 0306.17.0023, 0306.17.0025, 0306.17.0026, 0306.17.0028, 0306.17.0029, 0306.17.0041, 0306.17.0042, 1605.21.1030, and 1605.29.1010. These HTSUS subheadings are provided for convenience and for customs purposes only and are not dispositive, but rather the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Subsidies Valuation
- IV. Use of Facts Available and Adverse Inferences
- V. Benchmarks
- VI. Analysis of Programs
- VII. Discussion of the Issues
 - Comment 1: Whether the Accelerated Depreciation and Increase of Deductible Expense Program is Specific
 - Comment 2: Whether to Countervail Lending Programs Deferred at the Preliminary Determination
 - Comment 3: Whether to Apply AFA to Water in the Provision of Utilities at Reduced Rates in Industrial and Export Processing Zones Program
 - Comment 4: Whether to Select an Alternative Land for Less Than Adequate Remuneration (LTAR) Benchmark
 - Comment 5: Whether to Reconsider the Countervailability of the Import Duty Exemptions for Imports Used to Produce Exported Goods Program
 - Comment 6: Whether to Continue to Find Certain Programs Not Countervailable
 - Comment 7: Whether Commerce Should Implement Section 771B of the Act
- VIII. Recommendation

[FR Doc. 2024-24955 Filed 10-25-24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C-533-921]

Frozen Warmwater Shrimp From India: Final Affirmative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of frozen warmwater shrimp (shrimp) from India. The period of investigation (POI) is April 1, 2022, through March 31, 2023.

DATES: Applicable October 28, 2024.

FOR FURTHER INFORMATION CONTACT: Benjamin Nathan, AD/CVD Operations, Office II, Enforcement and Compliance,

International Trade Administration,
U.S. Department of Commerce, 1401
Constitution Avenue NW, Washington,
DC 20230; telephone: (202) 482–3834.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2024, Commerce published the *Preliminary Determination* in the **Federal Register**.¹ In the *Preliminary Determination*, and in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(4), Commerce aligned the final countervailing duty (CVD) determination with the final antidumping duty determination.² Commerce invited parties to comment on the *Preliminary Determination*.³ On July 19, 2024, Commerce released its Post-Preliminary Decision.⁴ On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.⁵ The deadline for the final determination is now October 21, 2024.

For a complete description of the events that followed the *Preliminary Determination*, see the Issues and Decision Memorandum.⁶ The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The products covered by this investigation are shrimp from India. For a complete description of the scope of the investigation, see appendix I.

¹ See *Frozen Warmwater Shrimp from India: Preliminary Affirmative Determination of Countervailable Subsidies, and Alignment of Final Determination With the Final Antidumping Duty Determination*, 89 FR 22386 (April 1, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

² See *Preliminary Determination*, 89 FR at 22386.

³ *Id.*

⁴ See Memorandum, “Post Preliminary Analysis,” dated July 19, 2024.

⁵ See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,” dated July 22, 2024.

⁶ See Memorandum, “Issues and Decision Memorandum for the Final Affirmative Determination of the Countervailing Duty Investigation of Frozen Warmwater Shrimp from India,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination*. Therefore, we made no changes to the scope of the investigation.

Verification

As provided in section 782(i) of the Act, in July and August 2024, Commerce verified all information reported by Devi Sea Foods Limited (Devi), Sandhya Aqua Exports Private Limited (Sandhya), and the Government of India (GOI). We used standard verification procedures, including an examination of relevant account records and original source documents provided by the respondents.⁷

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation, and the issues raised in the case and rebuttal briefs by parties in this investigation, are discussed in the Issues and Decision Memorandum. For a list of the issues raised by parties, and to which we responded in the Issues and Decision Memorandum, see Appendix II.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.*, a financial contribution by an “authority” that gives rise to a benefit to the recipient, and that the subsidy is specific.⁸ For a full description of the methodology underlying our final determination, see the Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on our review and analysis of the information received during verification and comments received from parties, for this final determination, we made certain changes to the countervailable subsidy rate calculations for Devi, Sandhya, and for all other producers/exporters. For a discussion of these changes, see the Issues and Decision Memorandum.

⁷ See Memoranda, “Verification of the Questionnaire Responses of the Government of India,” dated August 29, 2024; “Verification of the Questionnaire Responses of Devi Seafoods Private Limited,” dated August 29, 2024; and “Verification of the Questionnaire Responses of Sandhya Aqua Exports Private Limited,” dated August 29, 2024.

⁸ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

All-Others Rate

In accordance with section 705(c)(1)(B)(i) of the Act, we calculated an individual estimated countervailable subsidy rate for the two mandatory respondents, Devi and Sandhya. Section 705(c)(5)(A)(i) of the Act states that, for companies not individually investigated, Commerce will determine an all-others rate equal to the weighted-average countervailable subsidy rates established for exporters and/or producers individually investigated, excluding any zero and *de minimis* countervailable subsidy rates, and any rates determined entirely under section 776 of the Act.

In this investigation, we continue to calculate individual total net countervailable subsidy rates for Devi and Sandhya that are not zero, *de minimis*, or based entirely on facts otherwise available. We, therefore, continue to calculate the all-others rate using a weighted average of the individual estimated subsidy rates calculated for the examined respondents (Devi and Sandhya) using each company’s publicly-ranged sales value for their exports to the United States of subject merchandise,⁹ in accordance with section 705(c)(5)(A)(i) of the Act.

Final Determination

Commerce determines that the following estimated net countervailable subsidy rates exist for the period April 1, 2022, through March 31, 2023:

Company	Subsidy rate (percent <i>ad valorem</i>)
Devi Sea Foods Limited ¹⁰ ...	5.87
Sandhya Aqua Exports Private Limited ¹¹	5.63

⁹ With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company’s publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. See, *e.g.*, *Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part*, 75 FR 53661, 53663 (September 1, 2010); see also *Forged Steel Fluid End Blocks from Italy: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination with Final Antidumping Duty Determination*, 85 FR 31460, 31461 (May 26, 2020), unchanged in *Forged Steel Fluid End Blocks from Italy: Final Affirmative Countervailing Duty Determination*, 85 80022, 80023 (December 11, 2020).

Company	Subsidy rate (percent <i>ad valorem</i>)
All Others	5.77

Disclosure

Commerce intends to disclose its calculations performed to interested parties in this final determination within five days of its public announcement or, if there is no public announcement, within five days of the date of the publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination*, and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, Commerce instructed U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after April 1, 2024, the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 703(d) of the Act, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from warehouse, on or after July 30, 2024, but to continue the suspension of liquidation of all entries of subject merchandise on or before July 29, 2024.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a countervailing duty order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for such entries of subject merchandise in the amounts indicated above. Pursuant to section 705(c)(2) of the Act, if the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the

¹⁰ Commerce continues to determine that Devi is cross owned with Devi Sea Foods Inc, Devee Horizon LLP, Devee Power Corporation Limited, and Devee Superior Feeds Limited. See *Preliminary Determination PDM* at 9; see also Memorandum, "Post-Preliminary Analysis," dated July 19, 2024, at 5–6.

¹¹ Commerce continues to determine that Sandhya is cross owned with Neeli Sea Foods Private Limited, Vijay Aqua Processors Private Limited, and Neeli Aqua Farms. See *Preliminary Determination PDM* at 9.

suspension of liquidation will be refunded or cancelled.

ITC Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its final affirmative determination that countervailable subsidies are being provided to producers and exporters of shrimp from India. As Commerce's final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of import of shrimp from India. In addition, we are making available to the ITC all non-privileged and non-proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a countervailing duty order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the "Continuation of Suspension of Liquidation" section.

Administrative Protective Order

This notice will serve as the only reminder to parties subject to the APO of their responsibility concerning the destruction of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: October 21, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of this investigation includes certain frozen warmwater shrimp and prawns whether wild-caught (ocean harvested) or farm-raised (produced by aquaculture), head-on or head-off, shell-on or peeled, tail-on or tail-off, deveined or not deveined, cooked or raw, or otherwise processed in frozen form. "Tails" in this context means the tail fan, which includes the telson and the uropods.

The frozen warmwater shrimp and prawn products included in the scope, regardless of definitions in the Harmonized Tariff Schedule of the United States (HTSUS), are products which are processed from warmwater shrimp and prawns through freezing and which are sold in any count size.

The products described above may be processed from any species of warmwater shrimp and prawns. Warmwater shrimp and prawns are generally classified in, but are not limited to, the Penaeidae family. Some examples of the farmed and wild-caught warmwater species include, but are not limited to, whiteleg shrimp (*Penaeus vannamei*), banana prawn (*Penaeus merguensis*), fleshy prawn (*Penaeus chinensis*), giant river prawn (*Macrobrachium rosenbergii*), giant tiger prawn (*Penaeus monodon*), redspotted shrimp (*Penaeus brasiliensis*), southern brown shrimp (*Penaeus subtilis*), southern pink shrimp (*Penaeus notialis*), southern rough shrimp (*Trachypenaeus curvirostris*), southern white shrimp (*Penaeus schmitti*), blue shrimp (*Penaeus stylirostris*), western white shrimp (*Penaeus occidentalis*), and Indian white prawn (*Penaeus indicus*).

Frozen shrimp and prawns that are packed with marinade, spices or sauce are included in the scope. In addition, food preparations, which are not "prepared meals," that contain more than 20 percent by weight of shrimp or prawn are also included in the scope.

Excluded from the scope are: (1) breaded shrimp and prawns (HTSUS subheading 1605.20.10.20); (2) shrimp and prawns generally classified in the Pandalidae family and commonly referred to as coldwater shrimp, in any state of processing; (3) fresh shrimp and prawns whether shell-on or peeled (HTSUS subheadings 0306.36.0020 and 0306.36.0040); (4) shrimp and prawns in prepared meals (HTSUS subheading 1605.20.05.10); (5) dried shrimp and prawns; (6) canned warmwater shrimp and prawns (HTSUS subheading 1605.20.10.40); (7) certain dusted shrimp; and (8) certain battered shrimp. Dusted shrimp is a shrimp-based product: (1) that is produced from fresh (or thawed-from-frozen) and peeled shrimp; (2) to which a "dusting" layer of rice or wheat flour of at least 95 percent purity has been applied; (3) with the entire surface of the shrimp flesh thoroughly and evenly coated with the flour; (4) with the nonshrimp

content of the end product constituting between four and 10 percent of the product's total weight after being dusted, but prior to being frozen; and (5) that is subjected to IQF freezing immediately after application of the dusting layer. Battered shrimp is a shrimp-based product that, when dusted in accordance with the definition of dusting above, is coated with a wet viscous layer containing egg and/or milk, and par-fried.

The products covered by the scope are currently classified under the following HTSUS subheadings: 0306.17.0004, 0306.17.0005, 0306.17.0007, 0306.17.0008, 0306.17.0010, 0306.17.0011, 0306.17.0013, 0306.17.0014, 0306.17.0016, 0306.17.0017, 0306.17.0019, 0306.17.0020, 0306.17.0022, 0306.17.0023, 0306.17.0025, 0306.17.0026, 0306.17.0028, 0306.17.0029, 0306.17.0041, 0306.17.0042, 1605.21.1030, and 1605.29.1010. These HTSUS subheadings are provided for convenience and for customs purposes only and are not dispositive, but rather the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Use of Facts Available
- IV. Subsidies Valuation
- V. Analysis of Cross-Ownership
- VI. Changes Since the *Preliminary Determination*
- VII. Analysis of Programs
- VIII. Discussion of the Issues
 - Comment 1: Whether Commerce Erred in Its Export Promotion of Capital Goods Scheme (EPCGS) Calculation for Sandhya
 - Comment 2: Whether Commerce Erred in its Productivity-Linked Incentive (PLI) Calculation
 - Comment 3: Whether Commerce Erred in its Calculation of The Andhra Pradesh Power Subsidy for Aquaculture Farmers (PSA)
 - Comment 4: Whether Commerce Erred in Calculating the Grants for Food Processing
 - Comment 5: Whether Commerce Erred in Calculating the Pre-Shipment and Post-Shipment Export Financing Programs (EFPPS, EF2, and EF3)
 - Comment 6: Whether the EFPPS Program is Countervailable
 - Comment 7: Whether Section 771b of the Act is Applicable to this Investigation

- Comment 8: Whether the Duty Drawback Program (DDB) is Countervailable
- Comment 9: Whether the Remission of Duties and Taxes on Export Products (RoDTEP) is Countervailable
- Comment 10: Whether Neeli Sea Foods Private Limited (Neeli) Received Any Export Financing (EFPPS, EF2, or EF3) Benefit During the POI

IX. Recommendation

[FR Doc. 2024-24952 Filed 10-25-24; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Comments must be submitted by December 31, 2024.

ADDRESSES: Commerce encourages any person having information on foreign government subsidy programs which benefit articles of cheese subject to an in-quota rate of duty to submit such information in writing. All comments must be submitted through the Federal eRulemaking Portal at <https://www.regulations.gov>, Docket No. ITA-2020-0005. The materials in the docket will not be edited to remove identifying or contact information, and Commerce cautions against including any information in an electronic submission that the submitter does not want publicly disclosed. Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF formats only.

All comments should be addressed to Ryan Majerus, Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, at the U.S. Department of Commerce, 1401

Constitution Avenue NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Samuel Brummitt, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Ave. NW, Washington, DC 20230, telephone: (202) 482-7851.

SUPPLEMENTARY INFORMATION: On August 5, 2024 the U.S. Department of Commerce (Commerce), pursuant to section 702(h) of the Trade Agreements Act of 1979 (as amended) (the Act), published the quarterly update to the annual listing of foreign government subsidies on articles of cheese subject to an in-quota rate of duty covering the period January 1, 2024, through March 31, 2024.¹ In the *First Quarter 2024 Update*, we requested that any party that had information on foreign government subsidy programs that benefited articles of cheese subject to an in-quota rate of duty submit such information to Commerce.² We received no comments, information, or requests for consultation from any party.

Pursuant to section 702(h) of the Act, we hereby provide Commerce's update of subsidies on articles of cheese that were imported during the period April 1, 2024, through June 30, 2024. The appendix to this notice lists the country, the subsidy program or programs, and the gross and net amounts of each subsidy for which information is currently available. Commerce will incorporate additional programs which are found to constitute subsidies, and additional information on the subsidy programs listed, as the information is developed.

This determination and notice are in accordance with section 702(a) of the Act.

Dated: October 22, 2024.

Abdelali Elouaradia,
Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

SUBSIDY PROGRAMS ON CHEESE SUBJECT TO AN IN-QUOTA RATE OF DUTY

Country	Program(s)	Gross ³ subsidy (\$/lb)	Net ⁴ Subsidy (\$/lb)
27 European Union Member States. ⁵	European Union Restitution Payments	\$0.00	\$0.00
Canada	Export Assistance on Certain Types of Cheese	0.47	0.47

¹ See *Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty*, 89 FR 63405 (August 5, 2024) (*First Quarter 2024 Update*).

² *Id.*

³ Defined in 19 U.S.C. 1677(5).

⁴ Defined in 19 U.S.C. 1677(6).

⁵ The 27 member states of the European Union are: Austria, Belgium, Bulgaria, Croatia, Cyprus,

Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

SUBSIDY PROGRAMS ON CHEESE SUBJECT TO AN IN-QUOTA RATE OF DUTY—Continued

Country	Program(s)	Gross ³ subsidy (\$/lb)	Net ⁴ Subsidy (\$/lb)
Norway	Indirect (Milk) Subsidy	0.00	0.00
	Consumer Subsidy	0.00	0.00
	Total	0.00	0.00
Switzerland	Deficiency Payments	0.00	0.00

[FR Doc. 2024–24956 Filed 10–25–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–331–806]

Frozen Warmwater Shrimp From Ecuador: Final Affirmative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of frozen warmwater shrimp (shrimp) from Ecuador. The period of investigation (POI) is January 1, 2022, through December 31, 2022.

DATES: Applicable October 28, 2024.

FOR FURTHER INFORMATION CONTACT: Reginald Anadio or Zachary Shaykin, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3166 or (202) 482-5377, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2024, Commerce published its *Preliminary Determination* in the *Federal Register* and invited interested parties to comment.¹ In the *Preliminary Determination*, and in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(4), Commerce aligned this final countervailing duty (CVD) determination with the final antidumping duty (AD) determination of frozen warmwater shrimp from

¹ See *Frozen Warmwater Shrimp from Ecuador: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination with the Final Antidumping Duty Determination*, 89 FR 22379 (April 1, 2024) (*Preliminary Determination*), amended in *Frozen Warmwater Shrimp from Ecuador: Amended Preliminary Determination of Countervailing Duty Investigation*, 89 FR 31722 (April 25, 2024) (*Amended Preliminary Determination*).

Ecuador.² On July 12 and September 26, 2024, Commerce issued its post-preliminary determinations.³ On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.⁴ The deadline for the final determination is now October 21, 2024.

For a complete description of the events that followed the *Preliminary Determination*, see the Issues and Decision Memorandum.⁵ The Issues and Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The product covered by this investigation is frozen freshwater shrimp from Ecuador. For a complete description of this investigation, see Appendix I.

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination*. Therefore, we made no changes to the scope of the investigation.

² *Id.*, 89 FR at 22380.

³ See Memoranda, “Countervailing Duty Investigation of Frozen Warmwater Shrimp from Ecuador: Post-Preliminary Analysis,” dated July 12, 2024 (First Post-Preliminary Determination); and “Countervailing Duty Investigation of Frozen Warmwater Shrimp from Ecuador: Second Post-Preliminary Determination Calculations for Sociedad Nacional de Galapagos C.A.,” dated September 26, 2024 (Second Post-Preliminary Determination).

⁴ See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,” dated July 22, 2024.

⁵ See Memorandum, “Issues and Decision Memorandum for the Final Affirmative Determination of the Countervailing Duty Investigation of Frozen Warmwater Shrimp from Ecuador,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Verification

As provided in section 782(i)(1) of the Act, in July 2024, Commerce conducted verification of the subsidy information reported by Industrial Pesquera Santa Priscila S.A. (Santa Priscila), Sociedad Nacional de Galápagos C.A. (SONGA), and the Government of Ecuador (GOE) for use in our final determination. We used standard verification procedures, including an examination of relevant accounting records and original source documents provided by Santa Priscila, SONGA, and the GOE.⁶

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation, and the issues raised in the case and rebuttal briefs that were submitted by interested parties in this investigation are discussed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, see Appendix II.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.*, a financial contribution by an “authority” that gives rise to a benefit to the recipient, and that the subsidy is specific.⁷ For a full description of the methodology underlying our final determination, see the Issues and Decision Memorandum.

In making this final determination, Commerce relied, in part, on facts

⁶ See Memoranda, “Countervailing Duty Investigation of Frozen Warmwater Shrimp from Ecuador: Verification of the Questionnaire Responses of Sociedad Nacional de Galápagos C.A.,” dated August 13, 2024; “Countervailing Duty Investigation of Frozen Warmwater Shrimp from Ecuador: Verification of the Questionnaire Responses of Industrial Pesquera Santa Priscila S.A.,” dated August 22, 2024; and “Countervailing Duty Investigation of Frozen Warmwater Shrimp from Ecuador: Verification of the Questionnaire Responses of the Government of Ecuador,” dated September 3, 2024.

⁷ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

otherwise available, including with an adverse inference, pursuant to sections 776(a) and (b) of the Act. For a full discussion of our application of adverse facts available (AFA), see the *Preliminary Determination*,⁸ First Post-Preliminary Determination and Second Post-Preliminary Determination,⁹ and the Issues and Decision Memorandum section entitled “Use of Facts Otherwise Available and Application of Adverse Inferences.”

Changes Since the Preliminary Determination

Based on our review and analysis of the information at verification and comments received from interested parties, we made certain changes to the subsidy rate calculations for both Santa

Priscila and SONGA.¹⁰ For a discussion of these changes, see the Issues and Decision Memorandum.

All-Others Rate

In accordance with section 705(c)(1)(B)(i) of the Act, we calculated an individual estimated countervailable subsidy rates for the mandatory respondents, Santa Priscila and SONGA. Section 705(c)(5)(A)(i) of the Act states that, for companies not individually investigated, Commerce will determine an all-others rate equal to the weighted-average countervailable subsidy rates established for exporters and/or producers individually investigated, excluding any subsidy rates that are zero, *de minimis*, or determined entirely under section 776 of the Act.

In this investigation, we calculated individual total net countervailable subsidy rates for both Santa Priscila and SONGA that are not zero, *de minimis*, or based entirely on facts otherwise available. Therefore, we calculated the all-others rate using a weighted average of the individual estimated subsidy rates calculated for the examined respondents (Santa Priscila and SONGA) using each company’s publicly-ranged sales value for their exports to the United States of subject merchandise,¹¹ in accordance with section 705(c)(5)(A)(i) of the Act.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent <i>ad valorem</i>)
Industrial Pesquera Santa Priscila S.A	3.57
Sociedad Nacional de Galápagos C.A	4.41
All Others	3.78

Disclosure

We intend to disclose to interested parties the calculations and analysis performed in this final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination*, and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, Commerce instructed U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of entries of subject merchandise from Ecuador that were entered, or withdrawn from warehouse, for consumption on April 1, 2024, the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 703(d) of the Act, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered

or withdrawn from warehouse, on or after July 30, 2024, but to continue the suspension of liquidation of all entries of subject merchandise on or before July 29, 2024.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a countervailing duty order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for entries of subject merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or cancelled.

U.S. International Trade Commission Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its final affirmative determination that countervailable subsidies are being

provided to producers and exporters of shrimp from Ecuador. Because the final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of shrimp from Ecuador no later than 45 days after our final determination. In addition, we are making available to the ITC all non-privileged and nonproprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance. If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated and all cash deposits will be refunded. If the ITC determines

⁸ See *Preliminary Determination and Amended Preliminary Determination*.

⁹ See First Post-Preliminary Determination and Second Post-Preliminary Determination.

¹⁰ See Memorandum, “Final Determination Calculations for Santa Priscila,” dated concurrently with this notice, and Memorandum, “Final Determination Calculations for SONGA,” dated concurrently with this notice.

¹¹ With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the estimated subsidy rates calculated for

the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company’s publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. See, e.g., *Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results*

of Antidumping Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part, 75 FR 53661, 53663 (September 1, 2010); see also *Forged Steel Fluid End Blocks from Italy: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination with Final Antidumping Duty Determination*, 85 FR 31460, 31461 (May 26, 2020), unchanged in *Forged Steel Fluid End Blocks from Italy: Final Affirmative Countervailing Duty Determination*, 85 FR 80022, 80023 (December 11, 2020).

that such injury does exist, Commerce will issue a countervailing duty order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the “Continuation of Suspension of Liquidation” section.

Administrative Protective Orders

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published in accordance with sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: October 21, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of this investigation includes certain frozen warmwater shrimp and prawns whether wild-caught (ocean harvested) or farm-raised (produced by aquaculture), head-on or head-off, shell-on or peeled, tail-on or tail-off, deveined or not deveined, cooked or raw, or otherwise processed in frozen form. “Tails” in this context means the tail fan, which includes the telson and the uropods.

The frozen warmwater shrimp and prawn products included in the scope, regardless of definitions in the Harmonized Tariff Schedule of the United States (HTSUS), are products which are processed from warmwater shrimp and prawns through freezing and which are sold in any count size.

The products described above may be processed from any species of warmwater shrimp and prawns. Warmwater shrimp and prawns are generally classified in, but are not limited to, the Penaeidae family. Some examples of the farmed and wild-caught warmwater species include, but are not limited to, whiteleg shrimp (*Penaeus vannamei*), banana prawn (*Penaeus merguensis*), fleshy prawn (*Penaeus chinensis*), giant river prawn

(*Macrobrachium rosenbergii*), giant tiger prawn (*Penaeus monodon*), redspotted shrimp (*Penaeus brasiliensis*), southern brown shrimp (*Penaeus subtilis*), southern pink shrimp (*Penaeus notialis*), southern rough shrimp (*Trachypenaeus curvirostris*), southern white shrimp (*Penaeus schmitti*), blue shrimp (*Penaeus stylirostris*), western white shrimp (*Penaeus occidentalis*), and Indian white prawn (*Penaeus indicus*).

Frozen shrimp and prawns that are packed with marinade, spices or sauce are included in the scope. In addition, food preparations, which are not “prepared meals,” that contain more than 20 percent by weight of shrimp or prawn are also included in the scope.

Excluded from the scope are: (1) breaded shrimp and prawns (HTSUS subheading 1605.20.10.20); (2) shrimp and prawns generally classified in the Pandalidae family and commonly referred to as coldwater shrimp, in any state of processing; (3) fresh shrimp and prawns whether shell-on or peeled (HTSUS subheadings 0306.36.0020 and 0306.36.0040); (4) shrimp and prawns in prepared meals (HTSUS subheading 1605.20.05.10); (5) dried shrimp and prawns; (6) canned warmwater shrimp and prawns (HTSUS subheading 1605.20.10.40); (7) certain dusted shrimp; and (8) certain battered shrimp. Dusted shrimp is a shrimp-based product: (1) that is produced from fresh (or thawed-from-frozen) and peeled shrimp; (2) to which a “dusting” layer of rice or wheat flour of at least 95 percent purity has been applied; (3) with the entire surface of the shrimp flesh thoroughly and evenly coated with the flour; (4) with the nonshrimp content of the end product constituting between four and 10 percent of the product’s total weight after being dusted, but prior to being frozen; and (5) that is subjected to IQF freezing immediately after application of the dusting layer. Battered shrimp is a shrimp-based product that, when dusted in accordance with the definition of dusting above, is coated with a wet viscous layer containing egg and/or milk, and par-fried.

The products covered by the scope are currently classified under the following HTSUS subheadings: 0306.17.0004, 0306.17.0005, 0306.17.0007, 0306.17.0008, 0306.17.0010, 0306.17.0011, 0306.17.0013, 0306.17.0014, 0306.17.0016, 0306.17.0017, 0306.17.0019, 0306.17.0020, 0306.17.0022, 0306.17.0023, 0306.17.0025, 0306.17.0026, 0306.17.0028, 0306.17.0029, 0306.17.0041, 0306.17.0042, 1605.21.1030, and 1605.29.1010. These HTSUS subheadings are provided for convenience and for customs purposes only and are not dispositive, but rather the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Investigation
- IV. Diversification of Ecuador’s Economy
- V. Subsidies Valuation
- VI. Use of Facts Otherwise Available and Application of Adverse Inferences
- VII. Analysis of Programs
- VIII. Discussion of the Issues

- Comment 1: Commerce Should Countervail the Provision of Brackish Water
- Comment 2: Commerce Should Countervail the Provision of Fuel
- Comment 3: Commerce Should Revise the Benchmark Used To Value the Provision of Electricity
- Comment 4: Commerce Should Correct the Multiplier Used for Programs Benefitting Respondents’ Shrimp Suppliers
- Comment 5: Commerce Should Apply Adverse Facts Available (AFA) To Countervail Unverifiable and Omitted Income Tax Programs
- Comment 6: Commerce Should Revise the Denominator for the Investment Contract/Tax Incentives for Priority Sectors Under the 2010 Organic Production Code for Santa Priscila
- Comment 7: Commerce Should Make Certain Revisions to SONGA’s Subsidy Calculations
- Comment 8: Commerce Should Make Certain Revisions to Santa Priscila’s Subsidy Calculations
- Comment 9: Commerce Should Revise Its Countervailable Subsidy Calculation Regarding Provision of Land Concessions
- Comment 10: Commerce Should Find That Certain Tax Programs are not Countervailable
- Comment 11: Commerce Should Revise its Attribution of Benefits Received by Cross-Owned Input Suppliers to Santa Priscila
- Comment 12: Commerce Should Recalculate Its Countervailable Subsidy Calculation for SONGA Under the Refund of Currency Outflow Tax (ISD) On Inputs Program
- Comment 13: Section 771B Is Not Supported by the Record
- Comment 14: Commerce Should Adjust the Cash Deposit (CD) Rates
- Comment 15: Commerce’s Should Reverse Its Rejection of SONGA’s Minor Correction
- Comment 16: Commerce Should Correct its Application of AFA to SONGA and Naturisa, and Santa Priscila and Produmar Under the Motor Vehicle Tax Reduction Program
- IX. Recommendation

[FR Doc. 2024–24957 Filed 10–25–24; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–331–805]

Frozen Warmwater Shrimp From Ecuador: Final Negative Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that imports of frozen warmwater shrimp (shrimp) from Ecuador are not being, or not likely to be, sold in the United

States at less than fair value (LTFV) for the period of investigation (POI) October 1, 2022, through September 30, 2023.

DATES: Applicable October 28, 2024.

FOR FURTHER INFORMATION CONTACT: Kyle Clahane or Matthew Palmer, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-5449 or (202) 482-1678, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 30, 2024, Commerce published in the **Federal Register** its preliminary affirmative determination in the LTFV investigation of shrimp from Ecuador.¹ We invited interested parties to comment on the *Preliminary Determination*.² On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.³ The deadline for the final determination of this investigation is now October 21, 2024.

A summary of the events that occurred since Commerce published the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may

be found in the Issues and Decision Memorandum.⁴ The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The product covered by this investigation is shrimp from Ecuador. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination*. Therefore, we made no changes to the scope of the investigation.

Verification

Commerce was unable to conduct on-site verifications of the information relied on in making its final determination in this investigation. However, in August 2024, we took

additional steps in lieu of on-site verifications to verify the information relied upon in making this final determination, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act), by conducting virtual verifications of Industrial Pesquera Santa Priscila S.A. (Santa Priscila) and Sociedad Nacional de Galápagos C.A. (SONGA).⁵

Analysis of Comments Received

All issues raised in the case and rebuttal briefs submitted by interested parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice as Appendix II.

Changes Since the Preliminary Determination

We made certain changes regarding Santa Priscila and SONGA’s reported sales and cost data since the *Preliminary Determination*. For a discussion of these changes, see the Issues and Decision Memorandum.

Final Determination

Commerce determines that the following estimated weighted-average dumping margins exist:

Exporter/Producer	Weighted-average dumping margin (percent)
Sociedad Nacional de Galápagos C.A./Marina del Rey	0.00.
Industrial Pesquera Santa Priscila S.A./Tropical Packing Ecuador Tropack S.A	0.48 (<i>de minimis</i>).

Consistent with section 735(c) of the Act, Commerce has not calculated an estimated weighted-average dumping margin for all other producers and exporters because it has not made an affirmative final determination of sales at LTFV.

Disclosure

Commerce intends to disclose the calculations performed in connection with this final determination to interested parties within five days of any public announcement or, if there is no public announcement, within five

days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

Because Commerce has made a negative final determination of sales at LTFV with regard to subject merchandise, Commerce will not direct U.S. Customs and Border Protection to suspend liquidation or to require a cash deposit of estimated antidumping duties for entries of shrimp from Ecuador.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission of this final negative determination of sales at LTFV. As our final determination is negative, this proceeding is terminated in accordance with section 735(c)(2) of the Act.

Administrative Protective Order

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of

¹ See *Frozen Warmwater Shrimp from Ecuador: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures*, 89 FR 46857 (May 30, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

² *Id.* 89 FR at 46859.

³ See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,” dated July 22, 2024.

⁴ See Memorandum, “Issues and Decision Memorandum for the Final Affirmative Determination of Sales at Less Than Fair Value in the Investigation of Certain Frozen Warmwater Shrimp from Ecuador,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁵ See Memoranda, “Verification of the Cost Response of Sociedad Nacional de Galapagos C.A. in the Less-Than-Fair-Value Investigation of Frozen Warmwater Shrimp from Ecuador,” dated September 20, 2024 (SONGA’s Cost Verification

Report); “Sales Verification of Sociedad Nacional de Galápagos C.A.,” dated August 27, 2024 (SONGA’s Sales Verification Report) (collectively, SONGA’s Verification Reports); “Verification of the Cost Response of Industrial Pesquera Santa Priscila in the Antidumping Duty Investigation of Frozen warm Water Shrimp from Ecuador,” dated September 18, 2024 (Santa Priscila’s Cost Verification Report); and “Sales Verification of Industrial Santa Priscila,” dated September 19, 2024 (Santa Priscila’s Sales Verification Report) (collectively, Santa Priscila’s Verification Reports).

their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This final determination and notice are issued and published in accordance with sections 735(d) and 777(i) of the Act and 19 CFR 351.210(c).

Dated: October 21, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of this investigation includes certain frozen warmwater shrimp and prawns whether wild-caught (ocean harvested) or farm-raised (produced by aquaculture), head-on or head-off, shell-on or peeled, tail-on or tail-off, deveined or not deveined, cooked or raw, or otherwise processed in frozen form. "Tails" in this context means the tail fan, which includes the telson and the uropods.

The frozen warmwater shrimp and prawn products included in the scope, regardless of definitions in the Harmonized Tariff Schedule of the United States (HTSUS), are products which are processed from warmwater shrimp and prawns through freezing and which are sold in any count size.

The products described above may be processed from any species of warmwater shrimp and prawns. Warmwater shrimp and prawns are generally classified in, but are not limited to, the Penaeidae family. Some examples of the farmed and wild-caught warmwater species include, but are not limited to, whiteleg shrimp (*Penaeus vannamei*), banana prawn (*Penaeus merguensis*), fleshy prawn (*Penaeus chinensis*), giant river prawn (*Macrobrachium rosenbergii*), giant tiger prawn (*Penaeus monodon*), redspotted shrimp (*Penaeus brasiliensis*), southern brown shrimp (*Penaeus subtilis*), southern pink shrimp (*Penaeus notialis*), southern rough shrimp (*Trachypenaeus curvirostris*), southern white shrimp (*Penaeus schmitti*), blue shrimp (*Penaeus stylirostris*), western white shrimp (*Penaeus occidentalis*), and Indian white prawn (*Penaeus indicus*).

Frozen shrimp and prawns that are packed with marinade, spices or sauce are included in the scope. In addition, food preparations, which are not "prepared meals," that contain more than 20 percent by weight of shrimp or prawn are also included in the scope.

Excluded from the scope are: (1) breaded shrimp and prawns (HTSUS subheading 1605.21.1020); (2) shrimp and prawns generally classified in the Pandalidae family

and commonly referred to as coldwater shrimp, in any state of processing; (3) fresh shrimp and prawns whether shell-on or peeled (HTSUS subheadings 0306.36.0020 and 0306.36.0040); (4) shrimp and prawns in prepared meals (HTSUS subheadings 1605.21.0500 and 1605.29.0500); (5) dried shrimp and prawns; (6) canned warmwater shrimp and prawns (HTSUS subheading 1605.29.1040); and (7) certain battered shrimp. Battered shrimp is a shrimp-based product: (1) that is produced from fresh (or thawed-from-frozen) and peeled shrimp; (2) to which a "dusting" layer of rice or wheat flour of at least 95 percent purity has been applied; (3) with the entire surface of the shrimp flesh thoroughly and evenly coated with the flour; (4) with the non-shrimp content of the end product constituting between four and ten percent of the product's total weight after being dusted, but prior to being frozen; and (5) that is subjected to individually quick frozen (IQF) freezing immediately after application of the dusting layer. When dusted in accordance with the definition of dusting above, the battered shrimp product is also coated with a wet viscous layer containing egg and/or milk, and par-fried.

The products covered by the scope are currently classified under the following HTSUS subheadings: 0306.17.0004, 0306.17.0005, 0306.17.0007, 0306.17.0008, 0306.17.0010, 0306.17.0011, 0306.17.0013, 0306.17.0014, 0306.17.0016, 0306.17.0017, 0306.17.0019, 0306.17.0020, 0306.17.0022, 0306.17.0023, 0306.17.0025, 0306.17.0026, 0306.17.0028, 0306.17.0029, 0306.17.0041, 0306.17.0042, 1605.21.1030, and 1605.29.1010. These HTSUS subheadings are provided for convenience and for customs purposes only and are not dispositive, but rather the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Changes Since the *Preliminary Determination*
- IV. Discussion of the Issues
 - Comment 1: Whether Commerce Should Revise SONGA's Cost Adjustment for Its Purchases of Raw Shrimp From Affiliated Suppliers
 - Comment 2: Whether Commerce Should Recalculate SONGA's Reported Financial Expenses
 - Comment 3: Whether Revisions are Warranted to SONGA's Reported Indirect Selling Expenses
 - Comment 4: Whether Commerce Should Continue To Offset G&A Expenses by the Amount of Scrap Sales Revenue
 - Comment 5: Whether Commerce Should Revise SONGA's Per-Unit Costs for the Additional Wrapping and Finger-Laying Processes
 - Comment 6: Whether Commerce Should Compare U.S. Sales of Broken Shrimp to Constructed Value
 - Comment 7: Treatment of Clerical Errors in SONGA's Preliminary Margin Calculation
 - Comment 8: Inclusion of SONGA's Revised Sales and Cost Databases
 - Comment 9: Treatment of SONGA's Reported U.S. Customs Duty and Brokerage and Handling Expenses
 - Comment 10: Treatment of Export Subsidies for Santa Priscila and SONGA
 - Comment 11: Whether Commerce Should Apply Adverse Facts Available (AFA) to Santa Priscila for its Misrepresentation of its Payment Dates and its Failure To Report All Expenses
 - Comment 12: Whether Commerce Should Apply AFA to Santa Priscila's Credit Expenses, Other Discounts and Bank Charges.
 - Comment 13: Whether Commerce Should Apply the Market Price Adjustment to all Santa Priscila Raw Shrimp Purchases
 - Comment 14: Whether Commerce Should Reject Santa Priscila's Claimed Scrap Offset
 - Comment 15: Treatment of Santa Priscila's Return Expenses
 - Comment 16: Whether Commerce Should Incorporate Santa Priscila's Cost Verification Minor Corrections
 - Comment 17: Treatment of Clerical Errors in Santa Priscila's Preliminary Margin Calculation
- V. Recommendation

[FR Doc. 2024-24958 Filed 10-25-24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A-552-837]

Aluminum Extrusions From the Socialist Republic of Vietnam: Amended Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is amending its final affirmative determination in the less than fair value (LTFV) investigation of aluminum extrusions from the Socialist Republic of Vietnam (Vietnam) to correct ministerial errors. The period of investigation is April 1, 2023, through September 30, 2023.

DATES: Applicable October 28, 2024.

FOR FURTHER INFORMATION CONTACT: Rebecca Janz, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-2972.

SUPPLEMENTARY INFORMATION:

Background

On October 3, 2024, Commerce published in the **Federal Register** its final affirmative determination of sales at LTFV and final affirmative determination of critical circumstances, in part, in the investigation of aluminum extrusions from Vietnam.¹ Also on October 3, 2024, the petitioners submitted a timely allegation that Commerce made ministerial errors in the *Final Determination*.² No other interested party filed an allegation of a ministerial error or submitted a rebuttal to the petitioners' ministerial error allegation. We agree that we made ministerial errors in the *Final Determination*, and we are amending the weighted-average dumping margin for East Asia Aluminum Company Limited (East Asia) and the non-individually examined separate rate companies. Additionally, due to our revision of the weighted-average dumping margins, we are amending our final determination of critical circumstances with respect to these companies.

Scope of the Investigation

The product covered by this investigation is aluminum extrusions from Vietnam. For a complete description of the scope of this investigation, see *Final Determination*.³

Amendment to the Final Determination

Commerce reviewed the record, and we agree that the errors alleged by the petitioners constitute ministerial errors within the meaning of section 735(e) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.224(f).⁴ Specifically, we find that we made inadvertent errors in valuing East Asia's ocean freight and marine insurance expenses. Pursuant to 19 CFR 351.224(e), Commerce is amending the *Final Determination* to reflect the correction of the ministerial errors, as described in the Ministerial Error Memorandum.⁵ Based on the

¹ See *Aluminum Extrusions from the Socialist Republic of Vietnam: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances, in Part*, 89 FR 80530 (October 3, 2024) (*Final Determination*), and accompanying Issues and Decision Memorandum (IDM).

² See Petitioners' Letter, "Ministerial Error Allegation," dated October 3, 2024. The petitioners are U.S. Aluminum Extruders Coalition and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union.

³ See *Final Determination*, 89 FR at 80533.

⁴ See Memorandum, "Analysis of Ministerial Error Allegation," dated concurrently with this **Federal Register** notice (Ministerial Error Memorandum).

⁵ *Id.*

corrections, East Asia's final dumping margin changed from 14.15 percent to 16.02 percent. As a result, we are also revising the rate assigned to the non-individually examined separate rate companies from 14.15 percent to 16.02 percent. The amended estimated weighted-average dumping margins are listed in the "Amended Final Determination" section below.

Amendment to the Final Determination of Critical Circumstances, in Part

In the *Final Determination*, we found that critical circumstances exist with respect to the Vietnam-wide entity, but critical circumstances do not exist for imports of aluminum extrusions from Vietnam with respect to East Asia and the non-individually examined separate rate companies, pursuant to sections 735(a)(3)(A) and (B) of the Act, and 19 CFR 351.206.⁶ As a result of our amended final determination, we now find that importers of aluminum extrusions exported by East Asia and the non-individually examined separate rate companies knew or should have known that the exporter was selling the subject merchandise at less than its fair value and that there would be material injury by reason of such sales, pursuant to section 735(a)(3)(A)(ii) of the Act, and these imports of subject merchandise were massive over a relatively short period, pursuant to section 735(a)(3)(B). Accordingly, we are amending our *Final Determination* to find that critical circumstances do exist with respect to East Asia and the non-individually examined separate rate companies. For further discussion, see Ministerial Error Memorandum.

Amended Final Determination

The amended final estimated weighted-average dumping margins are as follows:

Exporter	Producer	Weighted-average dumping margin (percent)
East Asia Aluminum Company Limited.	East Asia Aluminum Company Limited.	16.02
Austdoor Group Joint Stock Company.	Austdoor Group Joint Stock Company.	16.02
BKQ Manufacturing and Trading Company Limited.	Fravi Vietnam Group Joint Stock Company.	16.02

Exporter	Producer	Weighted-average dumping margin (percent)
Viet Nam Chuangxing Aluminium Company Limited.	Vietnam Yongxing Aluminium Industry Co., Ltd.	16.02
Do Thanh Aluminium Joint Stock Company.	Do Thanh Aluminium Joint Stock Company.	16.02
Ha Noi DST Joint Stock Company.	Ha Noi DST Joint Stock Company.	16.02
Euroha Joint Stock Company.	Euroha Joint Stock Company.	16.02
Fravi Viet Nam Group Joint Stock Company.	Fravi Viet Nam Group Joint Stock Company.	16.02
Gold Well Co., Ltd.	Gold Well Co., Ltd.	16.02
Hong Xin Co., Ltd.	Vietnam Yongxing Aluminium Industry Co., LTD.	16.02
Hyundai Aluminium Vina Shareholding Company.	Hyundai Aluminium Vina Shareholding Company.	16.02
KIMSEN Industrial Corporation.	KIMSEN Industrial Corporation.	16.02
Mien Hua Precision Mechanical Co., Ltd.	Mien Hua Precision Mechanical Co., Ltd.	16.02
Ngoc Diep Aluminium Joint Stock Company.	Ngoc Diep Aluminium Joint Stock Company.	16.02
Nhon Trach Branch of Tung Kuang Industrial Joint Stock Company.	Nhon Trach Branch of Tung Kuang Industrial Joint Stock Company.	16.02
Northstar Precision (Vietnam) Co., Ltd.	Northstar Precision (Vietnam) Co., Ltd.	16.02
Sapa Ben Thanh Aluminium Profiles, Co., Ltd.	Sapa Ben Thanh Aluminium Profiles, Co., Ltd.	16.02
Song Hong Aluminum Shalumi Group Joint Stock Company.	Song Hong Aluminum Shalumi Group Joint Stock Company.	16.02
Shinyang Metal Korea Co., Ltd.	Shinyang Metal Korea Co., Ltd.	16.02
Shinyang Metal Vietnam Co., Ltd.	Shinyang Metal Vietnam Co., Ltd.	16.02

⁶ See *Final Determination*, 89 FR at 80531.

Exporter	Producer	Weighted-average dumping margin (percent)
Tan A Aluminum Company Limited.	Tan A Aluminum Company Limited.	16.02
Tin An Investment Production Trading Joint Stock Company.	Austdoor Group Joint Stock Company.	16.02
Tin An Investment Production Trading Joint Stock Company.	Viet Phap Aluminium Factory—Viet Phap Shal Aluminium Joint Stock Company.	16.02
Tin Kim Plastic Joint Stock Company.	Austdoor Group Joint Stock Company.	16.02
Tin Kim Plastic Joint Stock Company.	Viet Phap Aluminium Factory—Viet Phap Shal Aluminium Joint Stock Company.	16.02
Tung Kuang Industrial Joint Stock Company.	Tung Kuang Industrial Joint Stock Company.	16.02
Tung Shin Industrial Co., Ltd.	Tung Shin Industrial Co., Ltd.	16.02
Vietnam Beta Aluminum Company Limited.	Vietnam Beta Aluminum Company Limited.	16.02
Vietnam Yongxing Aluminium Industry Co., Ltd.	Vietnam Yongxing Aluminium Industry Co., Ltd.	16.02

Disclosure

Commerce intends to disclose the calculations performed in this amended final determination to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Amended Cash Deposits and Continuation of Suspension of Liquidation

The collection of cash deposits and suspension of liquidation will be revised according to the rates established in this amended final determination, in accordance with section 735(c)(1)(B) of the Act. These rates will be effective on the date of publication of this notice in the **Federal Register**. These suspension of

liquidation instructions will remain in effect until further notice.

In accordance with section 735(c)(4) of the Act, because Commerce now finds that critical circumstances exist for East Asia and the non-individually examined separate rate companies, Commerce intends to instruct U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of subject merchandise from these companies that were entered, or withdrawn from warehouse for consumption on or after February 7, 2024, which is 90 days before the publication of the *Preliminary Determination*⁷ in the **Federal Register**.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (ITC) of our amended final affirmative determination of sales at LTFV. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all cash deposits will be refunded or canceled, and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the “Amended Cash Deposits and Continuation of Suspension of Liquidation” section.

Notification to Interested Parties

This amended final determination and notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: October 22, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–25012 Filed 10–25–24; 8:45 am]

BILLING CODE 3510-DS-P

⁷ See *Aluminum Extrusions from the Socialist Republic of Vietnam: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures*, 89 FR 38075 (May 7, 2024).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–560–843]

Frozen Warmwater Shrimp From Indonesia: Final Negative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are not being provided to producers and exporters of frozen warmwater shrimp (shrimp) from Indonesia. The period of investigation is January 1, 2022, through December 31, 2022.

DATES: Applicable October 28, 2024.

FOR FURTHER INFORMATION CONTACT: Kelsie Hohenberger, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2517.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2024, Commerce published its *Preliminary Determination* in the **Federal Register** and invited interested parties to comment.¹ In the *Preliminary Determination*, and in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(4), Commerce aligned this final countervailing duty (CVD) determination with the final antidumping duty (AD) determinations of frozen warmwater shrimp from Ecuador and Indonesia.² On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.³ The deadline for the final determination is now October 21, 2024.

A summary of the events that occurred since Commerce published the *Preliminary Determination* may be found in the Issues and Decision Memorandum.⁴ The Issues and Decision

¹ See *Frozen Warmwater Shrimp from Indonesia: Preliminary Negative Countervailing Duty Determination, and Alignment of Final Determination With the Final Antidumping Duty Determination*, 89 FR 22383 (April 1, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

² *Id.*, 89 FR 22384.

³ See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,” dated July 22, 2024.

⁴ See Memorandum, “Issues and Decision Memorandum for the Final Negative Determination in the Countervailing Duty Investigation of Frozen

Memorandum is a public document and is made available to the public via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The merchandise covered by this investigation is shrimp from Indonesia. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination*. Therefore, we made no changes to the scope of the investigation.

Verification

As provided in section 782(i) of the Act, in May 2024, we conducted verifications of information submitted by the Government of Indonesia (GOI), PT. Bahari Makmur Sejati (BMS), PT. First Marine Seafoods (First Marine),⁵ and BMS and First Marine’s unaffiliated farmer-suppliers for use in our final determination. We used standard verification procedures, including an examination of relevant accounting records and original source documents provided by the GOI, BMS, First Marine, and the farmer-suppliers.⁶

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation, and the issues raised in the case and rebuttal briefs that were submitted by interested parties in this investigation are discussed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, see Appendix II.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.*, a financial contribution by an “authority” that gives rise to a benefit to the recipient, and that the subsidy is specific.⁷ For a full description of the methodology underlying our final determination, see the Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on our analysis of the comments received from interested parties and our verification findings, we made certain changes to the subsidy rate calculations for BMS. For a discussion of these changes, see the Issues and Decision Memorandum.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent <i>ad valorem</i>)
PT. Bahari Makmur Sejati ⁸	0.20 (<i>de minimis</i>).
PT. First Marine Seafoods/PT Khom Foods ⁹	0.71 (<i>de minimis</i>).

Disclosure

We intend to disclose to interested parties the calculations and analysis performed in this final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

In the *Preliminary Determination*, the total net countervailable subsidy rates for the individually examined respondents were *de minimis* and, therefore, we did not suspend liquidation of entries of frozen warmwater shrimp from Indonesia.¹⁰ Because Commerce determines that no countervailable subsidies are being

provided to the production or exportation of subject merchandise, Commerce will not direct U.S. Customs and Border Protection to suspend liquidation of any such entries.

International Trade Commission (ITC) Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of our final determination that countervailable subsidies are not being provided to producers and exporters of shrimp from Indonesia. Because the final determination is negative, this proceeding is terminated in accordance with section 705(c)(2) of the Act.

Administrative Protective Order (APO)

This notice will serve as the only reminder to parties subject to an APO of

their responsibility concerning the destruction of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/ destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Warmwater Shrimp from Indonesia,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁵ Commerce determined that First Marine is cross-owned with PT Khom Foods. Hereinafter, both companies are collectively referred to as First Marine, unless stated otherwise.

⁶ See Memoranda, “Verification of the Government of Indonesia Questionnaire Responses,” dated August 19, 2024; “Verification of the Questionnaire Responses of PT First Marine Seafoods,” dated August 9, 2024; “Verification of

the Questionnaire Responses of PT. First Marine Seafoods’ Unaffiliated Farmer-Supplier’s Questionnaire Responses,” dated August 9, 2024; “Verification of the Questionnaire Responses of PT Bahari Makmur Sejati,” dated August 23, 2024; and “Verification of the Questionnaire Responses of BMS’s Unaffiliated Farmer-Suppliers,” dated August 23, 2024.

⁷ See sections 771(5)(B) and (D) of the Act regarding financial contribution; see also section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

⁸ As discussed in the PDM, Commerce determined that PT Bahari Makmur Sejati is cross-owned with input suppliers PT International Packaging Manufacturing and PT Total Pack Indonesia.

⁹ As discussed in the PDM, Commerce determined that PT First Marine Seafoods is cross-owned with PT Khom Foods, a producer/distributor of subject merchandise.

¹⁰ See *Preliminary Determination*, 89 FR 22384.

Dated: October 21, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of this investigation includes certain frozen warmwater shrimp and prawns whether wild-caught (ocean harvested) or farm-raised (produced by aquaculture), head-on or head-off, shell-on or peeled, tail-on or tail-off, deveined or not deveined, cooked or raw, or otherwise processed in frozen form. “Tails” in this context means the tail fan, which includes the telson and the uropods.

The frozen warmwater shrimp and prawn products included in the scope, regardless of definitions in the Harmonized Tariff Schedule of the United States (HTSUS), are products which are processed from warmwater shrimp and prawns through freezing and which are sold in any count size.

The products described above may be processed from any species of warmwater shrimp and prawns. Warmwater shrimp and prawns are generally classified in, but are not limited to, the *Penaeidae* family. Some examples of the farmed and wild-caught warmwater species include, but are not limited to, whiteleg shrimp (*Penaeus vannamei*), banana prawn (*Penaeus merguensis*), fleshy prawn (*Penaeus chinensis*), giant river prawn (*Macrobrachium rosenbergii*), giant tiger prawn (*Penaeus monodon*), redspotted shrimp (*Penaeus brasiliensis*), southern brown shrimp (*Penaeus subtilis*), southern pink shrimp (*Penaeus notialis*), southern rough shrimp (*Trachypenaeus curvirostris*), southern white shrimp (*Penaeus schmitti*), blue shrimp (*Penaeus stylirostris*), western white shrimp (*Penaeus occidentalis*), and Indian white prawn (*Penaeus indicus*).

Frozen shrimp and prawns that are packed with marinade, spices or sauce are included in the scope. In addition, food preparations, which are not “prepared meals,” that contain more than 20 percent by weight of shrimp or prawn are also included in the scope.

Excluded from the scope are: (1) breaded shrimp and prawns (HTSUS subheading 1605.21.1020); (2) shrimp and prawns generally classified in the *Pandalidae* family and commonly referred to as coldwater shrimp, in any state of processing; (3) fresh shrimp and prawns whether shell-on or peeled (HTSUS subheadings 0306.36.0020 and 0306.36.0040); (4) shrimp and prawns in prepared meals (HTSUS subheadings 1605.21.0500 and 1605.29.0500); (5) dried

shrimp and prawns; (6) canned warmwater shrimp and prawns (HTSUS subheading 1605.29.1040); and (7) certain battered shrimp. Battered shrimp is a shrimp-based product: (1) that is produced from fresh (or thawed-from-frozen) and peeled shrimp; (2) to which a “dusting” layer of rice or wheat flour of at least 95 percent purity has been applied; (3) with the entire surface of the shrimp flesh thoroughly and evenly coated with the flour; (4) with the non-shrimp content of the end product constituting between four and ten percent of the product’s total weight after being dusted, but prior to being frozen; and (5) that is subjected to individually quick frozen (IQF) freezing immediately after application of the dusting layer. When dusted in accordance with the definition of dusting above, the battered shrimp product is also coated with a wet viscous layer containing egg and/or milk, and par-fried.

The products covered by the scope are currently classified under the following HTSUS subheadings: 0306.17.0004, 0306.17.0005, 0306.17.0007, 0306.17.0008, 0306.17.0010, 0306.17.0011, 0306.17.0013, 0306.17.0014, 0306.17.0016, 0306.17.0017, 0306.17.0019, 0306.17.0020, 0306.17.0022, 0306.17.0023, 0306.17.0025, 0306.17.0026, 0306.17.0028, 0306.17.0029, 0306.17.0041, 0306.17.0042, 1605.21.1030, and 1605.29.1010. These HTSUS subheadings are provided for convenience and for customs purposes only and are not dispositive, but rather the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Changes from the *Preliminary Determination*
- IV. Subsidies Valuation
- V. Analysis of Programs
- VI. Discussion of the Issues

Comment 1: Whether Commerce Should Apply Adverse Facts Available (AFA) To Countervail the Provision of Water or Port Facilities to First Marine

Comment 2: Whether Commerce Should Apply AFA To Countervail Export Financing From the Export-Import Bank of Indonesia (Eximbank)

Comment 3: Whether Commerce Should Apply Total AFA to the GR 55/2022 and Article 31E Income Tax Reduction Programs

Comment 4: Whether Commerce Should Correct the Benefit Calculations Under the Government Regulation 55/2022 and Article 31E Income Tax Reduction Programs

Comment 5: Whether Commerce Should Make Corrections to the Sales Denominators Used To Calculate the *Ad Valorem* Subsidy Rates

VII. Recommendation

[FR Doc. 2024–24954 Filed 10–25–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE383]

Marine Mammals and Endangered Species

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permits, permit amendments, and permit modifications.

SUMMARY: Notice is hereby given that permits, permit amendments, and permit modifications have been issued to the following entities under the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA), as applicable.

ADDRESSES: The permits and related documents are available for review upon written request via email to NMFS.Pr1Comments@noaa.gov.

FOR FURTHER INFORMATION CONTACT: Sara Young (Permit No. 27597), Erin Markin, Ph.D., (Permit No. 28148), Amy Hapeman (Permit No. 21163–01), and Malcolm Mohead (Permit 20347–02); at (301) 427–8401.

SUPPLEMENTARY INFORMATION: Notices were published in the **Federal Register** on the dates listed below that requests for a permit, permit amendment, or permit modification had been submitted by the below-named applicants. To locate the **Federal Register** notice that announced our receipt of the application and a complete description of the activities, go to <https://www.federalregister.gov> and search on the permit number provided in table 1 below.

TABLE 1—ISSUED PERMITS, PERMIT AMENDMENTS, AND PERMIT MODIFICATIONS

Permit No.	RTID	Applicant	Previous Federal Register Notice	Issuance date
20347–02	0648–XE179	University of Maine, 5741 Libby Hall, Room 202A, Orono, ME 04469 (Responsible Party: Gayle Zydlewski, Ph.D.).	89 FR 64879, August 8, 2024	October 1, 2024.
21163–01	0648–XR004	Marine Ecology and Telemetry Research, 2468 Camp McKenzie Trail NW, Seabeck WA 98380 (Responsible Party: Greg Schorr).	84 FR 54121, October 9, 2019	September 23, 2024.

TABLE 1—ISSUED PERMITS, PERMIT AMENDMENTS, AND PERMIT MODIFICATIONS—Continued

Permit No.	RTID	Applicant	Previous Federal Register Notice	Issuance date
27597	0648-XD928	NMFS Alaska Fisheries Science Center's Marine Mammal Laboratory, 7600 Sand Point Way NE, Seattle, WA 98115 (Responsible Party: John Bengtson, Ph.D.).	89 FR 36761, May 3, 2024	September 9, 2024.
28148	0648-XE164	NMFS Pacific Islands Regional Office, 1845 Wasp Boulevard, Building 176, Honolulu, HI 96818 (Responsible Party: Jamie Marchetti).	89 FR 63412, August 5, 2024	September 25, 2024.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), for Permit Nos. 20347-02, 21163-01, and 28148, and a final determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment (EA) or environmental impact statement (EIS).

For Permit No. 27597, a determination was made that the activities authorized are consistent with the Preferred Alternative in the Final Programmatic EIS for Steller Sea Lion and Northern Fur Seal Research (NMFS 2007). A supplemental EA (NMFS 2014) was prepared for the addition of unmanned aerial surveys to the suite of research activities analyzed under the EIS and concluded that issuance of the permits would not have a significant adverse impact on the human environment. An environmental review memo was prepared to summarize these findings.

As required by the ESA, as applicable, issuance of these permit was based on a finding that such permits: (1) were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in section 2 of the ESA.

Authority: The requested permits have been issued under the MMPA of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222-226), as applicable.

Dated: October 15, 2024.

Julia M. Harrison,

Chief, Permits and Conservation Division,
Office of Protected Resources, National
Marine Fisheries Service.

[FR Doc. 2024-24976 Filed 10-25-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XE320]

Atlantic Highly Migratory Species; Exempted Fishing, Scientific Research, Display, and Shark Research Fishery Permits; Letters of Acknowledgment

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of intent; request for comments.

SUMMARY: NMFS announces its intent to issue exempted fishing permits (EFPs), scientific research permits (SRPs), display permits, letters of acknowledgment (LOAs), and shark research fishery permits for Atlantic highly migratory species (HMS) (tunas, billfish, swordfish, and sharks) in 2025. EFPs and related permits other than LOAs exempt permit holders from specific portions of the regulations for the purposes of scientific research, data collection, the investigation of bycatch, and public display, among other things. LOAs acknowledge that researchers are conducting scientific research activities on board a scientific research vessel. Generally, EFPs and related permits are valid from the date of issuance through the end of the calendar year for which they are issued, unless otherwise specified in the permit, subject to the terms and conditions of individual permits.

DATES: NMFS will consider written comments received in response to this notice when issuing EFPs and related permits. Submit comments on or before November 27, 2024.

ADDRESSES: You may submit comments on this document, identified by NOAA-NMFS-2024-0109, electronically via the Federal e-Rulemaking Portal. Visit <https://www.regulations.gov> and type "NOAA-NMFS-2024-0109" in the Search box. Click on the "Comment" icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on <https://www.regulations.gov> without change. All personal identifying information (*e.g.*, name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Elsa Gutierrez, 301-427-8503, elsa.gutierrez@noaa.gov.

SUPPLEMENTARY INFORMATION: HMS fisheries (tunas, billfish, swordfish, and sharks) are managed under the 2006 Consolidated HMS Fishery Management Plan (FMP) and its amendments pursuant to the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) and consistent with the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*). ATCA is the implementing statute for binding recommendations of the International Commission for the Conservation of Atlantic Tunas. HMS implementing regulations are at 50 CFR part 635. The regulations specific to HMS EFPs and related permits can be found at § 635.32.

NMFS issues EFPs and related permits in cases where HMS regulations (*e.g.*, fishing seasons, prohibited species, authorized gear, closed areas, minimum sizes) may otherwise prohibit scientists and other interested parties from conducting scientific research; acquiring information and data related to HMS and fishing for HMS; enhancing safety at sea; collecting HMS for public education or display; investigating bycatch, economic discards, or regulatory discards in HMS fisheries; or conducting other fishing activities that NMFS has an interest in permitting or acknowledging. Consistent with §§ 600.745 and 635.32, a NMFS

Regional Administrator or Director may authorize, for limited testing, public display, data collection, exploratory fishing, compensation fishing, conservation engineering, health and safety surveys, environmental cleanup, and/or hazard removal purposes, the target or incidental harvest of species managed under an FMP or fishery regulations that would otherwise be prohibited. These permits exempt permit holders from the specific portions of the regulations that may otherwise be prohibited. Collection of HMS under EFPs, SRPs, display permits, and shark research fishery permits represents a small portion of the overall fishing mortality for HMS, and NMFS counts this mortality against the relevant quota, as appropriate and applicable. The terms and conditions of individual permits are unique; however, all permits include reporting requirements, limit the number and/or species of HMS to be collected (if appropriate), and only authorize collection and/or other research activities in Federal waters of the Atlantic Ocean, Gulf of Mexico, and Caribbean Sea (for Atlantic tunas, we may authorize the activities all the way to shore).

The Magnuson-Stevens Act exempts any scientific research activity conducted by a scientific research vessel from the definition of “fishing.” NMFS issues LOAs acknowledging such bona fide research activities involving species that are directly regulated only under the Magnuson-Stevens Act (e.g., most shark species) and not under ATCA. NMFS generally does not consider recreational or commercial vessels to be bona fide research vessels. However, if the researcher contracts a vessel only to conduct research and not participate in any commercial or recreational fishing activities during that research, NMFS may consider those vessels as bona fide research platforms while conducting the specified research. For example, in the past, NMFS has determined that commercial pelagic longline fishing vessels assisting with shark population surveys may be considered “bona fide research vessels” while engaged only in the specified research. For such activities, NMFS reviews the scientific research plans and may issue an LOA acknowledging that the proposed activity is scientific research for purposes of the Magnuson-Stevens Act.

While scientific research is not defined as “fishing” subject to the Magnuson-Stevens Act, scientific research is not exempt from regulation under ATCA. Therefore, NMFS issues SRPs that authorize researchers to conduct scientific research related to

HMS from bona fide research vessels for species managed directly under this statute (i.e., tunas, swordfish, and billfish). One example of research conducted under SRPs would be tunas, swordfish, and billfish scientific surveys conducted from NOAA research vessels.

NMFS issues EFPs for activities conducted from commercial or recreational fishing vessels. Examples of activities conducted under EFPs include collection of young-of-the-year bluefin tuna for genetic research from recreational fishing vessels; conducting billfish larval tows to determine billfish habitat use, life history, and population structure from private vessels; and tagging sharks caught on commercial or recreational fishing gear to determine post-release mortality rates from commercial or recreational fishing vessels.

NMFS issues display permits for the collection of HMS for public display. Collection of HMS for public display in aquaria often involves collection when the commercial fishing seasons are closed, collection of otherwise prohibited species (e.g., sand tiger sharks), and collection of fish below the regulatory minimum size. Not all HMS can be collected for public display. NMFS published the final rule for Amendment 2 to the 2006 Consolidated HMS FMP (73 FR 35778, June 24, 2008; corrected 73 FR 40658, July 15, 2008) that, among other things, prohibited the collection of dusky sharks for public display. In 2022, NMFS published a final rule (87 FR 39373, July 1, 2022) that, among other things, prohibited the collection of shortfin mako sharks for public display.

The majority of EFPs and related permits described in this annual notice relate to scientific sampling and tagging of HMS within existing quotas, and the impacts of these activities were previously analyzed in various environmental assessments and environmental impact statements for HMS management. In most such cases, NMFS intends to issue these permits without additional opportunity for public comment beyond what is provided in this notice. Occasionally, NMFS receives applications which may warrant further consideration, such as those for unanticipated research activities, for research that is outside the scope of general scientific sampling and tagging of HMS, or for research that is particularly controversial. In those instances, NMFS will provide additional opportunity for public comment, consistent with the regulations at § 600.745.

On May 10, 2024, the Environmental Protection Agency published a notice

announcing the availability of the Final Environmental Impact Statement for Amendment 15 to the 2006 Consolidated HMS FMP (89 FR 40481). In Amendment 15, NMFS prefers an alternative that would allow for cooperative research via an EFP within the various areas that are currently closed to pelagic longline fishing. NMFS would use the data collected to help assess the effectiveness of the pelagic longline closed areas. At this time, NMFS has not yet published any final rule for Amendment 15. NMFS is not aware of any researchers who plan to conduct research specific to the objectives in Amendment 15 in the closed areas in 2025. If after the publication of any final rule, NMFS receives such applications, NMFS may consider providing additional opportunity for public comment, dependent upon the particulars of the scientific research plan submitted, consistent with the regulations at § 600.745.

Additionally, this notice invites comments on the shark research fishery, which NMFS implemented in 2008 through Amendment 2 to the 2006 Consolidated HMS FMP. NMFS conducts this research fishery under the auspices of the EFP program. Shark research fishery participants assist NMFS in collecting valuable shark life history and other scientific data required in shark stock assessments. Since NMFS established the shark research fishery, the research fishery has allowed for:

- Fishery-dependent data collection for current and future stock assessments;
- Cooperative research to meet NMFS’ ongoing research objectives;
- Collection of updated life-history information used in the sandbar shark (and other species) stock assessments;
- Data collection on habitat preferences that might help reduce fishery interactions through bycatch mitigation;
- Evaluation of the utility of the mid-Atlantic closed area on the recovery of dusky sharks;
- Collection of hook-timer and pop-up satellite archival tag information to determine at-vessel and post-release mortality of dusky sharks; and
- Collection of sharks to update the weight conversion factor from dressed weight to whole weight.

Shark research fishery participants are subject to 100-percent observer coverage. In recent years, NMFS has required shark research fishery participants to retain all non-prohibited shark species dead at haulback and NMFS has counted that mortality

against the appropriate quotas of the shark research fishery participant. Additionally, in recent years, all shark research fishery participants were limited to a very small number of dusky shark mortalities on a regional basis. Once the designated number of dusky shark mortalities occurs in a specific region, certain terms and conditions are applied (e.g., soak time limits). While NMFS has not yet determined the specific terms and conditions of the 2025 shark research fishery permits, NMFS expects the terms and conditions to be similar to those in 2024 permits. For example, participants may continue to be limited in the number of sets

allowed on each trip and the number of hooks allowed on each set and on the vessel itself. A **Federal Register** notice describing the specific objectives for the 2025 shark research fishery and requesting applications from interested and eligible shark fishermen may be published in the near future. NMFS requests public comment regarding NMFS' intent to issue shark research fishery permits in 2025 during the comment period of this notice.

Table 1 summarizes the number of specimens authorized under EFPs and related permits thus far in 2024, as well as the number of specimens collected in 2023. The total amount of collections in

2023 was within the analyzed quotas for all quota-managed HMS species. The number of specimens collected in 2024 will be available when NMFS receives all 2024 interim and annual reports.

In all cases, NMFS counts mortalities associated with EFPs, SRPs, or display permits (except for larvae) against the appropriate quota. In 2023, NMFS issued a total of 46 EFPs, SRPs, display permits, and LOAs for the collection, sampling, and/or tagging of HMS and 3 shark research fishery permits. As of October 1, 2024, NMFS has issued a total of 46 EFPs, SRPs, display permits, and LOAs and 3 shark research fishery permits.

TABLE 1—SUMMARY OF HMS EXEMPTED FISHING PERMITS ISSUED IN 2023 AND 2024, OTHER THAN SHARK RESEARCH FISHERY PERMITS

Permit type	Species	2023			2024	
		Permits issued	Authorized fish (numbers) ¹	Fish kept/discarded dead (numbers)	Permits issued	Authorized fish (numbers) ¹
EFP	HMS	2	184	0	2	84
	Shark	8	¹ N/A	0	6	0
	Tuna	2	30	0	1	120
SRP	HMS	8	1,027	6	5	540
	Shark	0	0	0	1	1010
	Swordfish	1	30	0	1	0
Display	HMS	1	55	0	1	54
	Shark	3	223	47	3	223
Total		26	25	55	20	¹ 203
LOA	Shark	20	¹ N/A	102	26	¹ N/A

Note: "HMS" refers to multiple species being collected under a given permit type.

¹ NMFS issued some EFPs, SRPs, and LOAs for the purposes of tagging and the opportunistic sampling of HMS and were not expected to result in large amounts of mortality, thus no limits on sampling were set. NMFS will account for any mortality that may occur throughout 2024 under the appropriate HMS research and display quota.

NMFS does not currently anticipate any significant environmental impacts from the issuance of EFPs, SRPs, display permits, and shark research fishery permits, consistent with the assessment of such activities as identified in Categorical Exclusion B12 of the Companion Manual for NOAA Administrative Order 216-6A or within the environmental impacts analyses in existing HMS actions. Existing actions include the 1999 FMP, the 2006 Consolidated HMS FMP and its amendments, Amendment 2 to the 2006 Consolidated HMS FMP, the Environmental Assessment for the 2012 Swordfish Specifications, the Environmental Assessment for the 2022 Final Bluefin Tuna Quota and Atlantic Tuna Fisheries Management Measures, and the 2022 Zero Atlantic Shortfin Mako Shark Retention Limit Final Rule.

Final decisions on the issuance of any EFPs, SRPs, display permits, and shark research fishery permits will depend on:

- The submission of all required information about the proposed activities;
- NMFS' review of public comments received on this notice;
- The applicant's reporting history on past permits;
- If vessels or applicants were issued any prior violations of marine resource laws administered by NOAA;
- Consistency with relevant National Environmental Policy Act analyses; and
- Any consultations with appropriate Regional Fishery Management Councils, states, or Federal agencies.

Authority: 16 U.S.C. 971 *et seq.* and 16 U.S.C. 1801 *et seq.*

Dated: October 22, 2024.

Karen H. Abrams,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024-25023 Filed 10-25-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XE412]

Endangered Species; File No. 28294

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Matthew Fisher (Normandeu Associates Inc., 2233 Spring Street, West Lawn, PA 19609), has applied in due form for a permit to take Atlantic (*Acipenser oxyrinchus*) and shortnose (*A. brevirostrum*) sturgeon for purposes of scientific research.

DATES: Written comments must be received on or before November 27, 2024.

ADDRESSES: The application and related documents are available for review by selecting “Records Open for Public Comment” from the “Features” box on the Applications and Permits for Protected Species home page, <https://apps.nmfs.noaa.gov>, and then selecting File No. 28294 from the list of available applications. These documents are also available upon written request via email to NMFS.Pr1Comments@noaa.gov.

Written comments on this application should be submitted via email to NMFS.Pr1Comments@noaa.gov. Please include File No. 28294 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to NMFS.Pr1Comments@noaa.gov. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Erin Markin, Ph.D. or Malcolm Mohead, (301) 427-8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222-226).

The applicant requests to conduct research on Atlantic and shortnose sturgeon in freshwater and estuary areas of the Delaware River. Research objectives would include assessing and quantifying the presence of Atlantic and shortnose sturgeon at the egg, larval, juvenile and sub-adult/adult life stages. Other studies would also include assessing sturgeon home range, individual movement patterns, seasonal movements, habitat use, nursery areas, over-wintering habitat use, population dynamics, and habitat assessment.

Up to 265 juvenile and 25 adult/sub-adult shortnose sturgeon and 265 juvenile and 5 adult/sub-adult Atlantic sturgeon would be captured by gill net or trawl, measured, weighed, biologically sampled (tissue), marked (passive integrated transponder), and photographed/videoed, annually, prior to release. Sub-sets of Atlantic and shortnose sturgeon may be anesthetized and implanted with acoustic transmitters, gastric lavaged, and fin ray sampled. The applicant requests one unintentional mortality of juvenile and adult/subadult shortnose sturgeon and one juvenile Atlantic sturgeon annually, but no more than two of each species life stage over the life of the permit.

A total 300 shortnose and 100 Atlantic sturgeon of early life stages would be taken in directed lethal

research annually. The permit would be valid for up to 10 years from the date of issuance.

Dated: October 21, 2024.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024-24992 Filed 10-25-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XE413]

Endangered Species; File No. 21467

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application for a permit modification.

SUMMARY: Notice is hereby given that Karen Holloway-Adkins, Ph.D., East Coast Biologists, Inc., P.O. Box 33715, Indialantic, FL 32903, has requested a modification to scientific research Permit No. 21467-02.

DATES: Written comments must be received on or before November 27, 2024.

ADDRESSES: The modification request and related documents are available for review by selecting “Records Open for Public Comment” from the Features box on the Applications and Permits for Protected Species home page, <https://apps.nmfs.noaa.gov>, and then selecting File No. 21467 Mod 6 from the list of available applications. These documents are also available upon written request via email to NMFS.Pr1Comments@noaa.gov.

Written comments on this application should be submitted via email to NMFS.Pr1Comments@noaa.gov. Please include File No. 21467 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to NMFS.Pr1Comments@noaa.gov. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Erin Markin, Ph.D., or Amy Hapeman, (301) 427-8401.

SUPPLEMENTARY INFORMATION: The subject modification to Permit No. 21467-02, issued on July 2, 2021 (86 FR 43630, August 10, 2021), is requested under the authority of the Endangered Species Act of 1973, as amended (16

U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222-226).

Permit No. 21467-02 authorizes the permit holder to determine (1) spatial and temporal distribution, (2) mean size, (3) foraging habitats and diet composition, (4) body conditions and fibropapillomatosis ratios, (5) genetic origin, and (6) home-range, site fidelity, and residency times of green (*Chelonia mydas*) and loggerhead (*Caretta caretta*) sea turtles in Brevard County, Florida. Researchers may capture by tangle, cast, or dip net or hand, measure, mark, biologically sample, tag, weigh, and photograph sea turtles prior to release. The permit holder requests authorization to (1) increase the annual number of juvenile green sea turtles from 25 to 95 for the authorized methods listed above and (2) add 10 adult green turtles annually for capture by tangle net, measure, and photograph/video, prior to release. The permit is valid through September 30, 2027.

Dated: October 21, 2024.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024-24993 Filed 10-25-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XE418]

Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council (Pacific Council) and its advisory bodies will meet November 13-18, 2024, in Costa Mesa, CA and via webinar. The Council meeting will be live streamed with the opportunity to provide public comment remotely.

DATES: The Pacific Council meeting will begin on Thursday, November 14, 2024, at 10 a.m., Pacific Time (PT), reconvening at 8 a.m. on Friday, November 15 through Monday, November 18, 2024. All meetings are open to the public, except for a Closed Session held from 8 a.m. to 10 a.m., Thursday, November 14, 2024, to

address litigation and personnel matters. The Pacific Council will meet as late as necessary each day to complete its scheduled business.

ADDRESSES:

Meeting address: Meetings of the Pacific Council and its advisory entities will be held at the Hilton Orange County at 3050 Bristol Street in Costa Mesa, CA 92626; telephone: (714) 540-7000. Specific meeting information, including directions on joining the meeting, connecting to the live stream broadcast, and system requirements will be provided in the meeting announcement on the Pacific Council's website (see www.pcouncil.org). You may send an email to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov) or contact him at (503) 820-2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220-1384.

FOR FURTHER INFORMATION CONTACT: Mr. Merrick Burden, Executive Director, Pacific Council; telephone: (503) 820-2280 or (866) 806-7204 toll-free, or access the Pacific Council website, www.pcouncil.org, for the proposed agenda and meeting briefing materials.

SUPPLEMENTARY INFORMATION: The November 13-18, 2024 meeting of the Pacific Council will be streamed live on the internet. The broadcasts begin initially at 10 a.m. PT Thursday, November 14, 2024, and 8 a.m. PT Friday, November 15 through Monday, November 18, 2024. Broadcasts end when business for the day is complete. Only the audio portion and presentations displayed on the screen at the Pacific Council meeting will be broadcast. The audio portion for the public is listen-only except that an opportunity for oral public comment will be provided prior to Council Action on each agenda item. Additional information and instructions on joining or listening to the meeting can be found on the Pacific Council's website (see www.pcouncil.org).

The following items are on the Pacific Council agenda, but not necessarily in this order. Agenda items noted as "Final" refer to actions the Council may take requiring the transmission of a proposed fishery management plan, proposed plan amendment, or proposed regulations to the U.S. Secretary of Commerce, under sections 304 or 305 of the Magnuson-Stevens Fishery Conservation and Management Act. Additional detail on agenda items, Council action, and advisory entity meeting times, are described in Agenda Item A.3, Proposed Council Meeting

Agenda, and will be in the advance November 2024 briefing materials and posted on the Pacific Council website at www.pcouncil.org no later than Friday, October 25, 2024.

A. Call to Order

1. Opening Remarks
2. Roll Call
3. Agenda
4. Executive Director's Report

B. Open Comment Period

1. Comments on Non-Agenda Items

C. Administrative Matters

1. Council Coordination Committee Report
2. Fiscal Matters
3. Legislative Matters
4. Approve Council Meeting Record
5. Membership Appointments and Council Operating Procedures—Including Final 2025-27 Advisory Body Appointments
6. Future Council Meeting Agenda and Workload Planning

D. Cross Fishery Management Plan

1. National Marine Fisheries Service (NMFS) 2024 Accomplishments and 2025 Priorities
2. Marine Planning
3. Research and Data Needs
4. Council Operations and Priorities

E. Habitat Issues

1. Current Habitat Issues

F. Salmon Management

1. National Marine Fisheries Service Report
2. Final Methodology Review Results and Proposed Council Operating Procedure (COP) 15 Updates
3. Queets Spring/Summer Chinook Rebuilding Plan—Final
4. Final 2025 Preseason Management Schedule
5. Klamath River Fall Chinook Workgroup Progress Report and Recommendations
6. Sacramento River Fall Chinook Workgroup Progress Report and Recommendations

G. Pacific Halibut Management

1. 2025 Catch Sharing Plan and Annual Regulations—Final
2. Commercial Fishery Regulation Changes: Vessel Monitoring Systems, Seabird Avoidance, and Catch Reporting—Final

H. Highly Migratory Species Management

1. National Marine Fisheries Service Report
2. International Management Activities including Bluefin Tuna Trip Limits
3. Biennial Harvest Specifications and Management Measures—Final
4. Highly Migratory Species Roadmap Workshop Report and Next Steps

I. Groundfish Management

1. National Marine Fisheries Service Report
 2. Trawl Catch Share Program and Intersector Allocation Reviews: Hearing Officers and Locations
 3. Methodology Review: Final Fishery Impact Model Review Topics and Stock Assessment Methodologies
 4. Stock Definitions for Species Assessed in 2025 and 2027—Final
 5. Cordell Bank Conservation Area Revisions
 6. Inseason Adjustments and Technical Corrections for 2025-2026—Final Action
- J. Coastal Pelagic Species Management**
1. National Marine Fisheries Service Report
 2. Pacific Sardine Rebuilding Plan Fishery Management Plan Amendment (FMP)—Final
 3. Stock Assessment Prioritization

Advisory Body Agendas

Advisory body agendas will include discussions of relevant issues that are on the Pacific Council agenda for this meeting and may also include issues that may be relevant to future Council meetings. Proposed advisory body agendas for this meeting will be available on the Pacific Council website, www.pcouncil.org, no later than Friday, October 25, 2024 by the end of the business day.

Schedule of Ancillary Meetings

Day 1—Wednesday, November 13, 2024

Scientific and Statistical Committee 8 a.m.
 Salmon Technical Team 8 a.m.
 Groundfish Management Team 8 a.m.
 Groundfish Advisory Subpanel 8 a.m.
 Legislative Committee 10 a.m.
 Budget Committee 2 p.m.
 Enforcement Consultants 2 p.m.

Day 2—Thursday, November 14, 2024

Oregon State Delegation 7 a.m.
 California State Delegation 7 a.m.
 Washington State Delegation 7 a.m.
 Salmon Advisory Subpanel 8 a.m.
 Scientific and Statistical Committee 8 a.m.

Highly Migratory Species Advisory Subpanel 8 a.m.

Highly Migratory Species Management Team 8 a.m.

Groundfish Management Team 8 a.m.
 Groundfish Advisory Subpanel 8 a.m.
 Enforcement Consultants As Necessary

Day 3—Friday, November 15, 2024

Oregon State Delegation 7 a.m.
 California State Delegation 7 a.m.
 Washington State Delegation 7 a.m.
 Groundfish Advisory Subpanel 8 a.m.
 Groundfish Management Team 8 a.m.
 Highly Migratory Species Advisory Subpanel 8 a.m.

Highly Migratory Species Management Team 8 a.m.

Enforcement Consultants As Necessary
Day 4—Saturday, November 16, 2024

Oregon State Delegation 7 a.m.
California State Delegation 7 a.m.
Washington State Delegation 7 a.m.
Coastal Pelagic Species Advisory Subpanel 8 a.m.
Coastal Pelagic Species Management Team 8 a.m.
Enforcement Consultants As Necessary, Online

Day 5—Sunday, November 17, 2024

Oregon State Delegation 7 a.m.
California State Delegation 7 a.m.
Washington State Delegation 7 a.m.
Coastal Pelagic Species Advisory Subpanel 8 a.m.
Coastal Pelagic Species Management Team 8 a.m.
Enforcement Consultants As Necessary, Online

Day 6—Monday, September 23, 2024

Oregon State Delegation 7 a.m.
California State Delegation 7 a.m.
Washington State Delegation 7 a.m.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov; (503) 820-2412) at least 10 business days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 23, 2024.

Key Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024-24988 Filed 10-25-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XE406]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Maintenance and Rehabilitation of the Bellingham Shipping Terminal

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of renewal incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA), as amended, notification is hereby given that NMFS has issued a renewal incidental harassment authorization (IHA) to the Port of Bellingham to incidentally harass marine mammals incidental to maintenance and rehabilitation of the Bellingham Shipping Terminal in Bellingham, WA.

DATES: This renewal IHA is effective from November 7, 2024 through November 7, 2025.

ADDRESSES: Electronic copies of the original application, renewal request, and supporting documents (including NMFS **Federal Register** notices of the initial proposed and final authorizations, and the proposed renewal IHA), as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/action/incidental-take-authorization-port-bellinghams-bellingham-shipping-terminal-bellingham>. In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Craig Cockrell, Office of Protected Resources, NMFS, (301) 427-8401.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the “take” of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are promulgated or, if the taking is limited

to harassment, an incidental harassment authorization is issued.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other “means of effecting the least practicable adverse impact” on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to here as “mitigation measures”). NMFS must also prescribe requirements pertaining to monitoring and reporting of such takings. The definition of key terms such as “take,” “harassment,” and “negligible impact” can be found in the MMPA and NMFS’s implementing regulations (see 16 U.S.C. 1362; 50 CFR 216.103).

NMFS’ regulations implementing the MMPA at 50 CFR 216.107(e) indicate that IHAs may be renewed for additional periods of time not to exceed 1 year for each reauthorization. In the notice of proposed IHA for the initial IHA, NMFS described the circumstances under which we would consider issuing a renewal for this activity, and requested public comment on a potential renewal under those circumstances. Specifically, on a case-by-case basis, NMFS may issue a one-time 1-year renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical, or nearly identical, activities as described in the Detailed Description of Specified Activities section of the initial IHA issuance notice is planned or (2) the activities as described in the Description of the Specified Activities and Anticipated Impacts section of the initial IHA issuance notice will not be completed by the time the initial IHA expires and a renewal will allow for completion of the activities beyond that described in the **DATES** section of the notice of issuance of the initial IHA, provided all of the following conditions are met:

1. A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond 1 year from expiration of the initial IHA);

2. The request for renewal must include the following:

- An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.*, reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take); and

- A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized; and

3. Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

An additional public comment period of 15 days (for a total of 45 days), with direct notice by email, phone, or postal service to commenters on the initial IHA, is provided to allow for any additional comments on the proposed renewal. A description of the renewal process may be found on our website at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-harassment-authorization-renewals>.

History of Request

On November 6, 2023, NMFS issued an IHA to the Port of Bellingham to take marine mammals incidental to the Maintenance and Rehabilitation of the Bellingham Shipping Terminal Project in Bellingham, WA (88 FR 77972, November 11, 2023), effective from November 6, 2023 through November 6, 2024. On September 20, 2024, NMFS received an application for the renewal of that initial IHA. As described in the application for renewal IHA, the activities for which incidental take is requested are nearly identical to those covered in the initial authorization and will not be completed prior to its expiration. Under the initial IHA a number of piles have been removed but no pile installations have occurred. As required, the Port of Bellingham also provided preliminary monitoring data, which confirms that the Port of Bellingham had implemented the required mitigation and monitoring, and also showed that no impacts of a scale or nature not previously analyzed or

authorized have occurred as a result of the activities conducted. The notice of the proposed renewal incidental harassment authorization was published on October 4, 2024 (89 FR 80890). There are no changes from the proposed renewal IHA to the final renewal IHA.

Description of the Specified Activities and Anticipated Impacts

The purpose of the project at the Bellingham Shipping Terminal is to repair some of the failing wharf and pier structures of the terminal. As described in detail in the notice for the initial IHA (88 FR 77972, November 11, 2023), in-water construction will include both pile removal and installation of a multiple types of piles with vibratory and impact hammers. A minor change to the activities conducted by the Port of Bellingham was requested in the renewal letter. The initial IHA noted that the Port of Bellingham would limit vibratory pile driving time to 90 minutes per day. The Port of Bellingham will increase the vibratory pile driving time to 360 minutes per day for this renewal period. This change will increase the size of the Level A harassment zones and shutdown zones associated with vibratory pile driving and removal as compared with those analyzed in the initial IHA (see Description of Mitigation, Monitoring and Reporting Measures). The increase to shutdown zones follows the same goals for mitigation articulated in the notice of the initial proposed IHA, *i.e.*, the shutdown zones are equal to the estimated Level A harassment zones, and there is no increase to the estimated take numbers. Therefore, NMFS has determined that this change is minor and that the action is eligible for renewal. The construction is still expected to occur for 87 non-consecutive days. Sounds produced by these activities may result in take, by Level A harassment and Level B harassment, of marine mammals located in Bellingham Bay.

Incidental take resulting from the in-water pile driving and removal in this renewal will be at the same level as authorized in the initial IHA. Four marine mammal species are expected to experience Level B harassment and one of these species additionally has the potential for Level A harassment (see Estimated Take).

All documents related to the initial IHA are available on our website: <https://www.fisheries.noaa.gov/action/incidental-take-authorization-port-bellinghams-bellingham-shipping-terminal-bellingham>.

Detailed Description of the Activity

A detailed description of the demolition and construction activities for which take is authorized here may be found in the Notices of the Proposed and Final IHAs for the initial authorization. The location, timing, and nature of the activities, including the types of equipment planned for use, are identical to those described in the previous notices.

Description of Marine Mammals

A description of the marine mammals in the area of the activities for which take is authorized, including information on abundance, status, distribution, and hearing, may be found in the notices of the proposed and final IHAs for the initial authorization. NMFS has reviewed the monitoring data from the initial IHA, recent draft Stock Assessment Reports, information on relevant Unusual Mortality Events, and other scientific literature, and determined there is no new information that affects which species or stocks have the potential to be affected or the pertinent information in the Description of the Marine Mammals in the Area of Specified Activities contained in the supporting documents for the initial IHA.

It should be noted that the draft 2023 NMFS' Marine Mammal Stock Assessment Reports (SARs) updated stock abundances for the Eastern Distinct Population Segment for Steller sea lions (*Eumetopias jubatus*) and harbor seals (*Phoca vitulina*) (Carretta *et al.* 2023). For Steller sea lions, the abundance decreased slightly from the initial IHA stock abundance estimate of 43,201 individuals to 36,308 individuals. During the development of the initial IHA the Washington Northern Inland Waters stock of harbor seals had an unknown abundance. Since then, the abundance estimate in the draft 2023 SARs has been updated to 16,451 individuals. None of these population changes impact the findings made in support of the initial IHA. Additional information on all stocks affected by this action is available in the NMFS' U.S. Pacific SARs (available online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports>).

Potential Effects on Marine Mammals and Their Habitat

A description of the potential effects of the specified activity on marine mammals and their habitat for the activities for which take is authorized may be found in the notices of the

proposed and final IHAs for the initial authorization. NMFS has reviewed the monitoring data from the initial IHA, recent draft SARs, information on relevant Unusual Mortality Events, and other scientific literature, and determined that there is no new information that affects our initial

analysis of impacts on marine mammals and their habitat.

Estimated Take

A detailed description of the methods and inputs used to estimate take for the specified activity are found in the notices of the proposed and final IHAs for the initial authorization. Specifically, the source levels, days of

operation, and marine mammal occurrence data applicable to this authorization remain unchanged from the previously issued IHA. Similarly, the stocks taken, methods of take, and types of take remain unchanged from the previously issued IHA, as do the number of takes, which are indicated below in table 1.

TABLE 1—ESTIMATED TAKE BY LEVEL A AND LEVEL B HARASSMENT, BY SPECIES AND STOCK

Common name	Stock	Stock abundance ^a	Level A	Level B	Total take	Take as percentage of stock
Harbor porpoise	Washington Inland Waters	11,233	0	261	261	2.3
Steller sea lion	Eastern U.S.	36,308	0	87	87	0.2
California sea lion	U.S.	257,606	0	87	87	< 0.1
Harbor seal	Washington Northern Inland Waters.	16,451	264	2,029	3,050	18.5

^aStock or DPS size is Nbest according to NMFS 2023 Draft Stock Assessment Reports.

Description of Mitigation, Monitoring and Reporting Measures

The mitigation, monitoring, and reporting measures included as requirements in this authorization are nearly identical to those included in the **Federal Register** notice announcing the issuance of the initial IHA, and the discussion of the least practicable adverse impact included in that document and the notice of the proposed IHA remains accurate.

As noted above, the increase vibratory pile installation time from 90 minutes

per day to 360 minutes per day has increased the size of the shutdown zones as noted in table 2 of this section. The applicant and NMFS analyzed the Level A harassment and associated shutdown zones using vibratory pile installation duration of 90 minutes a day, for inputs in the optional User Spreadsheet tool as reported in table 5 of the final IHA **Federal Register** notice (88 FR 77972, November 14, 2023). In the request for renewal of the initial IHA the applicant requested that NMFS analyze and revise the shutdown zones associated with an increase in vibratory

pile driving time to 360 minutes per day. Using the optional User Spreadsheet tool the applicants and NMFS analyzed and revised the shutdown zones based on this expected increase in vibratory pile installation duration. The following standard mitigation measures are required:

- Shutdown zones for Level A harassment as specified in the initial IHA with the exception of vibratory pile installation where the Port of Bellingham expects to drive piles for 360 minutes a day. The updated shutdown zones are shown in table 2;

TABLE 2—UPDATED SHUTDOWN ZONES DURING VIBRATORY PILE INSTALLATION

Activity	Shutdown zones (m) ¹		
	HF cetaceans	Phocids	Otariids
Vibratory installation (360 minutes)	75 (30)	30 (20)	10 (10)

¹Shutdown zones shown in parentheses are what was included in the initial IHA.

- Protected species observers (PSO) observing the monitoring zones established in the initial IHA during all pile installation and removal activities;
- Soft start procedures for impact pile driving consisting of an initial set of strikes from the hammer at reduced energy, with each strike followed by a 30-second waiting period;
- The use of a marine pile-driving energy attenuator (*i.e.*, air bubble curtain system) will be implemented by the Port of Bellingham during impact pile driving of all steel pipe piles; and
- Prior to the start of daily in-water construction activity, or whenever a break in pile driving/removal of 30 minutes or longer occurs, PSOs will observe the shutdown and monitoring

zones for a period of 30 minutes. If a marine mammal is observed within the shutdown zone, a soft start cannot proceed until the animal has left the zone or has not been observed for 15 minutes.

Monitoring and reporting requirements associated with this renewal are as follows:

- A minimum of one PSO will be on duty during impact pile driving activities and a minimum of two PSOs during vibratory installation/removal;
- Observers will be required to use approved data forms; and
- A draft report will be submitted to NMFS within 90 days of the completion of marine mammal monitoring. The report will include marine mammal

observations pre-activity, during-activity, and post-activity during pile driving days (and associated PSO data sheets).

Comments and Responses

A notice of NMFS' proposal to issue a renewal IHA to the Port of Bellingham was published in the **Federal Register** on October 4, 2024 (89 FR 80890). That notice either described, or referenced descriptions of, the Port of Bellingham's activity, the marine mammal species that may be affected by the activity, the anticipated effects on marine mammals and their habitat, estimated amount and manner of take, and proposed mitigation, monitoring and reporting

measures. NMFS received no public comments.

Determinations

The construction activities are nearly identical to those analyzed for the initial IHA, as are the method of taking and the effects of the action. The higher vibratory drive time does increase the size of the Level A harassment zones and shutdown zones slightly. This increase in zone sizes, however, does not change the anticipated take numbers analyzed in the initial IHA. In analyzing the effects of the activities for the initial IHA, NMFS determined that the Port of Bellingham's activities will have a negligible impact on the affected species or stocks and that the authorized take numbers of each species or stock were small relative to the relevant stocks (e.g., less than one-third of the abundance of all stocks). Although some marine mammal abundances have changed since the initial IHA, none of this new information affects NMFS' determinations supporting issuance of the initial IHAs. The mitigation measures and monitoring and reporting requirements as described above are nearly identical to the initial IHA.

NMFS has concluded that there is no new information suggesting that our analysis or findings should change from those reached for the initial IHA. Based on the information and analysis contained here and in the referenced documents, NMFS has determined the following: (1) the required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; (4) the Port of Bellingham's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action, and; (5) appropriate monitoring and reporting requirements are included.

National Environmental Policy Act

This action is consistent with categories of activities identified in Category of Exclusion B4 (incidental take authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216-6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that

would preclude this categorical exclusion. Accordingly, NMFS determined that the issuance of the initial IHA qualified to be categorically excluded from further National Environmental Policy Act review. NMFS has determined that the application of this categorical exclusion remains appropriate for this renewal IHA.

Endangered Species Act

No incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that consultation under section 7 of the ESA is not required for this action.

Renewal

NMFS has issued a renewal IHA to the Port of Bellingham for the take of marine mammals incidental to the Maintenance and Rehabilitation of the Bellingham Shipping Terminal Project in Bellingham, WA from November 7, 2024 to November 7, 2025.

Dated: October 23, 2024.

Kimberly Damon-Randall,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2024-25021 Filed 10-25-24; 8:45 am]

BILLING CODE 3510-22-P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Wednesday, October 30, 2024—10:00 a.m. (See **MATTERS TO BE CONSIDERED**).

PLACE: The meeting will be held remotely, and in person at 4330 East-West Highway, Bethesda, Maryland 20814.

To attend the meeting remotely, please use the following link: <https://cpsc.webex.com/cpsc/j.php?MTID=m316a2dd3fc8c521a03226e1fc2027958>.

STATUS: Commission Meeting—Open to the Public.

MATTERS TO BE CONSIDERED:

Decisional Matter: FY 2025 Operating Plan.

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, 301-504-7479 (Office) or 240-863-8938 (Cell).

Dated: October 23, 2024.

Alberta E. Mills,

Commission Secretary.

[FR Doc. 2024-25066 Filed 10-24-24; 11:15 am]

BILLING CODE 6355-01-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Availability of Draft Environmental Impact Statement for the Enhanced Integrated Air and Missile Defense System on Guam

AGENCY: Missile Defense Agency (MDA), Department of Defense (DoD).

ACTION: Notice of availability.

SUMMARY: The MDA, as the lead agency, announces the availability of the Draft Environmental Impact Statement (EIS) (EISX-007-20-MDA-1725955966) for the proposed construction, deployment, and operation and maintenance of an Enhanced Integrated Air and Missile Defense (EIAMD) System on Guam (Proposed Action). The United States Army (USA), the United States Navy (USNAV), the United States Air Force (USAF), and the Federal Aviation Administration (FAA) are cooperating agencies on this Draft EIS. The Draft EIS was prepared in accordance with the National Environmental Policy Act of 1969 (NEPA); the Council on Environmental Quality Regulations for Implementing the Procedural Provisions of NEPA; and the agency implementing procedures of MDA, USA, USNAV, USAF, and FAA. The Draft EIS also supports compliance with the National Historic Preservation Act of 1966 (NHPA) and its implementing regulations.

DATES: The 75-day public comment period will be from October 25, 2024, to January 8, 2025. Comments must be postmarked or received on or before January 8, 2025 to ensure consideration in the Final EIS.

ADDRESSES: Written comments may be submitted by: Email: info@EIAMD-EIS.com, Online form: www.EIAMD-EIS.com, Mail: ManTech International Corporation, Attention: EIAMD EIS Project Support, PMB 403, 1270 N. Marine Corps Drive, Suite 101, Tamuning, Guam 96913-4331. Comments will also be accepted at the open house public meetings. *The public meetings will be held at the following locations:* (1) November 13, 2024, Hågat Mayor's Office Community Center Building 393, Route 2, Hågat, Guam; (2) November 14, 2024, Hilton Guam Resort Micronesian Room, 202 Hilton Road,

Tumon Bay, Guam; (3) November 15, 2024, Dededo Senior Center, 319 Iglesia Circle, Dededo, Guam. Mr. Mark Wright, MDA Public Affairs, at 571-231-8212 or by email to mda.info@mda.mil, may be contacted regarding the public meetings. All comments, including names and addresses, will be included in the administrative record, but to protect your personal information, addresses and phone numbers will be kept confidential unless release is otherwise required by law.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Wright, MDA Public Affairs, at 571-231-8212, or by email: mda.info@mda.mil. For more information, including a downloadable copy of the Draft EIS, visit the MDA website: <https://www.mda.mil/system/eiamd>.

SUPPLEMENTARY INFORMATION: Proposed Action and Alternative within the context of homeland defense, Guam is a key strategic location for sustaining and maintaining United States (U.S.) capabilities, deterring adversaries, responding to crises, and maintaining a free and open Indo-Pacific. An attack on Guam would be considered a direct attack on the U.S. and would be met with an appropriate response. Current U.S. forces are capable of defending Guam against regional ballistic missile threats. However, regional missile threats continue to increase and advance technologically. The U.S. Indo-Pacific Command identified a requirement for a 360-degree EIAMD capability on Guam as soon as possible to address the rapid evolution of adversary missile threats.

In the Draft EIS, MDA, in coordination with cooperating agencies, evaluated the potential environmental impacts associated with the Proposed Action as well as a No Action Alternative. The Proposed Action includes the construction, deployment, and operations and maintenance of a comprehensive, persistent, 360-degree EIAMD system to defend the people, infrastructure, and territory of Guam against the rapidly evolving threats of advanced cruise, ballistic, and hypersonic missile attacks from regional adversaries. The proposed system includes a combination of components from the MDA, USA, and USNAV, including missile defense radars, sensors, missile launchers and missile interceptors, and command and control systems. The MDA and USA need to strategically locate and integrate the various system components at multiple sites around Guam. To meet the purpose and need of the Proposed Action, MDA and USA have identified 16 proposed sites on Guam—eight are on Naval Base

Guam (NBG), including the NBG Munitions Site, six are on Andersen Air Force Base, and two are on Marine Corps Base Camp Blaz. The proposed EIAMD system components, associated support facilities (e.g., maintenance buildings, entry control, administrative buildings), and infrastructure (e.g., utility infrastructure, fuel storage facilities, water storage facilities) would be distributed across the proposed sites. Additionally, airspace restrictions would be necessary at sites where radars would be located to ensure that aircraft would not encounter high-intensity radiation fields (HIRF) resulting from the radar operations that exceed FAA's HIRF certification standards for aircraft electrical and electronic systems.

The environmental analysis in the Draft EIS addresses the following environmental resource areas: airspace management, health and safety, cultural, terrestrial biological, socioeconomic, environmental justice and protection of children, land use and recreation, transportation, visual quality, utilities, air quality, climate change, noise, water, and geology and soils. Mitigation measures that, if employed, could avoid, minimize, or mitigate potential environmental impacts resulting from the Proposed Action are also analyzed in the Draft EIS. The Draft EIS only analyzes peacetime operations.

The MDA and the USA, as the action proponents, are coordinating and consulting with appropriate Federal agencies as required by the Endangered Species Act, Coastal Zone Management Act, Clean Water Act, Clean Air Act, and other laws and regulations determined to be applicable to the project. This public comment period also supports compliance with Section 106 of the NHPA and its implementing regulations. The USNAV has determined that the proposed undertaking shall follow *The Programmatic Agreement Among the Commander, Navy Region Marianas, the Advisory Council on Historic Preservation, and the Guam Historic Preservation Officer, Regarding Navy Undertakings on the Island of Guam (2008)* to fulfill Section 106 responsibilities and to avoid, minimize, and/or mitigate effects on historic properties. Members of the public are welcome to provide input.

The MDA intends to publish the Final EIS in summer 2025 and sign a Record of Decision following the 30-day Final EIS waiting period.

Public Participation Invited: The MDA invites all interested members of the public, as well as Federal and territorial agencies, to comment on the Draft EIS and the project's potential to

affect historic properties pursuant to Section 106 of the NHPA. The Draft EIS is available for public review on the MDA website at www.mda.mil/system/eiamd and at the following public libraries: (1) University of Guam Robert F. Kennedy Memorial Library, UOG Station, Mangilao, Guam 96913; (2) Nieves M. Flores Memorial Library, 254 Martyr St., Agaña, Guam 96910.

In support of NEPA and NHPA Section 106 requirements, the MDA and cooperating agencies will host three in-person open house public meetings in Guam. Similar to the scoping meetings held in August 2023, the open-house format will include poster stations staffed by MDA and representatives of the cooperating agencies who can provide information and answer questions about the Proposed Action and the findings in the Draft EIS.

The public meetings will be held as follows: (1) November 13, 2024, from 4:00 to 7:00 p.m. Chamorro Standard Time (ChST) at Hågat Mayor's Office Community Center Building 393, Route 2, Hågat, Guam; (2) November 14, 2024, from 4:00 to 7:00 p.m. ChST at Hilton Guam Resort Micronesia Room, 202 Hilton Road, Tumon Bay, Guam; (3) November 15, 2024, from 5:00 to 8:00 p.m. ChST at Dededo Senior Center, 319 Iglesia Circle, Dededo, Guam. Attendees will be able to submit oral and written comments during the public meetings. Official oral comments will be recorded by a court reporter in a one-on-one setting.

Dated: October 23, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024-25027 Filed 10-24-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2024-SCC-0102]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Federal Family Educational Loan Program—Servicemembers Civil Relief Act (SCRA)

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before November 27, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting "Department of Education" under "Currently Under Review," then check the "Only Show ICR for Public Comment" checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the "View Information Collection (IC) List" link. Supporting statements and other supporting documentation may be found by clicking on the "View Supporting Statement and Other Documents" link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, (202) 570-8414.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Federal Family Educational Loan Program—Servicemembers Civil Relief Act (SCRA).

OMB Control Number: 1845-0093.

Type of Review: Extension without change of a currently approved ICR.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 4,408.

Total Estimated Number of Annual Burden Hours: 13,216.

Abstract: The Department of Education (the Department) is requesting an extension of the currently approved OMB information collection 1845-0093, Federal Family Education Loan (FFEL) Program Servicemembers Civil Relief Act (SCRA) based on a

decrease in the number of servicemembers accessing the benefit. The regulations require the FFEL loan holder to match its database against the Department of Defense (DOD) Defense Manpower Data Center (DMDC) or other official DOD database and automatically apply the interest rate limitation, as appropriate, to borrowers under the SCRA. There has been no change in the statute or in the regulations at 34 CFR 682.208(j). There is no form tied to this collection.

Dated: October 22, 2024.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024-24937 Filed 10-25-24; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Membership of the Performance Review Board

AGENCY: Office of Finance and Operations, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary publishes an updated list of persons who may be named to serve on the Performance Review Board that oversees the evaluation of performance appraisals for Senior Executive Service members of the Department of Education (Department).

DATES: These appointments are effective on October 28, 2024.

FOR FURTHER INFORMATION CONTACT: Jennifer Geldhof, Director, Executive Resources Division, Office of Human Resources, Office of Finance and Operations, U.S. Department of Education, 400 Maryland Avenue SW, Room 210-00, LBJ, Washington, DC 20202-4573. Telephone: (202) 580-9669. Email: Jennifer.Geldhof@ed.gov.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7-1-1.

SUPPLEMENTARY INFORMATION:

Membership

Under the Civil Service Reform Act of 1978, Public Law 95-454 (5 U.S.C. 4314(c)(4)), the Department must publish in the **Federal Register** a list of persons who may be named to serve on the Performance Review Board that oversees the evaluation of performance appraisals for Senior Executive Service members of the Department. On September 18, 2024, the Department of

Education published in the **Federal Register** (89 FR 76464) a list of persons who may be named to serve on the Performance Review Board. Since that date, there has been a change to the list because one of the persons named in the earlier notice is not available to serve on the Performance Review Board. This notice updates that list and the following persons may be named to serve on the Performance Review Board:

Ceja, Beatriz
Chapman, Christopher D.
Clay, Jacqueline
Juengst, Phillip R.
Shirley, Victory
St. Pierre, Tracey
Wood, Gary

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. At this site you can view this document, as well as all other Department documents published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access Department documents published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Signing Authority

This document of the U.S. Department of Education was signed on October 18, 2024, by Miguel A. Cardona, Secretary of Education. That document with the original signature and date is maintained by the U.S. Department of Education. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned has been authorized to sign the document in electronic format for publication, as an official document of the U.S. Department of Education. This administrative process in no way alters

the legal effect of this document upon publication in the **Federal Register**.

Sharon Cooke,

Associate Director, Communications Team, Office of the Executive Secretariat, Office of the Secretary, U.S. Department of Education.

[FR Doc. 2024-24991 Filed 10-25-24; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP25-86-000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 10.22.24 Negotiated Rates—Hartree Partners, LP R-7090-14 to be effective 11/1/2024.

Filed Date: 10/22/24.

Accession Number: 20241022-5019.

Comment Date: 5 p.m. ET 11/4/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to

contact OPP at (202) 502-6595 or OPP@ferc.gov.

Dated: October 22, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024-25000 Filed 10-25-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24-490-000]

Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed EcoEléctrica LNG Supply Pipeline Capacity Project: EcoEléctrica, L.P.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document, that will discuss the environmental impacts of the EcoEléctrica LNG Supply Pipeline Capacity Project involving adjustments to existing liquefied natural gas (LNG) sendout pressure control setpoints on EcoEléctrica, L.P. (EcoEléctrica) facilities in Peñuelas, Puerto Rico. The Commission will use this environmental document in its decision-making process to determine whether the project is in the public interest.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the project. As part of the National Environmental Policy Act (NEPA) review process, the Commission takes into account concerns the public may have about proposals and the environmental impacts that could result from its action whenever it considers the issuance of an authorization. This gathering of public input is referred to as "scoping." The main goal of the scoping process is to focus the analysis in the environmental document on the important environmental issues. Additional information about the Commission's NEPA process is described below in the *NEPA Process and Environmental Document* section of this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on November 20, 2024. Comments may be

submitted in written form. Further details on how to submit comments are provided in the *Public Participation* section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all written comments during the preparation of the environmental document.

If you submitted comments on this project to the Commission before the opening of this docket on July 5, 2024, you will need to file those comments in Docket No. CP24-490-000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

Public Participation

There are three methods you can use to submit your comments to the Commission. Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208-3676 or FercOnlineSupport@ferc.gov.

(1) You can file your comments electronically using the eComment feature, which is located on the Commission's website (www.ferc.gov) under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature, which is also located on the Commission's website (www.ferc.gov) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; a comment on a particular project is considered a "Comment on a Filing"; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (CP24-490-000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary,

Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Additionally, the Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Summary of the Proposed Project

EcoEléctrica proposes to increase the existing LNG Supply Pipeline sendout capacity between the LNG terminal in Peñuelas, Puerto Rico and the off-site truck loading facility (TLF) from 250 gallons per minute (gpm) to 500 gpm. EcoEléctrica states the project would satisfy the increasing demand for LNG from the TLF and its downstream users. The requested capacity increase would not require construction and would only require LNG sendout pressure control setpoint adjustments at the inlet of the LNG Supply Pipeline.

The general location of the project facilities is shown in appendix 1.¹

NEPA Process and the Environmental Document

Any environmental document issued by the Commission will discuss impacts that could occur as a result of the construction and operation of the

proposed project under the relevant general resource areas:

- environmental justice; and
- reliability and safety.

Commission staff will also evaluate reasonable alternatives to the proposed project or portions of the project and make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Following this scoping period, Commission staff will determine whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff's independent analysis of the issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its decision regarding the proposed project. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/Notice of Schedule* will be issued, which will open up an additional comment period. Staff will then prepare a draft EIS which will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS and revise the document, as necessary, before issuing a final EIS. Any EA or draft and final EIS will be available in electronic format in the public record through eLibrary² and the Commission's natural gas environmental documents web page (<https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents>). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate in the preparation of the environmental document.³ Agencies that would like to request cooperating agency status should follow the instructions for filing comments

provided under the *Public Participation* section of this notice.

Environmental Mailing List

The environmental mailing list includes: federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to GasProjectAddressChange@ferc.gov stating your request. You must include the docket number CP24-490-000 in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from the mailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments. OR

(2) Return the attached "Mailing List Update Form" (appendix 2).

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208-FERC, or on the FERC website at www.ferc.gov using the eLibrary link. Click on the eLibrary link, click on "General Search" and enter the docket number in the "Docket Number" field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or (866) 208-3676, or for TTY, contact (202) 502-8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission's calendar

¹ The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at www.ferc.gov using the link called "eLibrary". For instructions on connecting to eLibrary, refer to the last page of this notice. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll free, (886) 208-3676 or TTY (202) 502-8659.

² For instructions on connecting to eLibrary, refer to the last page of this notice.

³ The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Section 1501.8.

located at <https://www.ferc.gov/news-events/events> along with other related information.

Dated: October 22, 2024.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2024-25002 Filed 10-25-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC24-107-000.

Applicants: Split Rail Solar Energy LLC, Union Electric Company d/b/a Ameren Missouri.

Description: Supplement to July 30, 2024, Joint Application for Authorization Under Section 203 of the Federal Power Act of Split Rail Solar Energy LLC, et al.

Filed Date: 10/21/24.

Accession Number: 20241021-5133.

Comment Date: 5 p.m. ET 10/31/24.

Docket Numbers: EC25-9-000.

Applicants: Green Country Energy, LLC, Public Service Company of Oklahoma.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Green Country Energy, LLC, et al.

Filed Date: 10/15/24.

Accession Number: 20241015-5554.

Comment Date: 5 p.m. ET 12/16/24.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG25-18-000.

Applicants: OneLNG Power, LLC.

Description: OneLNG Power, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 10/22/24.

Accession Number: 20241022-5099.

Comment Date: 5 p.m. ET 11/12/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16-2449-004; ER21-628-004.

Applicants: Harry Allen Solar Energy LLC, Boulder Solar II, LLC.

Description: Supplement to 10/31/2023 Notice of Change in Status of Boulder Solar II, LLC et al.

Filed Date: 10/18/24.

Accession Number: 20241018-5224.

Comment Date: 5 p.m. ET 11/8/24.

Docket Numbers: ER21-136-005.

Applicants: Flat Ridge 3 Wind Energy, LLC.

Description: Supplement to 10/31/2023 Notice of Change in Status of Flat Ridge 3 Wind Energy, LLC.

Filed Date: 10/18/24.

Accession Number: 20241018-5226.

Comment Date: 5 p.m. ET 11/8/24.

Docket Numbers: ER21-2460-008.

Applicants: New York Independent System Operator, Inc.

Description: Third Informational Report Addressing NYISO Efforts to Improve Ability of Aggregations to Provide Ancillary Services in compliance with the Commission's 04/20/2023 Order.

Filed Date: 10/21/24.

Accession Number: 20241021-5207.

Comment Date: 5 p.m. ET 11/12/24.

Docket Numbers: ER24-2563-001.

Applicants: Sheetz Energy Inc.

Description: Tariff Amendment: Sheetz MBRA Tariff to be effective 10/22/2024.

Filed Date: 10/21/24.

Accession Number: 20241021-5182.

Comment Date: 5 p.m. ET 11/12/24.

Docket Numbers: ER25-172-000.

Applicants: SunZia Transmission, LLC.

Description: § 205(d) Rate Filing: Service Agreement No. 4—LGIA with SunZia Wind North and CAISO to be effective 12/31/9998.

Filed Date: 10/21/24.

Accession Number: 20241021-5169.

Comment Date: 5 p.m. ET 11/12/24.

Docket Numbers: ER25-173-000.

Applicants: SunZia Transmission, LLC.

Description: § 205(d) Rate Filing: 2nd Amended & Restated TSA with SunZia Wind (SA No. 1) to be effective 12/31/9998.

Filed Date: 10/21/24.

Accession Number: 20241021-5171.

Comment Date: 5 p.m. ET 11/12/24.

Docket Numbers: ER25-174-000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Mountain Parks Electric, Inc.

Withdrawal Agreement to be effective 12/21/2024.

Filed Date: 10/21/24.

Accession Number: 20241021-5187.

Comment Date: 5 p.m. ET 11/12/24.

Docket Numbers: ER25-175-000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Notice of Cancellation of ICSA Service Agreement No. 5365; AB2-160 to be effective 12/21/2024.

Filed Date: 10/22/24.

Accession Number: 20241022-5013.

Comment Date: 5 p.m. ET 11/12/24.

Docket Numbers: ER25-176-000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1166R44 Oklahoma Municipal Power Authority NITSA and NOA to be effective 10/1/2024.

Filed Date: 10/22/24.

Accession Number: 20241022-5014.

Comment Date: 5 p.m. ET 11/12/24.

Docket Numbers: ER25-177-000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Add a Compensation Mechanism for System Support Resources to be effective 12/31/9998.

Filed Date: 10/22/24.

Accession Number: 20241022-5017.

Comment Date: 5 p.m. ET 11/12/24.

Docket Numbers: ER25-178-000.

Applicants: WSPP Inc.

Description: § 205(d) Rate Filing: List of Members Update 2024 to be effective 10/21/2024.

Filed Date: 10/22/24.

Accession Number: 20241022-5021.

Comment Date: 5 p.m. ET 11/12/24.

Docket Numbers: ER25-179-000.

Applicants: AEP Texas Inc.

Description: § 205(d) Rate Filing: AEPTX-Wichita Solar I Generation Interconnection Agreement to be effective 10/2/2024.

Filed Date: 10/22/24.

Accession Number: 20241022-5030.

Comment Date: 5 p.m. ET 11/12/24.

Docket Numbers: ER25-180-000.

Applicants: AEP Texas Inc.

Description: § 205(d) Rate Filing: AEPTX-Flying Kite Solar Generation Interconnection Agreement to be effective 10/2/2024.

Filed Date: 10/22/24.

Accession Number: 20241022-5039.

Comment Date: 5 p.m. ET 11/12/24.

Docket Numbers: ER25-181-000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1637R4 Kansas Electric Power Cooperative, Inc. NITSA and NOA to be effective 10/1/2024.

Filed Date: 10/22/24.

Accession Number: 20241022-5073.

Comment Date: 5 p.m. ET 11/12/24.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18

CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Dated: October 22, 2024.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2024-24999 Filed 10-25-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98-1-000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to

respond to any facts or contentions made in a prohibited off-the-record communication and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e) (1) (v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. Each filing may be viewed on the Commission's website at <http://www.ferc.gov> using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll free at (866) 208-3676, or for TTY, contact (202) 502-8659.

Docket Nos.	File date	Presenter or requester
Prohibited:		
1. CP16-454-000	10-15-2024	FERC Staff. ¹
2. CP19-502-000	10-17-2024	FERC Staff. ²
Exempt:		
1. P-14861-002	10-15-2024	FERC Staff. ³
2. P-14861-002	10-17-2024	FERC Staff. ⁴
3. CP16-116-000	10-22-2024	Kickapoo Traditional Tribe of Texas.
4. CP16-454-000, CP16-455-000, CP20-481-000	10-22-2024	Kickapoo Traditional Tribe of Texas.

¹ Emailed comments dated 10/15/24 from Alejandro Garcia.

² Emailed comments dated 10/16/24 from David Robinson.

³ Memorandum regarding ex parte communication with Washington State Historic Preservation Office.

⁴ Memorandum regarding ex parte communication with Washington State Historic Preservation Office on 10/11/24.

Dated: October 22, 2024.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2024-25001 Filed 10-25-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 137-221]

Pacific Gas and Electric Company; Notice of Intent To Prepare an Environmental Assessment

On November 15, 2023, the Pacific Gas and Electric Company (licensee) filed an application for a non-capacity amendment at the Tiger Creek regulator dam of the Mokelumne River

Hydroelectric Project No. 137. The dam is located on Tiger Creek in Amador County, California.

The licensee proposes to construct a new 240-foot-long, 40-foot-wide concrete spillway and plunge pool at the right abutment of the Tiger Creek regulator dam. As part of the proposal, the licensee would construct a spoil area, and a temporary and permanent access road at the dam site which would be closed to the public during construction. The licensee also intends to develop a staging and spoils area on Doakes Ridge approximately 0.7 miles

southwest of the dam site and place a staging area and concrete batch plant on state route 88 in Pioneer, California. State route 88 and Tiger Creek Road between Pioneer and the dam site would be used as a haul route. The existing spillway would be abandoned in place. The licensee expects construction to take approximately 2 years.

On July 26, 2024, the Commission issued a public notice for the proposed amendment. On August 2, August 5, and August 20, 2024, the California Department of Fish and Wildlife, the California State Water Resources Control Board, and the U.S. Department of the Interior filed notices of intervention, respectively.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the project.¹ The planned schedule for the completion of the EA is June 18, 2025. Revisions to the schedule may be made as appropriate. The EA will be issued and made available for review by all interested parties during a 30-day public comment period. All comments filed on the EA will be reviewed by staff and considered in the Commission's final decision on the proceeding.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others to access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202)502-6595 or OPP@ferc.gov.

Any questions regarding this notice may be directed to Steven Sachs at 202-502-8666 or Steven.Sachs@ferc.gov.

Dated: October 22, 2024.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2024-24997 Filed 10-25-24; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2024-0159; FRL-11684-08-OCSP]

Certain New Chemicals or Significant New Uses; Statements of Findings for August 2024

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Toxic Substances Control Act (TSCA) requires EPA to publish in the **Federal Register** a statement of its findings after its review of certain TSCA submissions when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to premanufacture notices (PMNs), microbial commercial activity notices (MCANs), and significant new use notices (SNUNs) submitted to EPA under TSCA. This document presents statements of findings made by EPA on such submissions during the period from August 1, 2024 to August 31, 2024.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2024-0159, is available online at <https://www.regulations.gov> or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Rebecca Edelstein, New Chemical Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-1667 email address: edelstein.rebecca@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action provides information that is directed to the public in general.

B. What action is the Agency taking?

This document lists the statements of findings made by EPA after review of submissions under TSCA section 5(a) that certain new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment. This document presents statements of findings made by EPA during the reporting period.

C. What is the Agency's authority for taking this action?

TSCA section 5(a)(3) requires EPA to review a submission under TSCA section 5(a) and make one of several specific findings pertaining to whether the substance may present unreasonable risk of injury to health or the environment. Among those potential findings is that the chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment per TSCA section 5(a)(3)(C).

TSCA section 5(g) requires EPA to publish in the **Federal Register** a statement of its findings after its review of a submission under TSCA section 5(a) when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to PMNs, MCANs, and SNUNs submitted to EPA under TSCA section 5.

Anyone who plans to manufacture (which includes import) a new chemical substance for a non-exempt commercial purpose and any manufacturer or processor wishing to engage in a use of a chemical substance designated by EPA as a significant new use must submit a notice to EPA at least 90 days before commencing manufacture of the new chemical substance or before engaging in the significant new use.

The submitter of a notice to EPA for which EPA has made a finding of "not likely to present an unreasonable risk of injury to health or the environment" may commence manufacture of the chemical substance or manufacture or processing for the significant new use notwithstanding any remaining portion of the applicable review period.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

¹ In accordance with the Council on Environmental Quality's regulations, the unique identification number for documents relating to this environmental review is EAXX-019-20-000-1729247760. 40 CFR 1501.5(c)(4) (2024).

II. Statements of Findings Under TSCA Section 5(a)(3)(C)

In this unit, EPA provides the following information (to the extent that such information is not claimed as Confidential Business Information (CBI) on the PMNs, MCANs and SNUNs for which, during this period, EPA has made findings under TSCA section 5(a)(3)(C) that the new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment:

The following list provides the EPA case number assigned to the TSCA section 5(a) submission and the chemical identity (generic name if the specific name is claimed as CBI).

- J-24-0020, Genetically modified microorganism (Generic Name).

To access EPA’s decision document describing the basis of the “not likely to present an unreasonable risk” finding made by EPA under TSCA section 5(a)(3)(C), look up the specific case number at [https://www.epa.gov/reviewing-new-chemicals-under-toxic-](https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely)

substances-control-act-tsca/chemicals-determined-not-likely.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: October 22, 2024.

Lisa Christ,

Acting Director, New Chemicals Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2024-24945 Filed 10-25-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2017-0751; FRL-12313-01-OCSPF]

Pesticide Registration Review; Decisions and Case Closures for Several Pesticides; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA’s interim registration review decision for chlorine gas. In addition, this notice announces the closure of the registration review case

for *metschnikowia fructicola* strain NRRL Y-27328 because the last U.S. registrations for this pesticide have been canceled.

FOR FURTHER INFORMATION CONTACT:

For pesticide specific information, contact: The Chemical Review Manager for the pesticide of interest identified in Table 1 of Unit I.

For general information on the registration review program, contact: Melanie Biscoe, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 566-0701; email address: biscoe.melanie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Purpose of This Notice

Pursuant to 40 CFR 155.58(c), this notice announces the availability of EPA’s interim registration review decision for the pesticide shown in Table 1. The interim registration review decision is supported by rationales included in the docket established for the chemical.

TABLE 1—INTERIM REGISTRATION REVIEW DECISIONS BEING ISSUED

Registration review case name and number	Docket ID No.	Chemical review manager and contact information
Chlorine Gas	EPA-HQ-OPP-2010-0242	Erin Dandridge, dandridge.erin@epa.gov , (202) 566-0635.
Case Number 4022		

This notice also announces the closure of the registration review case for *Metschnikowia fructicola* strain NRRL Y-27328 (Case Number 6531) because the last U.S. registrations for these pesticides have been canceled. There is no docket number established for this registration review case as all products were cancelled in Case 6531 before the registration review assessments were initiated.

II. Background

EPA is conducting its registration review of the chemical listed in Table 1 of Unit I pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(g) (7 U.S.C. 136a(g)) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. FIFRA section 3(g) provides, among other things, that pesticide registrations are to be reviewed every 15 years. Consistent with 40 CFR 155.57, in its final registration review decision, EPA will ultimately determine whether a pesticide continues to meet the

registration standard in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). As part of the registration review process, the Agency has completed interim or final registration review decisions for the pesticide in Table 1 of Unit I.

Prior to completing the interim registration review decision in Table 1 of Unit I, EPA posted the proposed interim decision for the chemical and invited the public to submit any comments or new information, consistent with 40 CFR 155.58(a). EPA considered and responded to any comments or information received during these public comment periods in the respective interim decision or final registration review decisions.

For additional background on the registration review program, see: <https://www.epa.gov/pesticide-reevaluation>.

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 22, 2024.

Jean Anne Overstreet,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2024-25004 Filed 10-25-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2017-0720; FRL-12312-01-OCSPF]

Pesticide Registration Review; Pesticide Dockets Opened for Review and Comment; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of the EPA’s work plans and registration review case dockets for the following chemicals: capsaicin and related capsaicinoids; cis-jasmone; cyantraniliprole; GS-omega/kappa-Hxtx-Hv1a; male sea lamprey mating pheromone [3-Ketopetromyzonol-24-sulfate, ammonium salt]; methyl dihydrojasmolate (cyclopentaneacetic acid, 3- hydroxy- 2-pentyl-, methyl ester); methyl jasmonate; natamycin; prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclo-pentylacetate; and tobacco mild green mosaic tobamovirus strain U2. EPA is opening a 60-day public

comment period for these work plans and case dockets.

DATES: Comments must be received on or before December 27, 2024.

ADDRESSES: Submit your comments, to the docket identification (ID) number for the specific pesticide of interest provided in Table 1 of Unit I, by one of the following methods:

- *Federal eRulemaking Portal* at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI)

or other information whose disclosure is restricted by statute.

- *Mail:* <https://www.epa.gov/dockets/where-send-comments-epa-dockets>. OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001.

FOR FURTHER INFORMATION CONTACT:

For pesticide specific information, contact: The Chemical Review Manager for the pesticide of interest identified in Table 1 of Unit I.

For general questions on the registration review program, contact: Melanie Biscoe, Pesticide Re-Evaluation

Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001; telephone number: 202–566–0701; email address: biscoe.melanie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Purpose of This Notice

Pursuant to 40 CFR 155.50(b), this notice announces the availability of the EPA’s work plans and registration review case dockets for the pesticides shown in Table 1 and opens a 60-day public comment period on the work plans and case dockets.

TABLE 1—WORK PLANS BEING MADE AVAILABLE FOR PUBLIC COMMENT

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
Capsaicin and Related Capsaicinoids Case No. 4018	EPA-HQ-OPP–2024–0396.	Bibiana Oe, oe.bibiana@epa.gov , (202) 566–1538. Kendall Ziner, ziner.kendall@epa.gov , (202) 566–0621.
Cis-jasmone Case Number 6336	EPA-HQ-OPP–2024–0219.	Joseph Mabon, mabon.joseph@epa.gov , (202) 566–1535.
Cyantranilprole Case Number 5096	EPA-HQ-OPP–2024–0106.	Rachel Fletcher, fletcher.rachel@epa.gov , (202) 566–2354.
GS-omega/kappa-Hctx-Hv1a Case Number 6602	EPA-HQ-OPP–2024–0280.	Michael Glikes, glikes.michael@epa.gov , (202) 566–1461.
Male Sea Lamprey Mating pheromone, [3-Ketopetromyzonol-24-sulfate, ammonium salt] Case Number 6325.	EPA-HQ-OPP–2024–0382.	Susanne Cerrelli, cerrelli.susanne@epa.gov , (202) 566–1516.
Methyl Dihydrojasmolate (Cyclopentaneacetic acid, 3- hydroxy- 2-pentyl-, methyl ester) Case Number 6355.	EPA-HQ-OPP–2024–0219.	Joseph Mabon, mabon.joseph@epa.gov , (202) 566–1535.
Methyl jasmonate Case Number 6319	EPA-HQ-OPP–2024–0219.	Joseph Mabon, mabon.joseph@epa.gov , (202) 566–1535.
Natamycin Case Number 6316	EPA-HQ-OPP–2024–0132.	Joseph Mabon, mabon.joseph@epa.gov , (202) 566–1535.
Prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclo-pentylacetate Case Number 6322.	EPA-HQ-OPP–2024–0219.	Joseph Mabon, mabon.joseph@epa.gov , (202) 566–1535.
Tobacco mild green mosaic tobamovirus strain U2 Case Number 6533	EPA-HQ-OPP–2024–0263.	Bibiana Oe, oe.bibiana@epa.gov , (202) 566–1538.

II. Background

EPA is conducting its registration review of the chemicals listed in Table 1 of Unit I pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(g) (7 U.S.C. 136a(g)) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. FIFRA section 3(g) provides, among other things, that pesticide registrations are to be reviewed every 15 years. Consistent with 40 CFR 155.57, in its final registration review decision, EPA will ultimately determine whether a pesticide continues to meet the registration standard in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)).

Pursuant to 40 CFR 155.50, EPA initiates a registration review by establishing a public docket for a pesticide registration review case. Registration review dockets contain information that will assist the public in

understanding the types of information and issues that the Agency has considered during registration review. Consistent with 40 CFR 155.50(a), these dockets may include information from the Agency’s files including, but not limited to, an overview of the registration review case status, a list of current product registrations and registrants, any **Federal Register** notices regarding any pending registration actions, any **Federal Register** notices regarding current or pending tolerances, risk assessments, bibliographies concerning current registrations, summaries of incident data, and any other pertinent data or information. EPA includes in these dockets a Preliminary Work Plan (PWP), and in some cases a continuing work plan (CWP), summarizing information EPA has on the pesticide and the anticipated path forward.

Consistent with 40 CFR 155.50(b), EPA provides for at least a 60-day

public comment period on work plans and registration review dockets. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary changes to a pesticide’s workplan. During this public comment period, the Agency is asking that interested persons identify any additional information they believe the agency should consider during the registration reviews of these pesticides. The Agency identifies in each docket the areas where public comment is specifically requested, though comment in any area is welcome.

For additional background on the registration review program, see: <https://www.epa.gov/pesticide-reevaluation>.

III. What should I consider as I prepare a comment for EPA?

This notice is directed to the public in general and may be of interest to a wide range of stakeholders including

environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager identified in Table 1 of Unit I. In submitting a comment to EPA, please consider the following:

1. *Submitting CBI.* Do not submit this information to the EPA through www.regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to the EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

All comments should be submitted using the methods in **ADDRESSES** and must be received by the EPA on or before the closing date. These comments will become part of the docket for the pesticides included in Table 1 of Unit I. The Agency will consider all comments received by the closing date and may respond to comments in a "Response to Comments Memorandum"

in the docket or the Final Work Plan (FWP), as appropriate.

(Authority: 7 U.S.C. 136 *et seq.*)

Dated: October 22, 2024.

Jean Overstreet,

*Director, Pesticide Re-evaluation Division,
Office of Pesticide Programs.*

[FR Doc. 2024-24947 Filed 10-25-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2021-0245; FRL-12378-01-OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; EPA's Safer Choice Program Product and Partner Recognition Activities (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), EPA's Safer Choice Program Product and Partner Recognition Activities (EPA ICR Number 2692.02, OMB Control Number 2070-0221) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed revision of the ICR, which is currently approved through May 31, 2025. Public comments were previously requested via the **Federal Register** on May 8, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before November 27, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OPPT-2021-0245, to EPA online using www.regulations.gov (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 2822T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within

30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Katherine Sleasman, Office of Program Support (7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566-1204; email address: sleasman.katherine@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed revision of the ICR, which is currently approved through May 31, 2025. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on May 8, 2024, during a 60-day comment period (89 FR 38895). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Abstract: This ICR renewal covers the information collection activities associated with the reporting and recordkeeping requirements for individuals, businesses, organizations, and government entities participating in or collaborating with EPA's Safer Choice and Design for the Environment (DfE) programs (referred to collectively as "the Safer Choice program" in this document unless otherwise indicated). This ICR also includes additional sections for the Safer Choice cleaning service certification and third-party profiler (TPP) solicitations. These components are designed to:

- Improve data efficiency by electronic data collection via a cloud-based Salesforce system called the Safer Choice Community;
- Monitor the public's awareness of the Safer Choice program and the Safer Choice label and DfE logo;
- Clarify the Safer Choice Partner of the Year Awards application process and form;

- Describe information collected through the new Safer Choice cleaning service certification program; and,
- Clarify the TPP application process and form.

Form numbers: 9600–017, 9600–018, 9600–019, 9600–020, 9600–021, 9600–022, 9600–023, 9600–058, 9600–059, 9600–060, 9600–061.

Respondents/affected entities: Entities potentially affected by this ICR include a wide range of sectors that participate in the Safer Choice Program including chemical manufacturers, paint and coating manufacturing, merchant wholesalers, janitorial services, and environmental consulting firms.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 4,539 (total).

Frequency of response: On occasion.
Total estimated burden: 4,511 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$854,358 (per year), which includes \$553,850 annualized capital or operation & maintenance costs.

Changes in the estimates: There is an increase of 1,279 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase, which is discussed in more detail in the ICR, is due to an increase in annual consumer online surveys, which increased from 2,000 to 4,000 annually, the inclusion of a new program, the “Safer Choice Cleaning Service Certification,” and the inclusion of the TPP solicitation process. These changes qualify as a program change.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024–24986 Filed 10–25–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–OEJECR–2024–0479; FRL—12368–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Environmental Justice Thriving Communities Grantmaking Program: Applications for Subawards—November Launch

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an

information collection request (ICR), Environmental Justice Thriving Communities Grantmaking Program: Applications for Subawards—November Launch (EPA ICR Number 7790.01, OMB Control Number 2035–NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a request for emergency clearance of a new collection. A two-week public comment period has been initiated via a notice in the **Federal Register**.

DATES: Comments may be submitted on or before November 12, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–OEJECR–2024–0479 or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA’s policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT:

Aarti Iyer, Office of the Chief Financial Officer, Mail Code 2710A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–564–0214; email address: iyer.aarti@epa.gov.

SUPPLEMENTARY INFORMATION: This is a request for approval of a new collection. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

This notice allows for a 14 day public comment period. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA’s public docket, visit <http://www.epa.gov/dockets>.

Abstract: To meet the goals and objectives that demonstrate the U.S. Environmental Protection Agency (EPA’s) and the Administration’s commitment to achieving environmental justice and embedding environmental justice into Agency programs, the Environmental Justice

Thriving Communities Grantmaking Program provides about \$600 million in 11 cooperative agreements funding to “Grantmakers” who will function as pass-through entities for the Environmental Justice Thriving Communities Subgrants (2 CFR parts 200 and 1500). Each Grantmaker will collaborate with EPA to design and build their own processes to receive and evaluate applications to fund the initial development of community-led environmental justice projects. With this Information Collection Request (ICR), EPA seeks emergency clearance by October 31, 2024 for six Grantmakers to solicit applications for their first round of subgrants to be launched in November 2024.

This is the third of three related Grantmaker ICRs submitted on an emergency basis (see also 2090–0035 and 2090–0036). EPA cannot reasonably comply with the normal clearance procedures because subaward programs must be launched within 3 months, which does not allow sufficient time to obtain PRA clearance using the standard ICR process. Collection of the information requested under this emergency clearance (*i.e.*, applications) is essential for the Grantmakers to have a mechanism for selecting and distributing subaward grants to fund environmental justice projects in underserved communities, thus fulfilling the central objective of the program.

This emergency clearance will cover the first round of subaward applications solicited by six Grantmakers in November 2024. Subsequent rounds of applications will be authorized via a Standard ICR package for the Grantmaking Program that will be submitted for review via the standard ICR approval process.

Form Numbers: None.

Respondents/affected entities:

Respondents will include entities who are eligible to receive subawards, including community based nonprofit organizations, Puerto Rico, U.S. Territories and Freely Associated States, Native American organizations, local governments, and institutions of higher education.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 7,496 (total).

Frequency of response: Once.

Total estimated burden: 13,622 hours (total). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$897,264.38 (total), which includes \$178,057.92 annualized capital or operation & maintenance costs.

Requested approval date: October 31, 2024.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024-24985 Filed 10-25-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2021-0643; FRL-12136-01-OAR]

Phasedown of Hydrofluorocarbons: Notice of Information Availability for Regulations Implementing the American Innovation and Manufacturing Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The purpose of this notice is to alert stakeholders that the U.S. Environmental Protection Agency (EPA) has published frequently asked questions related to the regulations implementing the American Innovation and Manufacturing Act. While the questions broadly cover topics on hydrofluorocarbons, the Act itself, and the three new programs established under the Act, the majority of these new and updated frequently asked questions are related to the Technology Transitions program restrictions on the use of certain hydrofluorocarbons. The Agency has published and continues to update these frequently asked questions in the *Frequent Questions on the Phasedown of Hydrofluorocarbons* web area and in the existing rulemaking docket.

DATES: October 28, 2024.

FOR FURTHER INFORMATION CONTACT: Allison Cain, U.S. Environmental Protection Agency, Stratospheric Protection Division, telephone number: 202-564-1566; or email address: Cain.Allison@epa.gov. You may also visit EPA's website at <https://www.epa.gov/climate-hfcs-reduction> for further information.

SUPPLEMENTARY INFORMATION:

I. Background

The American Innovation and Manufacturing (AIM) Act of 2020 was enacted on December 27, 2020, and codified at 42 U.S.C. 7675. The AIM Act authorizes EPA to address climate-damaging hydrofluorocarbons (HFCs) by providing new authorities in three main areas: to phase down the production and consumption of listed HFCs, manage these HFCs and their substitutes, and facilitate the transition

to next-generation technologies through sector-based restrictions. Since the AIM Act was enacted, EPA has finalized a number of rulemakings that implement the AIM Act through three regulatory programs: the HFC Allowance Allocation Program, the Technology Transitions Program, and the Emissions Reduction and Reclamation Program. EPA has provided information to stakeholders about these three programs through our frequently asked questions web page.

The majority of the questions and responses relate to the Technology Transitions final rule published on October 24, 2023 (88 FR 73098). This rule facilitates sector-based transitions to next-generation technologies, as specified in the AIM Act. The rule limits the use of HFCs in specific technology sectors and subsectors, such as foams, aerosols, and refrigeration, air conditioning, and heat pumps. In most subsectors, EPA set a maximum global warming potential (GWP) limit on HFCs or HFC blends that can be used in new products and equipment. In a few subsectors, EPA listed the specific HFCs or HFC blends that are restricted. Compliance dates and GWP limits vary based on sector and subsector. The rule requires that new products and components using HFCs be labeled and that companies that manufacture or import such products or components using HFCs report information to EPA.

Since the publication of the various AIM Act rulemakings, EPA has posted information for stakeholders in question-and-answer form to help stakeholders understand key aspects of these the rules across regulatory programs. To maintain transparency and ensure consistency, EPA has been providing answers to common stakeholder inquiries in the form of frequently asked questions.

II. What information is available and where is it located?

EPA has published these frequently asked questions in the *Frequent Questions on the Phasedown of Hydrofluorocarbons* web page, available at: <https://www.epa.gov/climate-hfcs-reduction/frequent-questions-phasedown-hydrofluorocarbons>. EPA has also entered a document with the same title and content as the web page noted above in the rulemaking docket titled "Restrictions on Certain Uses of Hydrofluorocarbons under Subsection (i) of the American Innovation and Manufacturing Act." This docket can be accessed on [Regulations.gov](https://www.regulations.gov) using Docket ID No. EPA-HQ-OAR-2021-0643. EPA intends to update the list of questions and answers on the website

and in the docket periodically and may not issue a notice in the **Federal Register** each time that it does so.

Cynthia A. Newberg,

Director, Stratospheric Protection Division.

[FR Doc. 2024-24929 Filed 10-25-24; 8:45 am]

BILLING CODE 6560-50-P

EXECUTIVE OFFICE OF THE PRESIDENT

Office of National Drug Control Policy

Designation of Five Areas as High Intensity Drug Trafficking Areas

AGENCY: Office of National Drug Control Policy (ONDCP), Executive Office of the President.

ACTION: Notice of five High Intensity Drug Trafficking Areas (HIDTA) designations.

SUMMARY: The Director of the Office of National Drug Control Policy designated five additional areas as HIDTAs.

FOR FURTHER INFORMATION CONTACT: Questions regarding this notice should be directed to Shannon Kelly, National HIDTA Director, ONDCP, Executive Office of the President, Washington, DC 20503; (202) 841-5240.

SUPPLEMENTARY INFORMATION: The new areas are (1) Yavapai County in Arizona as part of the Arizona HIDTA; (2) Kankakee County in Illinois as part of the Chicago HIDTA; (3) Rensselaer County in New York as part of the New York/New Jersey HIDTA; (4) Beltrami County in Minnesota as part of the North Central HIDTA; and (5) Stearns County in Minnesota as part of the North Central HIDTA.

Authority: 21 U.S.C. 1706(b)(1).

Dated: October 22, 2024.

Brian Skinner,

General Counsel.

[FR Doc. 2024-24949 Filed 10-25-24; 8:45 am]

BILLING CODE 3280-F5-P

FEDERAL DEPOSIT INSURANCE CORPORATION

FDIC Advisory Committee on Economic Inclusion; Notice of Meeting

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of open meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given of a meeting of the FDIC Advisory Committee on Economic Inclusion. The Advisory Committee will provide advice and recommendations

on initiatives to expand access to banking services by underserved populations. The meeting is open to the public. The public's means to observe this meeting of the Advisory Committee on Economic Inclusion will be both in-person and via a Webcast live on the internet. In addition, the meeting will be recorded and subsequently made available on-demand approximately two weeks after the event. To view the live event, visit <http://fdic.windrosemedia.com>.

DATES: Wednesday, November 13, 2024, from 9 a.m. to 4 p.m.

ADDRESSES: The meeting will be held in the FDIC Board Room on the 6th floor of the FDIC Building located at 550 17th Street NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Requests for further information concerning the meeting may be directed to Debra A. Decker, Committee Management Officer of the FDIC at (202) 898-8748.

SUPPLEMENTARY INFORMATION:

Agenda: The agenda will include updates from Committee members about key challenges facing their communities or organizations. There will be presentations and panel discussions on qualitative research regarding consumer perceptions of banks and non-bank financial services firms, the FDIC's proposed rulemaking on recordkeeping for custodial deposit accounts with transactional features, as well as a review of results from the 2023 FDIC National Survey of the Unbanked and Underbanked Households. The agenda is subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

Type of Meeting: The meeting will be open to the public, limited only by the space available on a first-come, first-served basis. For security reasons, members of the public will be subject to security screening procedures and must present a valid photo identification to enter the building. Observers requiring auxiliary aids (e.g., sign language interpretation) for this meeting should email DisabilityProgram@fdic.gov to make necessary arrangements. This meeting will also be Webcast live via the internet at <http://fdic.windrosemedia.com>. To view the recording, visit [http://fdic.windrosemedia.com/index.php?category=Advisory+Committee+on+Economic+Inclusion++\(Come-IN\)](http://fdic.windrosemedia.com/index.php?category=Advisory+Committee+on+Economic+Inclusion++(Come-IN)). Written statements may be filed with the committee before or after the meeting.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on October 23, 2024.

James P. Sheesley,
Assistant Executive Secretary.

[FR Doc. 2024-25022 Filed 10-25-24; 8:45 am]

BILLING CODE 6714-01-P

**GENERAL SERVICES
ADMINISTRATION**

[Notice MG-2024-03; Docket No. 2024-0002; Sequence No. 19]

**Office of Federal High-Performance
Green Buildings; Green Building
Advisory Committee; Request for
Membership Nominations**

AGENCY: Office of Government-wide Policy, General Services Administration (GSA).

ACTION: Notice of request for membership nominations.

SUMMARY: This notice invites qualified candidates to apply for an appointment to serve as a member of GSA's Green Building Advisory Committee. The Green Building Advisory Committee provides advice to GSA as a statutorily (see below for citations) required Federal advisory committee. This is a competitive process for multiple open membership seats.

DATES: All nominations must be submitted to bryan.steverson@gsa.gov by 5:00 p.m., Eastern Time (ET), by November 27, 2024.

FOR FURTHER INFORMATION CONTACT: Mr. Bryan Steverson, Office of Federal High-Performance Green Buildings, GSA, at bryan.steverson@gsa.gov or 202-501-6115.

SUPPLEMENTARY INFORMATION:

Background

The Administrator of the GSA established the Green Building Advisory Committee (hereafter, "the Committee") on June 20, 2011 (76 FR 118) pursuant to section 494 of the Energy Independence and Security Act of 2007 (42 U.S.C. 17123, or EISA), in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. 1001 *et seq.*). Under this authority, the Committee advises GSA on how the Office of Federal High-Performance Green Buildings can most effectively accomplish its mission. Information about this Office is available online at <https://www.gsa.gov/hpb>, and information about the Committee may be found at <https://www.gsa.gov/gbac>. EISA requires the Committee to be represented by specific categories of members as well as "other relevant

agencies and entities, as determined by the Federal Director" (EISA § 494(b)(1)(B)). The specific categories of members include:

"(i) State and local governmental green building programs;

(ii) Independent green building associations or councils;

(iii) Building experts, including architects, material suppliers, and construction contractors;

(iv) Security advisors focusing on national security needs, natural disasters, and other dire emergency situations;

(v) Public transportation industry experts; and

(vi) Environmental health experts, including those with experience in children's health."

Member Responsibilities

New Committee members will be appointed to a three year term. Membership is limited to the specific individuals appointed and is non-transferrable. Committee members are expected to personally attend all meetings, review all Committee materials, and actively provide their advice and input on topics covered by the Committee. Committee members will not receive compensation, nor will they receive travel reimbursements from the Government except where a need has been demonstrated and funds are available.

Request for Membership Nominations

This notice provides an opportunity for individuals, or others on their behalf, to present their qualifications to serve as a member on the Committee. GSA values and welcomes diversity. In an effort to obtain nominations of diverse candidates, GSA encourages nominations from people of all communities, identities, races, ethnicities, backgrounds, abilities, cultures, and beliefs, including from underserved communities and all geographic locations of the United States of America. No person appointed to serve in an individual capacity shall be a federally registered lobbyist in accordance with the Presidential Memorandum "Lobbyists on Agency Boards and Commissions" (June 18, 2010) and OMB Final Guidance published in the **Federal Register** on October 5, 2011 and revised on August 13, 2014.

**Nomination Process for Advisory
Committee Appointment**

Individuals may nominate themselves or others. All nominees should have:

- At least 5 years of high-performance green building experience, which may

include a combination of project-based, research and policy experience.

- Academic degrees, certifications and/or training demonstrating green building and related sustainability and real estate expertise;
- Knowledge of Federal sustainability and energy laws and programs;
- Proven ability to work effectively with a diverse group of professionals in a collaborative, multidisciplinary environment.

- Qualifications appropriate to a specific statutory category of members listed above.

A nomination package shall include the following information for each nominee:

(1) A letter of nomination stating the name, title and organization of the nominee, nominee's field(s) of expertise, specific qualifications to serve on the Committee, and description of interest and qualifications;

(2) A professional resume or CV; and

(3) Complete contact information including name, return address, email address, and daytime telephone number of the nominee and nominator.

GSA reserves the right to choose Committee members based on qualifications, experience, Committee balance, statutory requirements and all other factors deemed critical to the success of the Committee. Candidates under consideration may be asked to provide specific financial information to ensure that the interests and affiliations of advisory committee members are reviewed for conformance with applicable conflict of interest statutes and other Federal ethics rules.

Kinga Porst Hydras,

Acting Federal Director, Office of Federal High-Performance Green Buildings, Office of Government-Wide Policy, General Services Administration.

[FR Doc. 2024-24971 Filed 10-25-24; 8:45 am]

BILLING CODE 6820-14-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC-2024-0085, NIOSH-153-F]

Request for Public Comment on the Draft Skin Notation Profiles: Allyl Alcohol, Formamide, Formic Acid, Phenothiazine, and Picric Acid

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) in the Centers for Disease Control and Prevention (CDC), an Operating Division of the Department of Health and Human Services (HHS), requests public comment on the draft Skin Notation Profiles: Allyl alcohol, Formamide, Formic Acid, Phenothiazine, and Picric Acid.

DATES: Electronic or written comments must be received by December 27, 2024.

ADDRESSES: You may submit comments, identified by docket number CDC-2024-0085 and docket number NIOSH-153-F, by either of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, OH 45226-1998.

Instructions: All information received in response to this notice must include the agency name and docket number (CDC-2024-0085; NIOSH-153-F). All relevant comments, including any personal information provided, will be posted without change to <https://www.regulations.gov>. Do not submit comments by email. CDC does not accept comments by email. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Naomi Hudson, DrPH, National Institute for Occupational Safety and Health, MS C-15, 1090 Tusculum Avenue, Cincinnati, OH 45226-1998. Telephone: (513) 533-8388.

SUPPLEMENTARY INFORMATION: NIOSH is requesting public comment on draft Skin Notation Profile documents for the chemicals Allyl alcohol, Formamide, Formic Acid, Phenothiazine, and Picric Acid. To facilitate the review of these documents, NIOSH requests responses to the following specific questions for each draft Profile document:

1. Does this document clearly outline the systemic health hazards associated with exposures of the skin to the chemical? If not, what specific information is missing from the document?

2. If the SYS or SYS (FATAL) notations are assigned, are the rationale and logic behind the assignment clear? If not assigned, is the logic clear why it was not (e.g., insufficient data, no identified health hazard)? If not clear, what clarification is suggested?

3. Does this document clearly outline the direct (localized) health hazards associated with exposures of the skin to

the chemical? If not, what specific information is missing from the document?

4. If the DIR, DIR (IRR), or DIR (COR) notations are assigned, are the rationale and logic behind the assignment clear? If not assigned, is the logic clear why it was not (e.g., insufficient data, no identified health hazard)? If not clear, what clarification is suggested?

5. Does this document clearly outline the immune-mediated responses (allergic response) associated with exposures of the skin to the chemical? If not, what specific information is missing from the document?

6. If the SEN notation is assigned, are the rationale and logic behind the assignment clear? If not assigned, is the logic clear why it was not assigned (e.g., insufficient data, no identified health hazard)? If not clear, what clarification is suggested?

7. If the ID (SK) or SK were assigned, are the rationale and logic outlined clearly within the document? If not clear, what clarification is suggested?

8. Are the conclusions supported by the data? If not, what changes are suggested?

9. Are the tables clear and appropriate? If not, what changes are suggested?

10. Are you aware of any scientific data reported in governmental publications, databases, peer-reviewed journals, or other sources that should be considered within this document? Please include the full reference citation for any additional scientific data to be considered.

11. There have been considerable improvements and advancements in dermal absorption studies and modeling since the publication of NIOSH Current Intelligence Bulletin 61: A Strategy for Assigning New NIOSH Skin Notations [NIOSH 2017]. In response to expert external peer reviewers' comments regarding the limitation of the skin to inhalation dose (SI) ratio information, the SI ratio was removed from the individual skin notation profile documents. Do you have any information to support removing or including the SI ratio information in these NIOSH documents?

The draft Skin Notation Profiles were developed to provide the scientific rationale behind the development of skin notation designations for the following chemicals:

- Allyl alcohol (CAS: 107-18-6)
- Formamide (CAS: 75-12-7)
- Formic acid (CAS: 64-18-6)
- Picric acid (CAS: 88-89-1)
- Phenothiazine (CAS: 92-84-2)

The Skin Notation Profiles provide a detailed summary of the health hazards

of chemical exposure to the skin. The final publication, which will address public comments, will be available on the NIOSH website and in the NIOSH docket (153-F) and in *Regulations.gov* (CDC-2024-0085).

Background: In 2009, NIOSH published Current Intelligence Bulletin (CIB) 61: A Strategy for Assigning New NIOSH Skin Notations [NIOSH 2009]. The CIB presents a strategic framework that is a form of hazard identification designed to do the following:

- Ensure that the assigned skin notations reflect the contemporary state of scientific knowledge
- Provide transparency behind the assignment process
- Communicate the hazards of chemical exposures of the skin
- Meet the needs of health professionals, employers, and other interested parties in protecting workers from chemical contact with the skin.

This strategy involves the assignment of multiple skin notations for distinguishing systemic (SYS), direct (DIR), and sensitizing (SEN) effects caused by exposure of skin (SK) to chemicals. Chemicals that are highly or extremely toxic and may be potentially lethal or life-threatening following exposures of the skin are designated with the systemic subnotation (FATAL). Potential irritants and corrosive chemicals are indicated by the direct effects subnotations (IRR) and (COR), respectively. The five draft Skin Notation Profiles available for review were developed following the framework in NIOSH CIB 61.

Reference

NIOSH [2009]. Current Intelligence Bulletin 61: A strategy for assigning new NIOSH skin notations. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication 2009-147, <https://www.cdc.gov/niosh/docs/2009-147/>.

Dated: October 23, 2024.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

[FR Doc. 2024-24983 Filed 10-25-24; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10856]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Withdrawal

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice; withdrawal.

SUMMARY: On Thursday, September 26, 2024, the Centers for Medicare & Medicaid Services (CMS) published a 30-day Paperwork Reduction Act of 1995 notice entitled, “Agency Information Collection Activities: Submission for OMB Review; Comment Request.” The notice invited public comment on Document Identifier: CMS-10856; Title of Information Collection: Medicaid Managed Care and Supporting Regulations; and Form Number: CMS-10856 (OMB control number 0938-1453). Through the publication of this document we are withdrawing the September 26, 2024, notice in its entirety.

DATES: This withdrawal is applicable on October 28, 2024.

SUPPLEMENTARY INFORMATION: Through the publication of this notice we are withdrawing FR document 2024-21982 which published in the **Federal Register** on September 26, 2024 (89 FR 78875). Upon further review the associated collection of information request was not ready for public review and comment. The 30-day notice will republish at a date to be determined.

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-25019 Filed 10-25-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10912]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by December 27, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: __, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10912 Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request; *Use:* Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (“the Act”). The Act establishes the Negotiation Program to negotiate maximum fair prices (“MFPs”), defined at 1191(c)(3) of the Act, for certain high expenditure, single source selected drugs covered under Medicare Part B and Part D (“selected drugs”). In accordance with section 1193(a) of the Act, any Primary Manufacturer of a selected drug that continues to participate in the Negotiation Program and reaches agreement upon an MFP must provide access to the MFP to MFP-eligible individuals, defined in section 1191(c)(2)(A) of the Act, and to pharmacies, mail order services, other

dispensing entities, providers and suppliers with respect to such MFP-eligible individuals who are dispensed that selected drug during a price applicability period. The purpose of this information collection request (ICR) is for CMS to collect information from manufacturers of drugs covered under Part D selected for negotiation under the Inflation Reduction Act for the initial price applicability years 2026 and 2027 and the dispensing entities that dispense the selected drugs to MFP-eligible individuals. To facilitate the effectuation of the MFP, CMS will engage a Medicare Transaction Facilitator (“MTF”). The MTF system will be composed of two modules: the MTF Data Module (MTF DM), and the MTF Payment Module (MTF PM).

Medicare Transaction Facilitator Data Elements: The MTF system will be composed of two modules: the MTF Data Module (MTF DM), and the MTF Payment Module (MTF PM). Primary Manufacturers participating in the Negotiation Program are required to participate in the MTF DM. Further, CMS intends to propose in future rulemaking to require Part D plan sponsors to include in their pharmacy agreements provisions requiring dispensing entities to participate in the MTF DM for purposes of data exchange. As such, for the purposes of this ICR, CMS assumes full participation in the MTF DM by affected Primary Manufacturers and dispensing entities. Meanwhile, participation in the MTF PM, for use in passing through payment from the Primary Manufacturer to dispensing entities, will be optional for Primary Manufacturers; as a result, dispensing entities may receive fund transfers from the MTF PM, or via an alternative process established by a Primary Manufacturer. As discussed in section 40.4 of the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (“final guidance”), CMS will engage the MTF DM to facilitate the exchange of certain claim-level data elements and payment elements for selected drugs. The data exchange component of the MTF will involve both the transmission of certain claim-level data elements to the Primary Manufacturer and receipt of claim-level payment elements from the Primary Manufacturer. Both Primary Manufacturers and dispensing entities will need to provide certain information at the onset of their enrollment in the

MTF DM system to facilitate effectuation of the MFP via refunds from Primary Manufacturers. Both Primary Manufacturers and dispensing entities will be able to submit complaints and disputes through their participation in the MTF DM. Primary Manufacturers will also submit information to fulfill their requirement to provide an MFP Effectuation Plan and transmit recurring data submissions reflecting their payment elements, as described in the final guidance. Given these information collection requirements, this ICR includes the following forms: (A) Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Enrollment Form; (B) Drug Price Negotiation Program MTF DM Primary Manufacturer Maximum Fair Price (MFP) Effectuation Plan Form; (C) Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form; and (D) Drug Price Negotiation Program Complaint and Dispute Intake Form. *Form Number:* CMS-10912 (OMB control number: 0938-New); *Frequency:* Once and Daily; *Affected Public:* Private sector, Business or other for-profit, and individuals; *Number of Respondents:* 85,853; *Total Annual Responses:* 93,120; *Total Annual Hours:* 821,560. (For policy questions regarding this collection contact Brennan Folsom at 667-414-0014.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-25009 Filed 10-25-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10261]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of

information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *November 27, 2024*.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To

comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Part C Medicare Advantage Reporting Requirements; *Use:* The Centers for Medicare and Medicaid Services (CMS) established reporting requirements for Medicare Advantage Organizations (MAOs) under the authority described in 42 CFR 422.516(a). Each MAO must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public at the times and in the manner that CMS requires. At the same time, each MAO must, in accordance with 42 CFR 422.516(a), safeguard the confidentiality of the provider-patient relationship.

Health plans can use this information to measure and benchmark their performance. CMS receives inquiries from the industry and other interested stakeholders about the beneficiary use of available benefits, including supplemental benefits, grievance and appeals rates, cost, and other factors pertaining to use of government funds, as well as the performance of MA plans. *Form Number:* CMS-10261 (OMB control number: 0938-1054); *Frequency:* Yearly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 783; *Total Annual Responses:* 7,830; *Total Annual Hours:* 225,575. (For policy questions regarding this collection contact Lucia Patrone at 410-786-8621 or Lucia.Patrone@cms.hhs.gov).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-25015 Filed 10-25-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Request for Information: Administration for Children and Families Development of Interoperability Standards for Human Service Programs

AGENCY: Office of the Chief Technology Officer, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for information (RFI).

SUMMARY: The Administration for Children and Families (ACF), in the U.S. Department of Health and Human Services (HHS), invites public comments to inform the use or adoption of interoperability standards for human services programs. ACF and state, local, and tribal governments all provide a number of health and human services programs for children, youth, families, communities, and individuals. ACF seeks public comment on the most effective approaches, technical standards, and technological tools that currently or could promote interoperability between health and human services programs. ACF collaborates with the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) as a critical steward and advisor for human services interoperability with responsibility for leading the development and harmonization of interoperability standards between health and human services in line with the HHS Data Strategy. The potential of interoperability across the full spectrum of health and human services is immense—it can enable efficient delivery of government services, enhance access to critical non-profit programs, and most importantly, improve overall individual and community outcomes. ACF has authority under the Title IV of the Social Security Act to designate use of interoperable data standards for several of its programs (e.g., Temporary Assistance for Needy Families (TANF), child support, child welfare, and foster care). The purpose of this RFI is to understand how ACF, in collaboration with ASTP/ONC, can better support interoperability between human services within and across states and local community resources, between states, and ACF.

DATES: Comments are due within 60 days of publication.

ADDRESSES: Submit responses to DataRx@acf.hhs.gov, a federal mailbox allowing the public to submit comments on documents agencies have published in the **Federal Register** and are open for comment. Simply type "ACF-2024-Interoperability-RFI" in the Comment or Submission search box, click Go, and follow the instructions for submitting comments.

Comments submitted in response to this notice are subject to the Freedom of Information Act and may be made available to the public. For this reason, please do not include any information of a confidential nature, such as sensitive personal information or

proprietary information. If you submit your email address, it will be automatically captured and included as part of the comment placed in the public docket. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public, notwithstanding the inclusion of the routine notice.

SUPPLEMENTARY INFORMATION:

1. Background

The Administration for Children and Families (ACF) requests comments to inform the use of interoperable data standards across human services programs. This will improve the quality of service delivery and increase efficiency in collaborations between agencies administering ACF programs and other government and non-government agencies that serve the same populations.

1.1 Regulation Development Process

The data exchange standardization requirements under the Social Security Act Title IV programs of child welfare and foster care (Titles IV–B and IV–E), child support (Title IV–D), and Temporary Assistance for Needy Families (TANF, Title IV–A) result from Public Laws 112–34,¹ 112–96,² 113–183,³ and 115–123.⁴ These laws require the designation of interoperable standards for data that must be exchanged: (1) between states and ACF; and/or (2) between states under specified programs.

ACF's Office of the Chief Technology Officer (OCTO) will lead the drafting of any regulations with respect to the programs described above with subject matter expertise from ACF program offices including, but not limited to, the Children's Bureau (CB), Family and Youth Services Bureau (FYSB), Office of Early Childhood Development (ECD), Office of Child Care (OCC), Office of Head Start (OHS), Office of Child Support Services (OCSS), Office of Community Services (OCS), Office of Family Assistance (OFA), and Office of Family Violence and Prevention Services (OFVPS).

Additionally, OCTO will coordinate and consult on the input received in response to this RFI both with the ASTP/ONC and with other agencies executing programs and policies involving human services interoperable data standards, such as the Centers for Medicare & Medicaid Services (CMS), Administration for Community Living (ACL), and the Health Resources and Services Administration (HRSA).

ASTP/ONC enable standards on behalf of HHS under section 3004 of the Public Health Service Act (PHSA) in 45 CFR part 170 Subpart B. As lead for the development and harmonization of interoperability standards between health and human services, ASTP/ONC may enable standards for human services which will be available for use by any HHS program, including ACF. Adopting standards in one location for HHS use enables alignment across HHS programs to further interoperability, including alignment described under Sections 13111 and 13112 of the Health Information Technology for Economic and Clinical Health Act ("HITECH Act") (Pub. L. 111–5, Title XIII, secs. 13111 and 13112).

1.2 For the Purposes of This Notice

Interoperability refers to the ability of different information systems, devices, or applications to connect, in a coordinated way, within and beyond organizational boundaries to access, exchange, and use data in a cooperative way between stakeholders, with the aim of optimizing the health and wellbeing of individuals and populations (adapted from HIMSS, 2019).⁵ The definition of interoperability in section 4003 of the 21st Century Cures Act calls for all electronically accessible information to be accessed, exchanged, and used without special effort on the user's part (Pub. L. 114–255).

Standards, for the purposes of this RFI, refer to any documented, consistent, and repeatable method for exchanging data through technical or non-technical means. There are technical standards for electronic data exchange, such as through data exchange standards, including Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR®). There are also standards of practice in the context of business processes, such as protocols for encryption, hashing, or establishment of accessible websites. These standards of practice are often codified in policies, interagency agreements, memoranda of understanding, service-level agreements, etc.

Human Services Interoperability refers to the ability of health and human service systems to exchange data for service planning, coordination, delivery, monitoring, and evaluation in an automated, standards-based, and integrated manner that improves outcomes for children, families, and communities. Human services refer to programs that may not exclusively be provided or funded by HHS but may include those funded through other federal agencies. Human services

include a wide variety of programs and services to enhance the quality of life, promote well-being, and address the needs of individuals and communities.

1.3 Purpose of Interoperable Data Standardization for Interoperability

The purpose of designating interoperable data standards is to ensure all parts of the human services delivery ecosystem can effectively and efficiently exchange information between and among programs for seamless service delivery. Effective and efficient information exchange can help appropriately reach people and deliver the right benefits, supporting coordinated case management, benefits enrollment, and new service delivery models. Interoperability promotes many objectives, from the availability of higher quality, more recent data that can be used to appropriately reach people and deliver the right benefits to coordinated case management, benefits enrollment, and new service delivery models.

Using timely and quality data, for example, a child welfare caseworker might be able to retrieve a family's current address from child support data to locate the family for an in-person visit or locate the non-custodial parent for possible placement of the children. Interoperable data standards between a public child welfare agency with care and custody of a child and a foster care placing agency could ensure both agencies have the most current information on the child in care. Interoperability can also help identify if household composition has changed, or a recipient has moved out of state, and changes to benefits levels are needed. For example, if a parent was reunited with their children exiting foster care, data sharing across information systems would allow the TANF agency to update the benefit eligibility for the family. Widespread adherence to data standards can enable better interoperability and reduce the burden of connecting disparate systems containing the information described in this example.

Interoperable data standards can also help to facilitate initiatives. For example, a Medicaid applicant works with a health insurance navigator during the annual Marketplace enrollment period and participates in a Social Determinants of Health (SDOH) questionnaire with the navigator, who recognizes that the applicant is experiencing challenges in securing adequate food and necessary clothing. The navigator could pre-fill an enrollment application for SNAP benefits and provide information to complete the enrollment. Also, the

navigator can provide the Medicaid applicant with the local food bank's name, location, phone number, and a resource for the community clothing closet. Further, with the Medicaid applicant's consent, the navigator can send an electronic message or alert to the local non-profits identified in a statewide network of non-profit community resources, allowing receiving organizations to reach out to the applicant to determine if they need additional support to get connected with services. Common standards can help simplify the complex interactions between different systems described in this scenario and ensure scalability as new entities seek to participate in the exchange.

ACF believes that designating nationally recognized interoperable data standards in the programs described above will make it easier to share data across multiple organizations. While likely more effective and cost-effective in the long run, ACF also recognizes that this approach may initially involve financial and time costs related to updating proprietary systems to use open standards. Therefore, as part of any future ACF programmatic and policy development, and in coordination with ASTP/ONC, ACF seeks to strike the appropriate balance between the benefits of interoperability and standardization and ease of implementation.

2. Legal Authority

Federal statutes require ACF to designate interoperable data standards to promote data exchange in state human services programs at the state level and with the federal government. Most recently, the Family First Prevention Services Act (FFPSA), enacted as part of Public Law (Pub. L.) 115–123, authorized optional Title IV–E funding for time-limited prevention services for mental health, substance abuse, and in-home parent skill-based programs for children or youth who are candidates for foster care, pregnant or parenting youth in foster care, and the parents or kin caregivers of those children and youth. This law amended Title IV–B of the Social Security Act to require that ACF must “designate data exchange standards to govern . . . (1) necessary categories of information that State agencies operating programs under State plans approved under this part are required under applicable Federal law to exchange with another State agency electronically; and (2) Federal reporting and data exchange required under applicable Federal law” (42 U.S.C. 629m(a)).

The statute further provides that ACF shall incorporate, to the extent practical, interoperable standards developed and maintained by intergovernmental partnerships and federal agencies with authority over contracting and financial assistance. The data exchange reporting standards shall incorporate a widely accepted, nonproprietary, searchable, computer-readable format; be consistent with and implement applicable accounting principles; be implemented in a manner that is cost-effective and improves program efficiency and effectiveness; and be capable of being continually upgraded as necessary (42 U.S.C. 629m(b)).

Additionally, ACF coordinates with the ASTP/ONC in a manner consistent with Sections 13111 and 13112 of the HITECH Act to ensure alignment across HHS and non-HHS agencies around health IT standards. ASTP/ONC adopts on behalf of HHS under section 3004 of the PHSA in 45 CFR part 170 Subpart B. ACF coordinates with ASTP/ONC pursuant to the provisions of the HITECH Act above when adopting, implementing, or upgrading health IT systems used for the direct exchange of individually identifiable health information between agencies and non-Federal entities.

The extent of data elements that need to be shared to enable improved service delivery and program management often exceeds the minimum legal requirements. As described throughout ACF's Confidentiality Toolkit⁶ in the Applicable Federal Legislation sections, data sharing beyond the minimum regulatory requirements (as referenced throughout this RFI) is permissible and encouraged when practical use cases exist.

3. Current Interoperability Standards and Initiatives

3.1 FHIR and Gravity Project

HL7[®] Fast Healthcare Interoperability Resources (FHIR[®]) is a rapidly maturing interoperability standard based on modern internet technology approaches. FHIR goes beyond document-level interoperability to data element-level exchange. It uses standardized application programming interface (API) standards to facilitate interoperable data standards, enabling more efficient application development across multiple device types. There is a growing open-source community developing around FHIR implementation.⁷

Today, several stakeholder efforts are underway to extend the use of FHIR to support the interoperability of human services information. For instance, the

Gravity Project⁸ is a stakeholder-led initiative to identify and harmonize social risk factor data for interoperable electronic health information exchange. The HL7 Gravity Accelerator⁹ established codes for data elements such as housing instability, food insecurity, transportation insecurity, etc. It creates a common terminology for exchanging content related to non-medical factors influencing health and human services outcomes. Another HL7 group is the Health and Social Services (HSS) Work Group, supported by ACF, which is focused on facilitating human services data content further. A project description of Enhancing the FHIR for Social Services and Social Determinants (EFSS) and a list of use cases can be found in Appendices 1 and 2.

3.2 United States Core Data for Interoperability (USCDI/USCDI+)

In the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* final rule (85 FR 25642)¹⁰ published in May 2020, ASTP/ONC adopted the United States Core Data for Interoperability (USCDI)¹¹ standard, which describes a standardized set of health data and constituent data elements for nationwide, interoperable health information exchange (85 FR 25669). USCDI is implemented in FHIR by mapping data elements and value sets to FHIR resources and implementation guides through the US Core Implementation Guide.¹² ASTP/ONC published Version 3 of the USCDI in July 2022¹³ and subsequently adopted Version 3 as the new baseline for the ASTP/ONC Certification Program in the *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing* (HTI–1) Final Rule (89 FR 1210). Version 3 included new data elements for social determinants of health (SDOH), which includes SDOH Problems/Health Concerns, SDOH Interventions, SDOH Goals, and SDOH Assessments. USCDI Version 4, published in July 2023,¹⁴ added 20 data elements to help address and mitigate health and healthcare inequities and disparities. Additional priorities for USCD v4 were to address underserved communities' needs, behavioral health integration with primary care and other physical care, and public health interoperability needs of reporting, investigation, and emergency response.

Further, ASTP/ONC oversees the USCDI+¹⁵ initiative to support identifying and establishing domain, or program-specific, datasets that build on the existing USCDI. Specifically, USCDI+ is a service that ASTP/ONC

provides to federal and industry partners to establish, harmonize, and advance the use of interoperable datasets that extend beyond the core data in the USCDI to meet specific programmatic and/or use case requirements. This approach allows ASTP/ONC to assure that new datasets build from the same core USCDI foundation, and allows for alignment of similar data needs across agency programs and corresponding data users and/or participants at the state and local levels.

3.3 Human Services Interoperability Innovations (HSII) Demonstration Program

ACF has focused on programmatic investments to advance human services interoperability. ACF's Human Services Interoperability Innovations (HSII) demonstration program¹⁶ was intended to expand data-sharing efforts by state and local governments, tribes, and territories to improve human services program delivery and to identify novel data-sharing approaches that can be replicated in other jurisdictions. These investments enabled ACF to fund entities to focus on addressing longstanding barriers to interoperability through cooperative agreements for the HL7 Care Plan for Maternal Opioid Misuse and the implementation of FHIR operating systems necessary to support Centers for Medicare and Medicaid Innovation (CMMI) Integrated Care for Kids model grantees in both New Jersey and Connecticut.

3.4 HL7 Human and Social Services (HSS) Workgroup

ACF led the creation of the HL7 Human and Social Services (HSS) Workgroup.¹⁷ The HSS Workgroup's mission is to provide a space to design and validate HL7 interoperable human services data standards. The group is also developing a common format for social services provider directory information. This project maps the definitions from Open Referral to the FHIR standard using an FHIR Facade before the Human Services Data API (HSDA).

4. Proposed Direction for Developing Interoperable Data Standards

The health sector has increasingly looked to FHIR as a core standard, catalyzed by the industry's embrace of FHIR and codified through the incorporation of ASTP/ONC-certified health IT systems featuring FHIR APIs into CMS program requirements for use of certified electronic health record technology (CEHRT) (for instance, Medicare Promoting Interoperability

Program and the Promoting Interoperability performance category of the Merit-Based Incentive Payment System (MIPS)),¹⁸ and ASTP/ONC's efforts to incorporate FHIR as part of the technical requirements for the Trusted Exchange Framework Common Agreement (TEFCA).¹⁹ Given the need for human services data to be interoperable with health data to support integrated case management at the person level and in light of the opportunity to significantly leverage health sector infrastructure such as Qualified Health Information Networks (QHINs) and existing data exchange pathways using FHIR, ACF is considering the HL7 FHIR standard as the foundation of data interoperability for ACF-covered domains.

5. Request for Information

ACF seeks a more interoperable human services data ecosystem with available and shareable data between care providers, programs, and the government to drive improved outcomes for children and families. To deliver that goal, more consistent use of interoperable standards and practices is needed at all levels. ACF recognizes that organizations may be limited in major IT system transitions without significant new funding. However, without government-backed standards, pilots, and processes, the current and future IT systems will maintain and even accelerate their current degree of fragmentation. Therefore, ACF is seeking input on how to support a drive toward interoperability across the field in economical, efficient, effective, and reasonable ways.

ACF also seeks feedback on proposed initial domain focus areas for standards development and pilots. These focus areas may encompass areas where HHS/ASTP/ONC and ACF have formal regulatory powers to set standards for child welfare and foster care as well as prevention, adoption and guardianship (Title IV–B and IV–E), child support (Title IV–D), and Temporary Assistance for Needy Families (TANF, Title IV–A). It also includes areas where ACF could engage more actively with standards development organizations, such as the HL7 Human and Social Services (HSS) Workgroup (currently focusing on food, housing, and economic insecurity as its priority use cases). We are interested in receiving input affecting additional programs.

ACF requests comments on the following topics. Please comment or respond to any questions that apply from the perspective of your agency, organization, program, or setting;

commenters are not required to respond to every question:

Input on specific topics

1. Practical enablers of/or barriers to interoperability:

1.1 Provide examples of the key enablers and/or inhibitors to using interoperable human services data standards (including data content and data exchange) in your program or agency.

1.2 How is the ability to exchange human services data impacted by state or federal law, policies, or other governing frameworks (including CMS Interoperability rules)?

1.3 What is the highest priority legal, policy, or governance issues to be addressed when moving to an interoperable ACF environment? (*e.g.*, minor consent, guardianship, Family Education Rights and Privacy Act (FERPA), privacy, security, sensitive data, parental controls, etc.)

1.4 Describe any mitigation strategies or policy levers that have effectively moved interoperable human services data exchange forward in your organization, state, or program.

2. Impact of lack of human services interoperable data standardization: Provide examples of existing and planned human services interoperable data efforts and to what degree, if any, does a lack of standardization negatively impact them.

2.1 What interoperable data standards are being used today in ACF-funded programs?

2.2 Describe any impediments experienced in current systems when accessing, analyzing, or sending data to the federal level.

2.3 What are the benefits of moving to a common interoperable data standard like Fast Healthcare Interoperability Resources (FHIR)?

3. Care coordination: ACF seeks comments on current care coordination activities and data standards to support the interoperable data exchange for service delivery, operations, and reporting.

3.1 How do you currently use interoperable data to support care coordination across human services, both between human services programs and between human services and health services? For example, are you able to collect medical data for children who have medical issues?

3.2 Describe use cases that benefit from interoperable data standards for advancing service coordination activities among state and federal programs (*e.g.*, clinical, administrative, operations). Tell us about systems currently used that are API-enabled.

3.3 What are the most important use cases where interoperable data standards or exchange protocols must be piloted/validated?

3.4 What federal support would be necessary or helpful to catalyze those efforts?

4. Interoperable data standards needed for operations and reporting: ACF recognizes that not all systems operate using interoperable data standards, and as a result, not all applications are capable of data exchange. Since 2021, ACF has sponsored an HL7 Human and Social Services (HSS) workgroup to develop data standards using FHIR specifications for Human and Social Services.

4.1 What ACF domains or programs would benefit from using an interoperable data standard for business operation and reporting?

4.2 To what extent is the HL7 or the HL7 FHIR standard used in ACF programs today?

4.3 Will your organization experience specific benefits or drawbacks if an interoperable data standard like FHIR is widely used in ACF programs?

4.4 Should any domain or program be exempt from using a standard like FHIR?

5. Standards in practice: In cases where human services data systems currently use interoperable data standards, describe how they do or do not incorporate the following:

5.1 Interoperable standards developed and maintained by an international voluntary consensus standards body such as HL7.

5.2 Interoperable standards developed and maintained by intergovernmental partnerships such as the National Information Exchange Model (NIEM).

5.3 Interoperable standards developed and maintained by specific federal agencies with authority over contracting and financial assistance.

6. Intra- and inter-state human services data sharing: Describe the types of human services agencies in your state that electronically exchange with other states, state agencies, or community organizations in healthcare or human services within your state.

6.1 How are they aligned, or not, with a specific industry standard(s), e.g., FHIR, to ensure ease of access and use of interoperable data?

6.2 What types of systems and non-proprietary, open-data standards are used to facilitate interoperability across programs?

6.3 Are there tools in use for normalizing and/or harmonizing data to standards?

6.4 Tell us about any significant data quality and matching issues to be addressed to make the data exchange meaningful.

6.5 What additional infrastructure would need to be developed to ensure that data is interoperable and actively exchanged?

7. Funding: Describe current funding mechanisms that support or hinder interoperable data systems' design, development, and implementation.

7.1 What types of funding have you leveraged to design, develop, and implement interoperable data systems (e.g., Advance Planning Documents and grants)?

7.2 What incentives or requirements would be needed to drive key use cases of data exchange once systems are interoperable (e.g., data quality and/or identity management)?

7.3 What barriers or challenges have you encountered with these funding mechanisms?

8. Technical Assistance: What technical assistance have you leveraged in designing, developing, and implementing interoperable data systems?

8.1 What technical assistance (such as subject matter expertise in data standards and coding/software development) would be necessary to move to an interoperable standard like FHIR?

8.2 What top actions should the federal government take to provide technical assistance to encourage human services interoperability?

9. United States Core Data for Interoperability (USCDI/USCDI+): Provide input to inform how ACF may identify, create, and standardize human services data elements leveraging the ASTP/ONC USCDI+ initiative, HL7 FHIR, and relevant HHS policy levers, including applicable regulations, to improve interoperability for human services programs. 9.1 How could an initiative such as USCDI+ be leveraged to harmonize human services data needed for care coordination, program evaluations, and reporting requirements?

9.2 What is the highest priority use case(s) that need further development in USCDI+ and FHIR to address ACF's stakeholders' needs?

9.3 What data elements are a high priority to enable comprehensive case management, including whole-person care, referrals, and research?

9.4 What technical and policy approaches effectively link human services data to health IT codes and

value sets to help improve interoperability, and use across multiple systems and domains?

10. General questions—Provide input on the current state of data that your organization receives and/or exchanges.

10.1 What information do you exchange, if any, and from whom?

10.2 What information to you currently collect and from whom?

10.3 What information do you need to exchange, that you have trouble exchanging and with whom? How does that challenge impact your work, community, etc.?

11. Other considerations: ACF welcomes comments on other aspects of recognizing and establishing interoperable data standards for human services programs you wish to provide.

Kevin M. Duvall,

Chief Technology Officer, Administration of Children and Families.

Endnotes

¹ Public Law 112–34—Child and Family Service Improvement and Innovation Act. (2011). Retrieved from <https://www.govinfo.gov/app/details/PLAW-112publ34/summary>.

² Public Law 112–96—Middle Class Tax Relief and Job Creation Act. (2012). Retrieved from <https://www.govinfo.gov/app/details/PLAW-112publ96/summary>.

³ Public Law 113–183—Preventing Sex Trafficking and Strengthening Families Act. (2014). Retrieved from <https://www.govinfo.gov/app/details/PLAW-113publ183/summary>.

⁴ Public Law 115–123—Bipartisan Budget Act of 2018. (2018). Retrieved from <https://www.govinfo.gov/app/details/PLAW-115publ123/summary>.

⁵ Health Information Management Systems Society: Interoperability Definition. (2021). Retrieved from HIMSS writes new definition of interoperability—Digital-health.

⁶ Administration of Children and Families (ACF): Confidentiality Toolkit. (2021). Retrieved from <https://www.acf.hhs.gov/opr/report/confidentiality-toolkit>.

⁷ Redox. Popular Open Source FHIR Libraries. (2021). Retrieved from <https://www.redoxengine.com/blog/popular-open-source-fhir-libraries/>.

⁸ Health Level Seven (HL7) Confluence. (2023). The Gravity Project. Consensus-driven standards on social determinants of health. Retrieved from <https://confluence.hl7.org/display/GRAV/The+Gravity+Project>.

⁹ HealthITbuzz. (2022). FAST Continues FHIR Scalability Work as a New HL7 FHIR Accelerator. Retrieved from <https://www.healthit.gov/buzz-blog/health-it/fast-continues-fhir-scalability-work-as-a-new-hl7-fhir-accelerator>.

¹⁰ National Archives Federal Register. (2020). 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. Retrieved from <https://www.federalregister.gov/documents/2020/05/>

01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-ona-health-it-certification.

¹¹ Office of the National Coordinator for Health IT. (2023). United States Core Data for Interoperability (USCDI). Retrieved from <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>.

¹² Office of the National Coordinator for Health IT. (2023) United States Core (US Core) Fast Healthcare Interoperability Resources (FHIR) Retrieved from <https://hl7.org/fhir/us/core/history.html>.

¹³ Office of the National Coordinator for Health IT. (2023) United States Core (US Core) Fast Healthcare Interoperability Resources (FHIR) Retrieved from <https://hl7.org/fhir/us/core/history.html>.

¹⁴ Office of the National Coordinator for Health IT. (2023). United States Core Data for Interoperability. Retrieved from <https://www.healthit.gov/isa/sites/isa/files/2023-10/USCDI-Version-4-October-2023-Errata-Final.pdf>.

¹⁵ Office of the National Coordinator for Health IT. (2023). United States Core Data for Interoperability Plus (USCDI+). Retrieved from <https://www.healthit.gov/topic/interoperability/uscdi-plus>.

¹⁶ Office of Planning, Research and Evaluation an Office of the Administration of Children & Families. (2023). Human Services Interoperability Innovations (HSII). Retrieved from <https://www.acf.hhs.gov/opre/project/human-services-interoperability-innovations-hsii-2020-2021>.

¹⁷ Health Level Seven (HL7) Confluence. (2023). Human and Social Services Home. Retrieved from <https://confluence.hl7.org/display/HSS/Human+and+Social+Services+Home>.

¹⁸ Centers for Medicare & Medicaid Services. (2020). CMS Interoperability and Patient Access Final Rule (CMS-9115-F). Retrieved from <https://www.cms.gov/interoperability/policies-and-regulations/cms-interoperability-and-patient-access-final-rule-cms-9115-f>.

¹⁹ The Sequoia Project. (2022). FHIR Roadmap v1.0. Retrieved from https://rce.sequoiaproject.org/wp-content/uploads/2022/01/FHIR-Roadmap-v1.0_updated.pdf.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection

Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Behavioral Health Integration Evidence Based Telehealth Network Program Outcome Measures

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than December 27, 2024.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland, 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Behavioral Health Integration Evidence Based Telehealth Network Program Outcome Measures, OMB No. 0906-xxxx—New.

Abstract: This clearance request is for OMB approval of a new information collection, the Behavioral Health Integration Evidence Based Telehealth Network Program (BHI EB-TNP) Outcome Measures. Under the BHI EB-TNP, HRSA administers grants in accordance with section 330I(d)(1) of the Public Health Service Act (42 U.S.C. 254c-14(d)(1)). The purpose of this program is to integrate behavioral health services into primary care settings using telehealth technology through telehealth networks and evaluate the effectiveness of such integration. This program supports evidence-based projects that utilize telehealth technologies through telehealth networks in rural and underserved areas to (1) improve access to integrated behavioral health services in primary care settings; and (2) expand and improve the quality of health information available to health care providers by evaluating the effectiveness of integrating telebehavioral health services into primary care settings and establishing

an evidence-based model that can assist health care providers. HRSA created a set of outcome measures to evaluate the effectiveness of grantees' services programs and monitor their progress using performance reporting data. The measures address behavioral health and substance use disorder priorities, originating and distant sites, specialties and services by site, volume of services by site and specialty, patient travel miles saved, and other uses of the telehealth network.

Need and Proposed Use of the Information: HRSA's goals for the program are to improve access to needed services, reduce rural practitioner isolation, improve health system productivity and efficiency, and improve patient outcomes. HRSA worked with program grantees to develop outcome measures to evaluate and monitor the progress of the grantees in each of these categories, with specific indicators to be reported annually through a performance monitoring data collection platform/website. Measures capture awardee-level and aggregate data that illustrate the impact and scope of program funding along with assessing these efforts. The measures are intended to inform HRSA's progress toward meeting program goals, specifically improving access to telebehavioral health services that support primary care providers.

Likely Respondents: BHI EB-TNP grantees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
BHI EB-TNP Outcome Measurement Report	27	1	27	5	135
Total	27	27	135

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–24962 Filed 10–25–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Electronic Individual Development Plan (eIDP) (National Eye Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit

comments in writing, or request more information on the proposed project, contact: Dr. Cesar E. Perez-Gonzalez, Training Director, Office of the Scientific Director, National Eye Institute, NIH, Building 31, Room 6A22, MSC 0250, Bethesda, Maryland 20892 or call non-toll-free number (301) 451–6763 or Email your request, including your address to: cesarp@nei.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on August 1, 2024, 89 FR 62749 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The National Eye Institute (NEI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Electronic Individual Development Plans, 0925–0772 and 10/31/2024-Extension, National Eye Institute (NEI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Eye Institute’s (NEI) Office of the Scientific Director (OSD) goal is to train the next generation of vision researchers and ophthalmologists. Trainees who participate in NEI research come with different levels of education (student, postbaccalaureate, predoctoral including graduate and medical students, postdoctoral fellows) and for different amounts of time (6 months to 5 years). Training at the NEI focuses on scientific and professional skill

development. To enhance their chances of obtaining their ideal career, completing an annual Individual Development Plan (IDP) is an important step in helping a trainee’s career and professional development and is standard practice in graduate and postdoctoral education. An IDP is an effective tool for trainees to think about their career goals and skills needed to achieve them during their time at the NEI. Trainees work together with their research mentor to organize and summarize their research projects, consider career goals, and set training goals and expectations, both for the mentee and mentor.

This information collection request is to implement an electronic Individual Development Plan (eIDP). The data collected comes from a detailed questionnaire focused on responses to professional goals and expectations while they are at the NEI. It is expected that the trainees will complete the eIDP annually and by doing so, it will help enhance the effectiveness of their training by setting clear goals that can be monitored not only by the trainee themselves but also by their mentor, the Training Director, and their Administrative Officer. In addition to this eIDP, the system will also implement an electronic exit survey. The data collected comes from a detailed questionnaire focused on responses to questions focused on trainee mentoring and professional experiences at the NEI as well as their plans after they depart. It is expected that the trainees will complete at the end of their tenure and that by doing so, the NEI Training Program can learn about ways to improve career development opportunities for future trainees as well as learn more about trainee job choices to better advise fellows. Additionally, we can use the survey to help determine mentor effectiveness and help identify problems in mentoring at the NEI.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 213.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
eIDP (Attachment 1)	Individuals	150	1	1	150
Exit Survey Part 1 (Attachment 2)	Individuals	150	1	5/60	13
Exit Survey Part 2 (Attachment 3)	Individuals	150	1	20/60	50
Total	450	213

Dated: October 23, 2024.

Cesar E. Perez-Gonzalez,

*Training Director, National Eye Institute,
National Institutes of Health.*

[FR Doc. 2024–25017 Filed 10–25–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: November 21, 2024.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G34, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Vishakha Sharma, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G34, Rockville, MD 20892, 301–761–7036, vishakha.sharma@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology,

and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 22, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–24975 Filed 10–25–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel: Tailoring HIV Curative Strategies to the Participant (UM1 Clinical Trial Not Allowed).

Date: December 2–3, 2024.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22 Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Kristina S. Wickham, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22,

Rockville, MD 20892, 301–761–5390, kristina.wickham@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 22, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–24980 Filed 10–25–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Cooperative Agreement (U01 Clinical Trial Required).

Date: November 19, 2024.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Barry J. Margulies, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities,

National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11, Rockville, MD 20892, (301) 761-7956, barry.margulies@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 22, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-24979 Filed 10-25-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR Panel: Biodata Management and Common Fund Data Sets.

Date: November 19–20, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Janice Duy, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301-594-3139, janice.duy@nih.gov.

Name of Committee: Social and Community Influences on Health Integrated Review Group Population and Public Health Approaches to HIV/AIDS Study Section.

Date: November 19–20, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: In Person and Virtual Meeting.

Contact Person: Aubrey S. Madkour, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000C, Bethesda, MD 20892, (301) 594-6891, madkouras@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; The Cancer Drug Development and Cancer Therapeutics.

Date: November 19, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Lambratu Rahman Sesay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, 301-905-8294, rahman-sesay@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR Panel: Advancing HIV Service Delivery Through Pharmacies and Pharmacists.

Date: November 20–21, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Mark P. Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-806-6596, rubertm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Musculoskeletal Sciences.

Date: November 20, 2024.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Chee Lim, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4128 Bethesda, MD 20892, (301) 435-1850, limc4@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR-22-180: Maximizing Investigators' Research Award (R35).

Date: November 20–21, 2024.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Mufeng Li, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 507-9155, mufeng.li@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Cellular Signaling and Aging.

Date: November 20, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Robert O'Hagan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 (240) 909-6378, ohaganr2@csr.nih.gov.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group Immunobiology of Transplantation and Alloimmunity Study Section.

Date: November 20–21, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Anthony David Foster, Scientific Review Officer, The Center for Scientific Review, The National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-3297, anthony.foster@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Pain Mechanisms.

Date: November 20, 2024.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kirk Thompson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301-435-1242, kgt@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 23, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-24977 Filed 10-25-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Shared Instrumentation: Interdisciplinary Molecular Sciences and Technologies (S10).

Date: November 21–22, 2024.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4196, MSC 7812, Bethesda, MD 20892, 301–435–2902, gubina@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Disease Control and Applied Immunology.

Date: November 21, 2024.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892, 301–996–5819, zhengli@csr.nih.gov.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; HIV Coinfections and HIV Associated Cancers Study Section.

Date: November 21–22, 2024.

Time: 9:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Joshua D. Powell, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–5370 josh.powell@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Gastroenterology.

Date: November 21–22, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Santanu Banerjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2106, Bethesda, MD 20892, (301) 435–5947 banerjees5@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Oral and Dental Sciences.

Date: November 21, 2024.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Carmen Bertoni, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 805B, Bethesda, MD 20892, (301) 867–5309, bertonic2@csr.nih.gov.

Name of Committee: Center for Scientific Review, Special Emphasis Panel; Biobehavioral Medicine, Lifestyle Change and Health Outcomes.

Date: November 21, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kristen Prentice, Ph.D.

Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892 (301) 496–0726 prenticekj@mail.nih.gov.

Name of Committee: Center for Scientific Review, Special Emphasis Panel; Fellowships: Infectious Diseases and Immunology Panel C.

Date: November 21–22, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Melinda H. Krick, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 808G, Bethesda, MD 20892, (301) 435–1199 krickmh@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 22, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–24978 Filed 10–25–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Dental & Craniofacial Research, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

Date: December 3, 2024.

Time: 10:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Address: National Institute of Dental & Craniofacial Research, 31 Center Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Yun Mei, M.D., Scientific Review Officer, Scientific Review Branch, National Institute of Dental & Craniofacial Research, National Institutes of Health, 31 Center Drive, Bethesda, MD 20892, 301–827–4639, email: yun.mei@nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: October 22, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–24951 Filed 10–25–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below.

Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/>.

Name of Committee: National Advisory Board on Medical Rehabilitation Research.

Date: December 2–3, 2024.

Time: December 02, 2024, 10:00 a.m. to 5:00 p.m.

Agenda: NICHD Director's Report, NCMRR Director's report; NABMRR Liaison to NICHD Advisory Council Report; Scientific Talk on Collaboration; Report from the NIH Disability Research Coordinating Committee; Scientific Talk on Bilateral Task Training Post Stroke; Updates on the NIH Research Plan on Rehabilitation; Nominations for next Chair.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20817 (In Person and Virtual Meeting).

Time: December 03, 2024, 10:00 a.m. to 2:00 p.m.

Agenda: Implementation of the NIH's Simplified Review Framework; Scientific Talk on BCI; Election of Chair; Talk on Community Engagement in Research; Planning for next meeting in May 2025.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20817 (In Person and Virtual Meeting).

Contact Person: Ralph M. Nitkin, Ph.D., Deputy Director, National Center for Medical Rehabilitation, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Room 2116, Bethesda, MD 20892–7510, (301) 402–4206, nitkinr@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Persons listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this

notice at least 10 days in advance of the meeting. Interested individuals and representatives of an organization may submit a letter of intent, a brief description of the organization represented and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at <https://www.nih.gov/about-nih/visitor-information/campus-access-security> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <https://www.nichd.nih.gov/about/advisory/nabmrr>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 22, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–24982 Filed 10–25–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention's (CSAP) Drug Testing Advisory Board (DTAB) will convene via web conference on December 3, 2024, from 10 a.m. EST to 2:30 p.m. EST.

The board will meet in open session December 3, 2024, from 10 a.m. EST to 2:30 p.m. EST to hear updates from the Department of Transportation (DOT),

the Department of Defense (DoD) and the Nuclear Regulatory Commission (NRC), and updates from HHS on the Federal Workplace Drug Testing Program and Mandatory Guidelines. Additionally, the board will hear presentations regarding a collaboration between the Department of Defense and the Division of Workplace Programs as well as data presented for consideration regarding evaluation of the cutoff for an invalid pH result in urine.

Data provided by HHS-certified laboratories indicates that invalid urine pH results cycle with the seasonal temperature fluctuations. Data will be presented to facilitate and inform decisions regarding a possible adjustment in the cutoff for urine pH to reduce this cyclical effect while continuing to identify potential tampering of specimens.

Meeting registration information can be completed at <https://snacregister.samhsa.gov/>. Web conference and call information will be sent after completing registration. Meeting information and a roster of DTAB members may be obtained by accessing the SAMHSA Advisory Committees website, <https://www.samhsa.gov/about-us/advisory-councils/meetings>, or by contacting the Designated Federal Officer, Lisa Davis.

Committee Name: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention, Drug Testing Advisory Board.

Dates/Time/Type: December 3, 2024, from 10:00am EST to 2:30pm EST: Open.

Place: Virtual.

To Submit Comments: Requests to make public comment during the public comment period of the December DTAB meeting must be made in writing at least 7 days prior to the meeting to the following email: DFWP@samhsa.hhs.gov.

Contact: Lisa S. Davis, M.S., Social Science Analyst, Center for Substance Abuse Prevention, 5600 Fishers Lane, Rockville, Maryland, 20857, Telephone: (240) 276–1440, Email: Lisa.Davis@samhsa.hhs.gov.

Anastasia Flanagan,

Public Health Advisor, Division of Workplace Programs.

[FR Doc. 2024–24972 Filed 10–25–24; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 81**

[Docket No. USCG–2024–0907]

Certificate of Alternative Compliance for the Delta Marine Industries Shipyard Hull #107050**AGENCY:** Coast Guard, DHS.**ACTION:** Notification of issuance of a certificate of alternative compliance.

SUMMARY: The Coast Guard announces that the Chief, Prevention Division, Thirteenth District has issued a certificate of alternative compliance from the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), for The Delta Marine Industries Shipyard Hull #107050. We are issuing this notice because its publication is required by statute. Due to the construction and placement of the masthead light, Delta Marine Industries Shipyard Hull #107050 cannot fully comply with the light, shape, or sound signal provisions of the 72 COLREGS without interfering with the vessel's design and construction. This notification of issuance of a certificate of alternative compliance promotes the Coast Guard's marine safety mission.

DATES: The Certificate of Alternative Compliance was issued on August 15, 2024.

FOR FURTHER INFORMATION CONTACT: For information or questions about this notice call or email Ms. Jill L. Lazo, Thirteenth District, U.S. Coast Guard, telephone (571) 607–1461, email jill.L.Lazo@uscg.mil.

SUPPLEMENTARY INFORMATION: The United States is signatory to the International Maritime Organization's International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), as amended. The special construction or purpose of some vessels makes them unable to comply with the light, shape, or sound signal provisions of the 72 COLREGS. Under statutory law, however, specified 72 COLREGS provisions are not applicable to a vessel of special construction or purpose if the Coast Guard determines that the vessel cannot fully comply with those requirements without interfering with special function of the vessel.¹

The owner, builder, operator, or agent of a special construction or purpose vessel may apply to the Coast Guard District Office in which the vessel is

being built or operated for determination that compliance with alternate requirements is justified,² and the Chief of the Prevention Division would then issue the applicant a certificate of alternative compliance (COAC) if he or she determines that the vessel cannot fully comply with 72 COLREGS light, shape, and sound signal provisions without interference with the vessel's special function.³ If the Coast Guard issues a COAC, it must publish notice of this action in the **Federal Register**.⁴

The Chief, Thirteenth Coast Guard District, certifies that Delta Marine Industries Shipyard Hull #107050 is a vessel of special construction or purpose, and that, with respect to the position of the masthead light, it is not possible to comply fully with the requirements of the provisions enumerated in the 72 COLREGS, without interfering with the normal operation, construction, or design of the vessel. The Chief, Thirteenth Coast Guard District, Prevention Division further finds and certifies that the masthead light is in the closest possible compliance with the applicable provisions of the 72 COLREGS.⁵

This notice is issued under authority of 33 U.S.C. 1605(c) and 33 CFR 81.18.

Dated: October 21, 2024.

D.A. Jensen,

Captain, U.S. Coast Guard, Chief, Prevention Division, Thirteenth Coast Guard District.

[FR Doc. 2024–25025 Filed 10–25–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard**

[Docket No. USCG–2024–0883]

Information Collection Request to Office of Management and Budget OMB Control Number: 1625–0033**AGENCY:** Coast Guard, DHS.**ACTION:** Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information:

² 33 CFR 81.5.

³ 33 CFR 81.9.

⁴ 33 U.S.C. 1605(c) and 33 CFR 81.18.

⁵ 33 U.S.C. 1605(a); 33 CFR 81.9.

1625–0033, Display of Fire Control Plans for Vessel; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before December 27, 2024.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2024–0883] to the Coast Guard using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public participation and request for comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at <https://www.regulations.gov>. Additionally, copies are available from: COMMANDANT (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, fax 202–372–8405, or email hqs-dg-m-cg-61-pii@uscg.mil for questions on these documents.

SUPPLEMENTARY INFORMATION:**Public Participation and Request for Comments**

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.*, chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated

¹ 33 U.S.C. 1605.

collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, USCG–2024–0883, and must be received by December 27, 2024.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. We review all comments received, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Display of Fire Control Plans for Vessels.

OMB Control Number: 1625–0033.

Summary: This information collection is for the posting or display of specific plans on certain categories of commercial vessels. The availability of these plans aid firefighters and damage control efforts in response to emergencies.

Need: Under 46 U.S.C. 3305 and 3306, the Coast Guard is responsible for ensuring the safety of inspected vessels and has promulgated regulations in 46 CFR parts 35, 78, 97, 109, 131, 169, and 196 to ensure that safety standards are met.

Forms: None.

Respondents: Owners and operators of vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 472 hours to 493 hours a year, due to an increase in the estimated annual number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 22, 2024.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2024–25026 Filed 10–25–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7091–N–07]

60-Day Notice of Proposed Information Collection: Voucher Management System (VMS) Form OMB Control No.: 2577–0282

AGENCY: Office of the Assistant Secretary for Public and Indian Housing (PIH), HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: Comments Due December 27, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to www.regulations.gov. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; telephone (202) 402–3400, (this is not a toll-free number) or email at Colette.Pollard@hud.gov, for a copy of the proposed forms or other available information.

FOR FURTHER INFORMATION CONTACT:

Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email

Colette.Pollard@hud.gov or telephone (202) 402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard. **SUPPLEMENTARY INFORMATION:** This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection:

Voucher Management System (VMS).

OMB Approval Number: 2577–0282.

Type of Request: Extension to a previously approved collection.

Form Number: HUD–52663, HUD–52672, HUD–52673, HUD–52681, HUD–52681–B.

The automated forms in collection 2577–0282 (Voucher for Payment of Annual Contributions and Operating Statement Housing Assistance Payments Program Supplemental Reporting Form) is entered by the PHA into the Voucher Management System (VMS) on a monthly basis during each calendar year to track leasing and HAP expenses by voucher category, as well as data concerning fraud recovery, PHA-held equity, etc. The automated form HUD–52681–B is also utilized by the same programs as the manual forms. This request is just an extension of these forms which are set to expire 03/31/2025.

Description of the need for the information and proposed use: The Voucher Management System (VMS) supports the information management needs of the Housing Choice Voucher (HCV) Program and management functions performed by the Financial Management Center (FMC) and the Financial Management Division (FMD) of the Office of Public and Indian Housing and the Real Estate Assessment Center (PIH–REAC). This system's primary purpose is to provide a central system to monitor and manage the Public Housing Agency (PHAs) use of vouchers and expenditure of program funds, and is the base for budget formulation and budget implementation. The VMS collects PHAs' actual cost data that enables HUD to perform and control cash management activities; the costs reported are the base for quarterly HAP and Fee obligations and advance

disbursements in a timely manner, and reconciliations for overages and shortages on a quarterly basis.

Respondents: Public Housing Authorities.

Estimated Number of Respondents: 2,153.

Estimated Number of Responses: 25,836.

Frequency of Response: monthly (HUD-52681, HUD-52681-B)/annually

(HUD-52663, HUD-52672, HUD-52673, HUD-52681).

Average Hours per Response: 2.

Total Estimated Burdens: 51,672.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Total	2,153	12	25,836	2	51,672	\$35.67	\$1,843,140.24

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Lora Roult,

Director, Office of Policy, Programs and Legislative Initiatives.

[FR Doc. 2024-24984 Filed 10-25-24; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-6497-N-01]

Notice of HUD-Held Non Vacant Loan Sales (HNVLs 2025-1)

AGENCY: Office of the Assistant Secretary for Housing Federal Housing Commissioner, U.S. Department of Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: This notice announces HUD's intention to competitively offer approximately 1,180 home equity

conversion mortgages (HECM, or reverse mortgage loans) secured by occupied properties with a loan balance of approximately \$500 million. The sale will consist of due and payable Secretary-held reverse mortgage loans. The mortgage loans consist of first liens secured by real property that is occupied, where the borrower and co-borrowing spouse are deceased, and heirs have not come forward in the time elapsed. The Secretary will prioritize up to 50 percent of the offered assets for award to nonprofit organizations or governmental entity bidders with a documented housing mission. This notice also generally describes the bidding process for the sale and certain entities who are ineligible to bid. This is the first sale offering of its type and will be held on December 11, 2024.

DATES: For this sale action, the Bidder Information Package (BIP) will be made available to qualified bidders on or about November 12, 2024. Bids for the HNVLs 2025-1 sale will be accepted on the Bid Date of December 11, 2024. HUD anticipates that award(s) will be made on or about December 16, 2024 (the Award Date).

ADDRESSES: To become an eligible bidder and receive the BIP for the December sale, prospective bidders must complete, execute, and submit a Confidentiality Agreement and Qualification Statement acceptable to HUD. The documents will be available in preview form with free login on the Transaction Specialist (TS), Falcon Capital Advisors, website: <http://www.falconassetsales.com>. This website contains information and links to register for the sale and electronically complete and submit documents.

If you cannot submit electronically, please submit executed documents via mail or facsimile to Falcon Capital Advisors: Falcon Capital Advisors, 427 N Lee Street, Alexandria, VA 22314, Attention: Glenn Ervin, HUD HNVLs Loan Sale Coordinator. eFax: 1-202-393-4125.

FOR FURTHER INFORMATION CONTACT: John Lucey, Director, Office of Asset Sales, Room 9216, Department of Housing and Urban Development, 451 Seventh Street

SW, Washington, DC 20410-8000; telephone 202-708-2625, extension 3927 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

SUPPLEMENTARY INFORMATION: This notice announces HUD's intention to sell in HNVLs 2025-1 due and payable Secretary-held reverse mortgage loans. HUD is offering 1,180 reverse mortgage notes with a loan balance of approximately \$500 million. The mortgage loans consist of first liens secured by real property that is occupied, where the borrower and co-borrowing spouse are deceased, and heirs have not come forward in the time elapsed.

A listing of the mortgage loans will be included in the due diligence materials made available to eligible bidders. The mortgage loans will be sold without FHA insurance and with servicing released. HUD will offer eligible bidders an opportunity to bid competitively on the mortgage loans.

The Bidding Process

The BIP describes in detail the procedure for bidding in HNVLs 2025-1. The BIP also includes the applicable standardized non-negotiable Conveyance, Assignment and Assumption Agreements for HNVLs 2025-1 (CAAs). The CAAs will contain first look requirements and mission outcome goals.

HUD will evaluate the bids submitted and determine the successful bids, in terms of the best value to HUD, in its sole and absolute discretion. If a bidder is successful, it will be required to submit a deposit which will be calculated based upon the total dollar value of the bidder's potential award. Award will be contingent on receiving the deposit in the timeframe outlined in the deposit letter. The deposit amount

will be applied towards the purchase price at settlement.

This notice provides some of the basic terms of sale. The CAAs will be released in the BIP or BIP Supplement, as applicable. These documents provide comprehensive contractual terms and conditions to which eligible bidders will acknowledge and agree. To ensure a competitive bidding process, the terms of the bidding process and the CAAs are not subject to negotiation.

Due Diligence Review

The BIP describes how eligible bidders may access the due diligence materials remotely via a high-speed internet connection.

Mortgage Loan Sale Policy

HUD reserves the right to remove mortgage loans from a sale at any time prior to the Award Date and the settlement date for the mortgage loans. HUD also reserves the right to reject any and all bids, in whole or in part, and include any reverse mortgage loans in a later sale. Deliveries of mortgage loans will occur in conjunction with settlement and servicing transfer no later than 60 days after the Award Date.

The reverse mortgage loans offered for sale were insured by and were assigned to HUD pursuant to section 255 of the National Housing Act, as amended. The sale of the reverse mortgage loans is pursuant to HUD's authority in section 204(g) of the National Housing Act.

Mortgage Loan Sale Procedure

HUD selected an open competitive whole-loan sale as the method to sell the reverse mortgage loans for this specific sale transaction. For the HNVLS 2025–1 sale, HUD has determined that this method of sale optimizes HUD's return on the sale of these reverse mortgage loans, affords the greatest opportunity for all eligible bidders to bid on the reverse mortgage loans, and provides the quickest and most efficient vehicle for HUD to dispose of the due and payable reverse mortgage loans.

Bidder Ineligibility

In order to bid in HNVLS 2025–1 as an eligible bidder, a prospective bidder must complete, execute, and submit a Confidentiality Agreement, a Qualification Statement (HUD–9611), and an Addendum for Nonprofit and Government Pools and Sub-pools (HUD–9612), as applicable (collectively, for these bidders, the Qualification Statement (HUD–9611) and Addendum for Nonprofit and Government Pools and Sub-pools (HUD–9612), as applicable, shall be defined as the Qualification Statement) that is

acceptable to HUD. Eligible bidders seeking to be awarded loans on a priority basis must submit the Confidentiality Agreement, Qualification Statement (HUD–9611), and Addendum for Nonprofit and Government Pools and Sub-pools (HUD–9612), and Housing Mission Supplemental Certification (collectively, for these bidders, the Qualification Statement (HUD–9611) and Addendum for Nonprofit and Government Pools and Sub-pools (HUD–9612), and Housing Mission Supplemental Certification shall be defined as the Qualification Statement) that is acceptable to HUD. In the Qualification Statement, the prospective bidder must provide certain representations and warranties regarding the prospective bidder, including (i) the prospective bidder's board of directors, (ii) the prospective bidder's direct parent, (iii) the prospective bidder's subsidiaries, (iv) any related entity with which the prospective bidder shares a common officer, director, subcontractor or subcontractor who has access to Confidential Information as defined in the Confidentiality Agreement or is involved in the formation of a bid transaction (collectively the "Related Entities"), and (v) the prospective bidder's repurchase lenders. The prospective bidder is ineligible to bid on any of the reverse mortgage loans included in HNVLS 2025–1 if the prospective bidder, its Related Entities, or its repurchase lenders, are any of the following, unless other exceptions apply as provided for in the Qualification Statement.

1. An individual or entity that is currently debarred, suspended, or excluded from doing business with HUD pursuant to the Governmentwide Suspension and Debarment regulations at 2 CFR parts 180 and 2424;

2. An individual or entity that is currently suspended, debarred, or otherwise restricted by any department or agency of the federal government or of a state government from doing business with such department or agency;

3. An individual or entity that is currently debarred, suspended, or excluded from doing mortgage related business, including having a business license suspended, surrendered or revoked, by any federal, state, or local government agency, division, or department;

4. An entity that has had its right to act as a Government National Mortgage Association ("Ginnie Mae") issuer terminated and its interest in mortgages backing Ginnie Mae mortgage-backed securities extinguished by Ginnie Mae;

5. An individual or entity that is in violation of its neighborhood stabilizing outcome obligations or post-sale reporting requirements under a Conveyance, Assignment and Assumption Agreement executed for any previous mortgage loan sale of HUD;

6. An employee of HUD's Office of Housing, a member of such employee's household, or an entity owned or controlled by any such employee or member of such an employee's household with household to be inclusive of the employee's father, mother, stepfather, stepmother, brother, sister, stepbrother, stepsister, son, daughter, stepson, stepdaughter, grandparent, grandson, granddaughter, father-in-law, mother-in-law, brother-in-law, sister-in-law, son-in-law, daughter-in-law, first cousin, the spouse of any of the foregoing, and the employee's spouse;

7. A contractor, subcontractor, and/or consultant or advisor (including any agent, employee, partner, director, or principal of any of the foregoing) who performed services for or on behalf of HUD in connection with the sale;

8. An individual or entity that knowingly acquired or will acquire prior to the sale date material non-public information, other than that information which is made available to Bidder by HUD pursuant to the terms of this Qualification Statement, about mortgage loans offered in the sale;

9. An individual or entity which knowingly employs or uses the services of an employee of HUD's Office of Housing (other than in such employee's official capacity); or

10. An individual or entity that knowingly uses the services, directly or indirectly, of any person or entity ineligible under 1 through 10 to assist in preparing any of its bids on the mortgage loans.

The Qualification Statement has additional representations and warranties which the prospective bidder must make, including but not limited to the representation and warranty that the prospective bidder or its Related Entities are not and will not knowingly use the services, directly or indirectly, of any person or entity that is, any of the following (and to the extent that any such individual or entity would prevent the prospective bidder from making the following representations, such individual or entity has been removed from participation in all activities related to this sale and has no ability to influence or control individuals involved in formation of a bid for this sale):

(1) An entity or individual is ineligible to bid on any included reverse mortgage loan or on the pool containing such reverse mortgage loan because it is an entity or individual that:

(a) Serviced or held such reverse mortgage loan at any time during the six-month period prior to the bid, or

(b) Is any principal of any entity or individual described in the preceding sentence;

(c) Any employee or subcontractor of such entity or individual during that six-month period; or

(d) Any entity or individual that employs or uses the services of any other entity or individual described in this paragraph in preparing its bid on such reverse mortgage loan.

In addition, for those eligible bidders seeking to be awarded mortgage loans on a priority basis and signing the Housing Mission Supplemental Certification, each prospective bidder must provide documentation and certify that its charitable or government purpose has a qualifying housing mission and that its participation in the sale is a furtherance of that housing mission.

Freedom of Information Act Requests

HUD reserves the right, in its sole and absolute discretion, to disclose information regarding HNVLS 2025–1, including, but not limited to, the identity of any successful qualified bidder and its bid price or bid percentage for any pool of loans or individual loan, upon the closing of the sale of all the mortgage loans. Even if HUD elects not to publicly disclose any

information relating to HNVLS 2025–1, HUD will disclose any information that HUD is obligated to disclose pursuant to the Freedom of Information Act and all regulations promulgated thereunder.

Scope of Notice

This notice applies to HNVLS 2025–1 and does not establish HUD’s policy for the sale of other mortgage loans.

Julia R. Gordon,

Assistant Secretary for Housing—FHA Commissioner.

[FR Doc. 2024–24994 Filed 10–25–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2024–0162; FXIA1671090000–245–FF09A30000]

Emergency Exemption: Issuance of Emergency Permit To Import Endangered Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, have waived the 30-day public notice period and have issued an endangered species permit for the import and release into the wild of one loggerhead sea turtle (*Caretta caretta*), which was rescued from the wild in Canada, for the purpose of enhancing the propagation or survival of the species. This permit is for a single import.

ADDRESSES: You may obtain materials pertaining to the permit application by submitting a Freedom of Information Act (FOIA) request to the Service’s FOIA office at <https://www.doi.gov/foia/foia-request-form>.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, by phone at 703–358–2104 or via email at DMAFR@fws.gov. Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), have issued an emergency permit to conduct certain activities with an endangered loggerhead sea turtle (*Caretta caretta*), in response to a permit application that we received under the authority of section 10(a)(1)(A) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*)

We issued the requested permit subject to certain conditions set forth in the permit. For the application, we found that (1) the application was filed in good faith, (2) the granted permit would not operate to the disadvantage of the endangered species, and (3) the granted permit would be consistent with the purposes and policy set forth in section 2 of the ESA.

PERMIT ISSUED UNDER EMERGENCY EXEMPTION

Permit No.	Applicant	Permit issuance date
PER11660838	SeaWorld California, San Diego, CA	October 4, 2024.

SeaWorld California, of San Diego, California, requested a permit to import a female loggerhead sea turtle from the Vancouver Aquarium in British Columbia, Canada. The turtle was rescued by the Stranding Network and taken to the Vancouver Aquarium for rehabilitation. SeaWorld has imported the turtle and, after rehabilitation, will release the turtle into the wild. The Service determined that an emergency affecting the viability of the turtle existed, and that no reasonable alternative was available to the applicant.

On October 4, 2024, the Service issued permit no. PER11660838 to SeaWorld California to import a female loggerhead sea turtle from the

Vancouver Aquarium in British Columbia, Canada, and release the turtle in the wild.

Authority

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and its implementing regulations.

Brenda Tapia,

Supervisory Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2024–24965 Filed 10–25–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[245A2100DD/AAKC001030/ A0A501010.999900]

Receipt of Documented Petition for Federal Acknowledgment as an American Indian Tribe

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Department of the Interior (Department) gives notice that the group known as the Tripanick Nansemond Family Indian Tribe has filed a documented petition for Federal

acknowledgment as an American Indian Tribe with the Assistant Secretary—Indian Affairs. The Department seeks comment and evidence from the public on the petition.

DATES: Comments and evidence must be postmarked by February 25, 2025.

ADDRESSES: Copies of the narrative portion of the documented petition, as submitted by the petitioner (with any redactions appropriate under 25 CFR 83.21(b)), and other information are available at the Office of Federal Acknowledgment's (OFA) website: www.bia.gov/as-ia/ofa. Submit any comments or evidence to: Department of the Interior, Office of the Assistant Secretary—Indian Affairs, Attention: Office of Federal Acknowledgment, Mail Stop 4071 MIB, 1849 C Street NW, Washington, DC 20240, or by email to: Ofa_Info@bia.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Wendi-Starr Brown, Acting Director, Office of the Assistant Secretary—Indian Affairs, Department of the Interior, (202) 513-7650.

SUPPLEMENTARY INFORMATION: On July 31, 2015, the Department's revisions to 25 CFR part 83 became final and effective (80 FR 37861). A key goal of the revisions was to improve transparency through increased notice of petitions and providing improved public access to petitions. Today, the Department informs the public that a complete documented petition has been submitted under the current regulations, that portions of that petition are publicly available on the website identified above for easy access, and that we are seeking public comment early in the process on this petition.

Under 25 CFR 83.22(b)(1), OFA publishes this notice that the following group has filed a documented petition for Federal acknowledgment as an American Indian Tribe to the Assistant Secretary—Indian Affairs: Tripanick Nansmond Family Indian Tribe. The contact information for the petitioner is Mr. Robert Bass, 1142 11th Lane, Burlington, Kansas 66839.

Also, under 25 CFR 83.22(b)(1), OFA publishes on its website the following:

- i. The narrative portion of the documented petition, as submitted by the petitioner (with any redactions appropriate under 25 CFR 83.21(b));
- ii. The name, location, and mailing address of the petitioner and other information to identify the entity;
- iii. The date of receipt;
- iv. The opportunity for individuals and entities to submit comments and evidence supporting or opposing the petitioner's request for acknowledgment

within 120 days of the date of the website posting; and

v. The opportunity for individuals and entities to request to be kept informed of general actions regarding a specific petitioner.

The Department publishes this notice and request for comment in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by Department Manual part 209, chapter 8.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2024-24961 Filed 10-25-24; 8:45 am]

BILLING CODE 4337-15-P

DEPARTMENT OF THE INTERIOR

[256D0102DM/DS6240000/DLSN00000/000000/DX62401]

Fiscal Year 2022 Service Contract Inventory

AGENCY: Office of Acquisition and Property Management, Interior.

ACTION: Notice of public availability.

SUMMARY: The Department of the Interior is publishing this notice to advise the public of the availability of the Fiscal Year (FY) 2022 Service Contract Inventory, in accordance with section 743 of division C of the Consolidated Appropriations Act of 2010.

ADDRESSES:

Obtaining Documents:

The Office of Federal Procurement Policy (OFPP) guidance is available online.

The Department of the Interior has posted its FY 2022 Service Contract Inventory on the Office of Acquisition and Property Management portion of the Department of the Interior website.

FOR FURTHER INFORMATION CONTACT:

Valerie Green, Acquisition Analyst, Policy Branch, Office of Acquisition and Property Management (PAM), Department of the Interior. Phone number: 202-513-0797, Email: Valerie_green@ios.doi.gov.

SUPPLEMENTARY INFORMATION:

Introduction

Section 743 of division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111-117) requires civilian agencies to prepare an annual inventory of their service contracts. The analyses help inform agency managers whether contractors are being used appropriately or if rebalancing the workforce may be required.

In addition to the agency analyses, the process includes extracting contract

data from the Federal Procurement Data System (FPDS) and the System for Award Management (SAM) and the consolidated output file is posted for public use.

The Inventory provides information on service contract actions over \$25,000 that the Department made in FY 2022. The information is organized by function to show how contracted resources are distributed throughout the Department. The Department's analysis of its Service Contract Inventory is summarized in the FY 2022 Service Contract Inventory Report. The 2022 Report was developed in accordance with guidance issued on December 19, 2011, and November 5, 2010, by the Office of Management and Budget's Office of Federal Procurement Policy.

Authority

The authority for this action is the Consolidated Appropriations Act of 2010 (Pub. L. 111-117).

Megan Olsen,

Director, Office of Acquisition and Property Management.

[FR Doc. 2024-24859 Filed 10-25-24; 8:45 am]

BILLING CODE 4334-63-P

DEPARTMENT OF THE INTERIOR

National Indian Gaming

Commission Fee Rate and Fingerprint Fees

AGENCY: National Indian Gaming Commission, Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given that the National Indian Gaming Commission has adopted its annual fee rates of 0.00% for tier 1 and 0.08% (.0008) for tier 2, which maintain the current fee rates. These rates shall apply to all assessable gross revenues from each gaming operation under the jurisdiction of the Commission. If a tribe has a certificate of self-regulation, the fee rate on Class II revenues shall be 0.04% (.0004) which is one-half of the annual fee rate. The annual fee rates are effective November 1, 2024, and will remain in effect until new rates are adopted. The National Indian Gaming Commission has also adopted its fingerprint processing fee of \$44 per card which represents a decrease of \$9 per card. The fingerprint processing fee is effective November 1, 2024, and will remain in effect until the Commission adopts a new rate.

FOR FURTHER INFORMATION CONTACT:

Yvonne Lee, National Indian Gaming Commission, 1849 C Street NW, Mail

Stop #1621, Washington, DC 20240; telephone (202) 632-7003; fax (202) 632-7066.

SUPPLEMENTARY INFORMATION: The Indian Gaming Regulatory Act (IGRA) established the National Indian Gaming Commission, which is charged with regulating gaming on Indian lands.

Commission regulations (25 CFR part 514) provide for a system of fee assessment and payment that is self-administered by gaming operations.

Pursuant to those regulations, the Commission is required to adopt and communicate assessment rates and the gaming operations are required to apply those rates to their revenues, compute the fees to be paid, report the revenues, and remit the fees to the Commission. All gaming operations within the jurisdiction of the Commission are required to self-administer the provisions of these regulations, and report and pay any fees that are due to the Commission. It is necessary for the Commission to maintain the fee rate to ensure that the agency has sufficient funding to fully meet its statutory and regulatory responsibilities. In addition, it is critical for the Commission to maintain constantly an adequate transition carryover balance to cover any cash flow variations.

Pursuant to 25 CFR part 514, the Commission must also review annually the costs involved in processing fingerprint cards and set a fee based on fees charged by the Federal Bureau of Investigation and costs incurred by the Commission. Commission costs include Commission personnel, supplies, equipment & infrastructure costs, and postage to submit the results to the requesting tribe. The decrease in FY25 fingerprint processing fee is attributable largely to the completion of the Agency's hardware refresh of core networking and server computing devices in FY24 which has reduced the support time for on-premises systems and infrastructure supporting fingerprint processing. In addition, the successful establishment of the CJIS Audit Unit (CAU) within the Division of Technology has significantly decreased the cross-divisional resources previously required to ensure compliance with the Federal Bureau of Investigation Criminal Justice Information Services (FBI CJIS) requirements. FY25 fingerprint processing fee's decrease also reflects the cost savings resulting from the completion of one-time capital investments associated with the Washington, DC headquarters office relocation in FY24. In FY25 the Commission will also continue its

commitment to take necessary measures to comply with the FBI CJIS requirements which ensure the NIGC and participating tribes can continue to use FBI criminal history report information (CHRI) to assist in determining a key employee or primary management official's eligibility for a gaming license.

Dated: October 23, 2024.

Sharon M. Avery,
Acting Chair.

Dated: October 23, 2024.

Jean Hovland,
Vice Chair.

[FR Doc. 2024-24968 Filed 10-25-24; 8:45 am]

BILLING CODE 7565-01-P

JUDICIAL CONFERENCE OF THE UNITED STATES

Committee on Rules of Practice and Procedure; Meeting of the Judicial Conference

AGENCY: Judicial Conference of the United States.

ACTION: Committee on Rules of Practice and Procedure; Notice of open meeting.

SUMMARY: The Committee on Rules of Practice and Procedure will hold a meeting in a hybrid format with remote attendance options on January 7, 2025 in San Diego, CA. The meeting is open to the public for observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: <https://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books>.

DATES: January 7, 2025.

FOR FURTHER INFORMATION CONTACT: H. Thomas Byron III, Esq., Chief Counsel, Rules Committee Staff, Administrative Office of the U.S. Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7-300, Washington, DC 20544, Phone (202) 502-1820, RulesCommittee_Secretary@ao.uscourts.gov.

(Authority: 28 U.S.C. 2073.)

Dated: October 23, 2024.

Shelly L. Cox,
Management Analyst, Rules Committee Staff.

[FR Doc. 2024-25005 Filed 10-25-24; 8:45 am]

BILLING CODE 2210-55-P

DEPARTMENT OF JUSTICE

[OMB Number 1121-0NEW]

Agency Information Collection Activities: Proposed New Information Collection Activity; Comment Request, Proposed Study Entitled "The Study of Interpersonal Violence Among Young Adults Pilot Project"

AGENCY: National Institute of Justice, U.S. Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, National Institute of Justice, is submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until December 27, 2024.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Erica Howell, Social Science Research Analyst, Office on Violence and Victimization Prevention, by email at erica.howell@usdoj.gov or telephone at (202) 616-8663.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the National Institute of Justice, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Evaluate whether and, if so, how the quality, utility, and clarity of the information to be collected can be enhanced.
- Minimize the burden of collecting information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g.,

permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* New survey.

2. *The Title of the Form/Collection:* “The Study of Interpersonal Violence among Young Adults Pilot Project.”

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The applicable component within the U.S. Department of Justice is the National Institute of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* In the fiscal year (FY) 2023, the National Institute of Justice (NIJ) awarded Westat, a professional research services organization, along with their partners at New York University and the University of Cincinnati, to conduct “The Study of Interpersonal Violence among Young Adults Pilot Project” (Jan. 1, 2024–December 31, 2025), which will inform the implementation of a longitudinal study expected to begin in FY2026.

The longitudinal study titled “National Longitudinal Cohort Study of Interpersonal Violence Among College-Aged Women and Men,” also referred to as the Long IVY study, is a critically needed, nationally representative, longitudinal panel survey of interpersonal violence among young adults (ages 18–24) who do and do not attend college. It will examine trajectories of risk and protective factors

(at the individual, family, and community levels, including exposure to community violence) that predict victimization and perpetration of interpersonal violence and the recovery of those victimized. Interpersonal violence comprises (1) physical and psychological intimate partner violence, (2) nonconsensual sexual contact, and (3) stalking by current and former intimate partners and non-partners.

The longitudinal study design includes recruiting 17,000 young adults with a goal of retaining 10,000 in the final sample after five annual data collection waves (and interim micro assessments) across six years. The first survey will be administered in the fall of the school year after the participant’s high school class graduates, and the final survey will be administered after they turn 23.

At a stage of the lifespan when people are most vulnerable to interpersonal violence, this study will address gaps in knowledge about the experiences of young adults not engaged in post-secondary education and the differences in experiences between groups. The innovative emphasis on identifying risk and protective factors over time will provide new evidence about how best to prevent interpersonal violence, for whom, which subpopulations are most in need of victimization services, and what factors accelerate healing and wellness for those who’ve been harmed.

The Study of Interpersonal Violence among Young Adults Pilot Project (the current study) will recruit a national

probability sample of approximately 5,000 young adults, with a goal of retaining 250–300 after a one-time data collection in response to the recruitment form. The form will be administered in the spring/summer of the recruitment year 2025, and respondents must have either graduated high school or are no longer be in high school. Respondents must be 18 to be eligible for recruitment.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The pilot study’s estimated range of burden for respondents is expected to be between 8 and 14 minutes for completion. Based on instrument testing results, an average of 12 minutes per respondent is expected to be spent. The following factors were considered when creating the burden estimate: the estimated total number of respondents. NIJ estimates that approximately 168 respondents will fully complete the questionnaire, yielding a modified response rate of 55%.

6. *An estimate of the total public burden associated with the pilot data collection:* For the pilot study, the estimated public burden associated with this collection is 691 hours, which includes the time it takes each of the expected respondents to open all mailing materials and complete the questionnaire. It is estimated that each of the 168 respondents will take 12 minutes, on average, to complete the questionnaire. See the table below for calculations.

Pilot study: 2025	Number	Burden in minutes	Total burden	
Initial letter	5,000	2	10,000	
Reminder Postcard	5,000	0.5	10,000	
Second Reminder	4,902	2	9,803	
Final reminder	4,836	2	9,672	
Completed Survey	168	12	2,016	
Total burden	41,492	minutes.
.....	691.5	hours.
Total Returns	60	4	104	168.
Response rate assumption	0.3	0.082	0.021	
Check RR calculation	0.30	0.09	0.02	
	Strata 1	Strata 2	Strata 3	
Initial letter & postcard	200	50	4,750	200.
2nd reminder	164	47.54	4,690.15	50.
final reminder	140	45.9	4,650.25	4,750.
completed survey	60	4	104	
Estimated Response rate based on eligible households	55%
Overall Yield rate of all households	3.4%

If additional information is required, contact Darwin Arceo, Department Clearance Officer, United States

Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution

Square, 145 N Street NE, Washington, DC 20530.

Dated: October 23, 2024.

Darwin Arceo,
Department Clearance Officer For PRA, U.S. Department of Justice.

[FR Doc. 2024-25007 Filed 10-25-24; 8:45 am]

BILLING CODE 4410-18-P

DEPARTMENT OF JUSTICE

[OMB Number 1105-0104]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Reinstatement With Change of a Previously Approved Collection; Contract Guard Personal Qualification Statement

AGENCY: U.S. Marshals Service, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The U.S. Marshals Service, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until November 27, 2024.

FOR FURTHER INFORMATION CONTACT: The proposed information collection was previously published in the **Federal Register** on August 20, 2024 at 89 FR 67495, allowing a 60-day comment period. If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Assistant Chief Karl Slazer/Management Support Division, U.S. Marshals Service

Headquarters, 1215 S Clark St., Ste. 10017, Arlington, VA 22202-4387, by telephone at 202-360-7359 or by email at karl.slazer@usdoj.gov.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Abstract: This form will primarily be used to collect applicant reference information. Reference checking is an objective evaluation of an applicant’s past job performance based on information collected from key individuals (*e.g.*, supervisors, peers, subordinates) who have now and worked with the applicant. Reference checking is a necessary supplement to

the evaluation of resumes and other descriptions of training and experience, and allows the selecting official to hire applicants with a strong history of performance. The questions on this form have been developed following the OPM, MSPB, and DOJ “Best Practice” guidelines for reference checking.

Overview of this information collection:

1. *Type of Information Collection:* Reinstatement with change of a previously approved collection.
2. *The Title of the Form/Collection:* Contract Guard Personal Qualification Statement.
3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* USM-234.
4. *Affected public who will be asked or required to respond, as well as the obligation to respond:*
 - *Affected Public:* Contract Guard (DSO, ASO, CDO, PSO, CSO, and SSO) Job Applicants.
 - The obligation to respond is voluntary.
5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 1000 respondents will utilize the form, and it will take each respondent approximately 45 minutes to complete the form.
6. *An estimate of the total annual burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 750 hours, which is equal to 1000 (total # of annual responses) * (45 mins).
7. *An estimate of the total annual cost burden associated with the collection, if applicable:*

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response (minutes)	Total annual burden (hours)
Ex: Survey (individuals or households).	1,000	1/annually	1,000	45	750
<i>Unduplicated Totals</i>	<i>1,000</i>	<i>1,000</i>	<i>750</i>

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and

Planning Staff, Two Constitution Square, 145 N Street NE, 4W-218, Washington, DC.

Dated: October 23, 2024.

Darwin Arceo,
Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024-24990 Filed 10-25-24; 8:45 am]

BILLING CODE 4410-04-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On October 17, 2024, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of Florida in the lawsuit entitled *United States v. Petroleum Products Corp., et al.*, Civil Action No. 1:91-cv-02014-BB.

In the filed Amended Complaint, the United States, on behalf of the U.S. Environmental Protection Agency ("EPA"), alleges that the Defendants are liable under the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9606 and 9607(a), for the response costs EPA incurred to respond to the releases and/or threatened releases of hazardous substances into the environment at the Petroleum Products Corporation Superfund Site located generally at 3150 Pembroke Road in Pembroke Park, Broward County, Florida that the Settling Defendants owned and operated. The Consent Decree requires the Settling Defendants to perform Remedial Action for the Site, pay past response costs for the Site and pay future costs related to the work. The Estimate for the Remedial Action is more than \$57,000,000. The Settling Defendants are responsible for performing the Work, but the FDEP will pay for at least \$30 million of it through a statutory trust fund and a petroleum product cleanup program established in 1987.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States v. Petroleum Products Corp., et al.*, D.J. Ref. No. 90-11-3-585/3. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	pubcomment-ees.enrd@usdoj.gov .
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

Any comments submitted in writing may be filed in whole or in part on the

public court docket without notice to the commenter.

During the public comment period, the Consent may be examined and downloaded at this Justice Department website: <https://www.justice.gov/enrd/consent-decrees>. If you require assistance accessing the Consent Decree, you may request assistance by email or by mail to the addresses provided above for submitting comments.

Scott Bauer,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2024-24969 Filed 10-25-24; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF JUSTICE

Federal Bureau of Prisons

Record of Decision; Proposed Development of a New Federal Correctional Institution and Federal Prison Camp—Letcher County, Kentucky

I. Introduction

This Record of Decision (ROD) pursuant to the National Environmental Policy Act (NEPA) of 1969, as amended, documents the decision regarding the proposal by the United States (U.S.) Department of Justice (DOJ), Federal Bureau of Prisons (FBOP) to acquire properties totaling approximately 500 acres in area in order to construct and operate a new Federal Correctional Institution (FCI) and Federal Prison Camp (FPC) in Letcher County, Kentucky. The ROD describes the alternatives considered and the rationale for selecting the chosen alternative.

The purpose of this ROD is to publish the Agency's decision with respect to the environmental review process. The decision is based on information and analysis contained in the Draft Environmental Impact Statement (DEIS) issued March 1, 2024, and the Final EIS (FEIS) issued July 12, 2024, together with various technical studies, other EISs conducted since 2015, and comments and input received from federal and state agencies, elected officials, organizations, and individuals.

II. Background

The mission of the FBOP is for corrections professionals to foster a humane and secure environment and ensure public safety by preparing individuals for successful re-entry into society. Congress, in 2006, directed the FBOP to initiate investigations leading to development of a new federal

correctional facility in Letcher County, Kentucky (see H.R. Rep. No. 109-272 that accompanies Pub. L. 109-108). In response, the FBOP has conducted a wide range of technical investigations and feasibility studies to comply with Congress' directive including publication of a DEIS (2015), FEIS (2015), Revised FEIS (2016), Draft Supplemental Revised FEIS (2017), Final Supplemental Revised FEIS (2017) and Record of Decision (2018) with each prepared in support of development of a new high-security United States Penitentiary (USP) and FPC in Letcher County.

In July 2019, the Acting FBOP Director Hugh J. Hurwitz withdrew the 2018 ROD based on new cost and Adults in Custody (AIC) population trend information that came to light, which may have been relevant to the environmental analysis for the Proposed Action. The FBOP has continuously evaluated its current and projected future AIC populations and determined that the need to house medium-security AIC in the Mid-Atlantic Region supersedes the need to house high-security AIC. Since the design, construction, and operation of a high-security USP differs from a medium-security FCI, the potential environmental impacts of its development and operation would also be different. As a result of the 2018 ROD being withdrawn, the FBOP undertook new evaluations and analyses in accordance with current Council on Environmental Quality and NEPA guidelines, DOJ procedures for implementing NEPA, and other federal regulations as part of preparation of a new DEIS. The FBOP published a DEIS on March 1, 2024, and a FEIS on July 12, 2024, to develop a new FCI in Letcher County, Kentucky to meet its immediate and long-term needs.

III. Purpose and Need for the Project

The purpose and need for developing the proposed FCI and FPC was determined by the growing number of aged and obsolete federal correctional facilities, which are no longer cost-effective or sustainable to operate and maintain. The FBOP is responsible for all aspects of facility and infrastructure operations, maintenance, repairs, and renovations including interior and exterior finishes; roofs and structural systems; perimeter fences and other security measures; mechanical, electrical, plumbing, lighting, and utility systems; communication equipment, and fire protection and life safety systems. The condition of facilities, infrastructure, and equipment is critical to effective correctional

facility operation and security. This is the case with the federal prison system where facilities and infrastructure are in continuous use and require frequent maintenance ranging from routine inspections and repairs to large-scale upgrades, renovations, and replacements. Of the FBOP's many institutions, 62 were developed between 1890 and 1991, 55 institutions were developed between 1992 and 2007, and five were developed since 2008.

The FBOP proposes to acquire approximately 500 acres in Letcher County to construct and operate a modern new FCI, FPC, and ancillary facilities to meet the need to house medium- and minimum-security AIC in the Mid-Atlantic Region. Ancillary facilities would include a central utility plant, garage/landscape building, outside warehouse, staff training building and outdoor firing range, water storage tank, access drive, and internal roadways and parking lots. The proposed FCI would be designed to house 1,152 medium-security AIC with the FPC designed to house 256 minimum-security AIC for a total population of 1,408 AIC.

IV. Alternatives Considered

A. No Action Alternative

The No Action Alternative is defined as a decision by the FBOP not to proceed with the Proposed Action, thereby precluding development of a new FCI/FPC to house a portion of the federal AIC population in the Mid-Atlantic Region and maintaining the status quo.

Adopting the No Action Alternative would avoid the potential short-term, temporary impacts associated with FCI/FPC construction, among them increased noise levels, fugitive dust emissions, soil erosion, fuel consumption with the associated air emissions, and traffic volumes. Adopting the No Action Alternative would also avoid the potential permanent impacts to land use, biological resources, utility services, visual and aesthetic resources, and traffic volumes associated with FCI/FPC construction and operation. Implementation of the No Action Alternative, however, would result in the loss of positive benefits including contributing to achieving the mandates of Congress; the need for modern, secure, efficient and cost-effective institutions; the societal benefits derived from efficient operation of the federal criminal justice system; and the economic and employment opportunities which would become

available as a result of FCI/FPC development.

The FBOP has a need for modern and secure correctional facilities and infrastructure nationwide. With increasing numbers of federal correctional facilities becoming outdated, physically and operationally obsolete, and costly to operate and maintain, the FBOP is required to continuously improve the system's infrastructure through repair and renovation of existing facilities when possible and construction of new institutions when necessary. The No Action Alternative does not meet the purpose and need for the Proposed Action and has been eliminated from consideration.

B. Letcher County Alternatives

In 2006, Congress directed the FBOP to initiate various investigations for development of a new federal correctional institution in Letcher County, Kentucky. In conformance with that directive, the FBOP has focused its attention and resources upon the 339-square-mile area comprising Letcher County at the exclusion of other areas of the Mid-Atlantic Region and the U.S. as a whole.

Planning for a new federal correctional facility began in earnest in 2008. At that time, FBOP officials began familiarizing themselves with Letcher County by gathering technical information and engaging elected officials, federal, state and local governmental agencies, members of the business community, leaders of educational and health care institutions, utility providers, and others knowledgeable of local conditions affecting development. With assistance from community members, the process of identifying prospective sites began with a focus on physical conditions and characteristics influencing development in Letcher County along with the availability of public services and infrastructure. Candidate sites were identified on the basis of initial development requirements:

- Sufficient land area to accommodate the institution and a buffer zone between the facility and neighboring properties.
- Relatively level building sites or properties that could be altered to accommodate development.
- Ability to avoid sensitive environmental resources including floodplains, wetlands, threatened and endangered species habitats, and cultural and historic resources.
- Avoidance of potential conflicts with adjoining or nearby land uses.

- Availability of utility and transportation infrastructure.
- Willingness of owners to consider a sale of their property.

Sites that satisfied these initial requirements were evaluated further by applying increasingly rigorous criteria to ensure that all issues or potential issues are adequately addressed. Sites that appear suitable on the basis of the initial evaluations were subjected to in-depth analysis and documented in the form of EISs and other technical studies.

1. Identification of Alternative Sites

After the FBOP's site requirements were shared with Letcher County representatives, four candidate sites—Meadow Branch, Payne Gap, Roxana, and Van/Fields sites, were made available for evaluation for possible acquisition and development. All four sites are located in proximity of the City of Whitesburg (Letcher County seat).

The FBOP conducted a Site Reconnaissance Study (2008) to determine the suitability of each for development. Based on the results of the Site Reconnaissance Study, the FBOP determined that the four sites should be studied further in the form of a Feasibility Study. Completed in 2011, the Feasibility Study assessed cultural resources, wetlands, geologic conditions, and infrastructure availability and provided in-depth analyses of each site while identifying constraints that could eliminate a site from further consideration.

While conducting the Feasibility Study, the offer to consider the Meadow Branch site was withdrawn and the site was dropped from consideration. For the remaining sites, various technical studies were conducted. However, as the Feasibility Study neared completion, the Van/Fields site owners were no longer interested in selling the property, necessitating its removal from consideration. The remaining two sites, Payne Gap and Roxana, were considered viable alternatives and were the subject of a DEIS published in February 2015 and subsequent EISs published between July 2015 and September 2017.

2. Search for Other Alternative Sites

During the development of the current EIS the FBOP conducted another search in Letcher County for sites that would be suitable for development based on the siting criteria. The site search, undertaken from June to November 2022, revealed small pockets of relatively level topography scattered throughout the county. Many of these locations comprise previous surface mines, which were reclaimed after the mineral deposits were extracted and are

being redeveloped for housing and small-scale warehouse and light industrial uses as well as golf courses and other recreational uses. In addition to areas where the surface extraction of coal took place, large tracts of land in Letcher County were subjected to underground coal mining, which depending upon the depth of the mines and mining methods, rendered such lands equal to or less suitable than the Roxana and Payne Gap sites.

Many of the sites reviewed in 2022 were located within lower elevations and adjoining or near streams and rivers that are susceptible to flooding during severe weather events. No properties examined in 2022 were found sufficiently level and unencumbered to accommodate the proposed development without significant topographic alterations and the associated environmental impacts.

In addition to a site's physical characteristics, the interest and cooperation of property owners is another key factor in determining a site's potential for FBOP use. During the initial planning phase, the FBOP seeks out owners willing to negotiate a sale of their holdings thereby avoiding other methods of property acquisition. In 2022, inquiries and outreach were made to several property owners to ascertain their willingness to discuss their land holdings; however, none of the property owners approached showed any interest in participating in such a discussion. As a result, the effort to identify other alternative locations in Letcher County for development of the proposed project ended in favor of continuing to consider the Payne Gap and Roxana sites as alternatives.

3. Alternative Location, Payne Gap Site

This alternative involves acquisition of approximately 753 acres known as the Payne Gap Site and located 11 miles east of Whitesburg. The site is situated on a steeply sloping upland landform above the Kentucky River at its confluence with the Laurel Fork. U.S. Route 119 is located along the north end of the site and would be the means of vehicular access. The site is covered by secondary growth forests and portions of the original topography have been altered by past mining activities with spoil piles, unpaved roads, and fill piles covering the site. Mining permit applications indicate both surface and underground mining operations dating to the 1950s have occurred within the site. Summer roosting habitat and winter hibernaculum for the endangered northern long eared bat have also been identified at the Payne Gap Site.

To accommodate development approximately 300 acres of the Payne Gap Site would require extensive rock and spoil excavation and fill material to level and prepare the site for development. While site preparation would require the removal of mine spoil, there are no slurry ponds or coal mine waste facilities located on or near the Payne Gap Site and no active mining is occurring on site.

4. Alternative Location, Roxanna Site

This alternative involves acquisition of approximately 500 acres known as the Roxana Site and located 10 miles west of Whitesburg. Much of the site consists of relatively steep terrain with similarly steep terrain extending beyond the site boundaries to the north and south. However, portions of the original topography have been altered by past mining activities rendering the central portion of the site relatively level. The site is also covered by secondary growth forests which have occurred since surface mining ended. Mining permit applications indicate mining operations dating to the 1960s have occurred within the site.

To accommodate development, approximately 200 acres of the site would require extensive excavation of spoil material and lesser amounts of structural fill and spoil fill. Preparation of the site for construction activities would also require dynamic compaction, clearing and alteration of previously mined areas, and forest clearing. Excavations would include the removal of mine spoil. No slurry ponds or coal mine waste facilities are located on or within two miles of the Roxana Site and no active mining is occurring on site.

C. Preferred Alternative

Development of the proposed medium-security FCI and minimum-security FPC at the Roxana Site is considered the Preferred Alternative as it best meets the project needs and, on balance, would have fewer impacts to the human environment. Threatened and endangered species habitat was also a factor in the identification of the Preferred Alternative with development at the Payne Gap Site potentially impacting a significant amount of summer roosting habitat versus the amount that would be affected at the Roxana Site. Development at the Payne Gap Site would also have significant impacts to wastewater and natural gas infrastructure, while the Roxana Site would have less than significant impacts to utility infrastructure.

Based upon these and other potential environmental impacts applicable to

each site, including wetlands and stream impacts and significantly greater site preparation required for the Payne Gap Site, development of the proposed project at the Roxana Site has been determined by the FBOP to be the Preferred Alternative. The Preferred Alternative meets the project objectives, is technically feasible, would have fewer natural resource and other environmental impacts, and incorporates measures to avoid or minimize environmental impacts to the extent practicable. Reinforcing the Roxana Site as the Preferred Alternative is the preference expressed by Letcher County's elected representatives, community leaders, members of local institutions and businesses to developing the proposed correctional facility at the Roxana Site.

V. Avoidance, Minimization, and Mitigation Measures

Based on the findings represented by the DEIS and FEIS (2024), the FBOP shall implement the avoidance, minimization, and mitigation measures described below to lessen the potential adverse environmental impacts associated with the Preferred Alternative. With regards to socioeconomic considerations, southeastern Kentucky in general, and Letcher County in particular, has experienced steady declines in population, commercial activity, and other social and economic indices. Expanded employment and economic opportunities arising from FCI/FPC development are considered beneficial to achieving the social and economic goals of Letcher County and the surrounding region. The Preferred Alternative is also not expected to result in adverse impacts to Environmental Justice populations, therefore, mitigation measures for social, economic, and Environmental Justice are not warranted.

1. Topography, Geology, Soils, and Hydrology

(a) Earthwork and related ground disturbance shall be minimized by developing the FCI/FPC in a compact, campus-style arrangement thereby limiting the area subject to disturbance.

(b) To the degree feasible, site preparation activities would only disturb areas necessary for the current phase of construction.

(c) Engineering studies of surface and subsurface conditions shall be conducted to ensure appropriate standards and sound building practices are specified prior to construction. Risks associated with seismic activity and measures to minimize such risks shall

be addressed during design and construction.

(d) A Soil Erosion and Sediment Control Plan (E&S Control Plan) shall be prepared describing measures for controlling erosion and sedimentation during construction. Attention would be directed toward erosion potential and other engineering characteristics of rocks, spoil material, and soils to be encountered during construction. The E&S Control Plan shall be submitted to the Kentucky Department of Environmental Protection, Division of Water for approval prior to implementation.

(e) During construction, erosion control measures would be inspected and replaced or repaired as required. Erosion control measures to be maintained following construction shall include lawns and landscaping, discharge pipe aprons, pipe outlet channels, and similar controls.

(f) To ensure safe and secure operation of the FCI/FPC during a severe weather event, the FBOP shall prepare an Adverse Weather Plan and Institution Evacuation Plan that will, among other things, define the food and other provisions, emergency equipment, fuel, and similar necessities to be stockpiled on-site at all times to maintain uninterrupted operation and safeguard AICs and FBOP employees who would remain at their posts for the duration of the severe weather event and its aftermath.

2. Water Resources

(a) A Clean Water Act, Section 404 permit application shall be prepared to document potential impacts and mitigation measures for review and approval by the U.S. Army Corps of Engineers. It is anticipated that mitigation shall consist of payment into the in-lieu fee mitigation program managed by the Kentucky Department of Fish and Wildlife Resources.

(b) A Stormwater Pollution Prevention Plan (SWPPP) shall be prepared addressing temporary and permanent surface water and stormwater management controls. The SWPPP shall be submitted to the Kentucky Department of Environmental Protection, Division of Water for review and approval prior to implementation.

(c) In accordance with the SWPPP, stormwater collection infrastructure shall be installed to control runoff by directing stormwaters into basins to attenuate the intensity of the flow and to allow suspended solids in the stormwater to settle out prior to discharge to receiving streams.

(d) A Groundwater Protection Plan shall be prepared describing temporary

and permanent groundwater protection measures and submitted to the Kentucky Department of Environmental Protection, Watershed Management Branch, Groundwater Section for review and approval prior to implementation.

3. Biological Resources

(a) Impacts to common vegetation and wildlife during construction shall be minimized by limiting the area of disturbance to the extent possible. Upon completion of construction, disturbed areas would be re-vegetated with native plant species.

(b) Under the Conservation Memoranda of Agreement with U.S. Fish and Wildlife Service, the FBOP shall contribute to the Imperiled Bat Conservation Fund as compensatory mitigation for potential adverse effects on special status bat species.

(c) FBOP shall review, revise and update as necessary, and resubmit its Biological Assessment to reinstate formal consultations with the U.S. Department of the Interior, Fish and Wildlife Service (USFWS) under Section 7 of the Endangered Species Act. FBOP shall ensure that the FCI/FPC project is implemented as documented in the updated Biological Assessment and subsequent updated Biological Opinion (BO) to be issued by USFWS.

(d) Conservation measures documented in the Biological Assessment shall be incorporated in project design and construction including: avoiding tree removal during June and July and blasting from November 15 through March 31; conduct construction activities from April 15 through October 31 in suitable Indiana bat and/or northern long-eared bat habitat during daylight hours; require vehicles and equipment to be inspected to remove visible plant and seed material prior to entering the project area; and fence off potential bat hibernacula and install warning signs around the area to prevent disturbance.

4. Cultural Resources

(a) A minimum 100-foot buffer from all development shall be maintained around the Frazier Cemetery (Kentucky Historical Society, Site 15Lr115).

(b) If improvements are necessary to KY 160 and/or KY 588 which result in Adverse Effects on National Register-eligible resources, consultations shall be undertaken with the Kentucky State Historic Preservation Office, Native American Tribes, the Advisory Council on Historic Preservation, and other appropriate organizations. Based on the potential impacts and results of the consultations, measures to mitigate for Adverse Effects shall be determined,

agreed upon, and implemented as appropriate.

5. Hazardous Materials

(a) Locations of petroleum extraction-related releases at the compressor station, the damaged aboveground storage tank (AST), and the AST open drain valve shall be tested to identify contaminated soils with necessary remediation conducted in compliance with applicable regulations of the Kentucky Department of Environmental Protection, Hazardous Waste Branch.

(b) Contaminated soils shall be disposed of only at permitted disposal facilities.

(c) Remediation reports and records shall be submitted to the Kentucky Department of Environmental Protection, Hazardous Waste Branch in accordance with applicable regulations.

(d) Construction materials considered hazardous shall be stored and handled in accordance with applicable environmental, public safety, and occupational health regulations to prevent polluting soil, surface waters, or groundwater. Storage of hazardous materials shall be minimized or avoided where practicable.

(e) Staging areas shall be established prior to construction for the temporary storage and handling of hazardous materials. Liquid storage areas shall be provided with secondary containment systems. Stored materials shall be removed from designated areas by authorized personnel only and recorded by personnel overseeing construction.

(f) FCI/FPC operation shall adhere to applicable regulations governing the handling, storage, and disposal of hazardous wastes.

(g) Biohazardous medical wastes shall be stored, collected and disposed of in accordance with institution policies and procedures and applicable regulations.

6. Visual and Aesthetic Resources

(a) Development shall be directed towards the central portion of the site in a compact, campus-style arrangement that limits visual and physical presence from neighboring properties while allowing for the majority of the site's forests, understory, and topography to remain undisturbed.

(b) Design features that are sensitive to the site's visual environment shall be employed including developing structures that are primarily one and two stories in height and unobtrusive to the degree possible.

(c) Buffer areas consisting of forest stands and other vegetation shall be maintained between the facility and its security perimeter and neighboring

properties to maintain visual compatibility.

(d) Outdoor lighting shall comply with FBOP Technical Design Guidelines (Section 26 25 00—Exterior Lighting) including NFPA 70—National Electric Code; NFPA 101—Life Safety Code; IESNA—Lighting Handbook, Reference, and Application; the American Correctional Association; and the Buy American Act.

(e) Measures to limit unwanted light shall be specified, including use of full cutoff luminaires for security, parking lot, roadway, and pathway lighting resulting in maximum downlighting and minimal upward dispersal of light to the sky.

(f) Low-reflective surface materials shall be specified where practical to minimize upward reflection of light.

(g) Access drive location and design shall be given careful attention including placement of directional signage and lighting fixtures leading to the FCI/FPC.

(h) Design, construction, and maintenance of all facilities and infrastructure shall adhere to a high standard.

7. Community Facilities and Services

(a) Construction and operating policies and procedures shall be communicated to and coordinated with the Letcher County Sheriff's Office, the Kentucky State Police, and local police departments and fire protection companies operating in Letcher County.

(b) Agreements shall be established with local emergency ambulance services in cases requiring an employee or AIC to be transported to an area medical facility.

(c) Agreements shall be established with area medical facility(s) for emergency care in cases involving employees and AIC.

8. Land Use

(a) Setbacks and buffer areas shall be established to achieve land use compatibility between the facility and neighboring properties.

(b) The distance and mountainous conditions separating Lilley Cornett Woods from the project site and the large undeveloped acreage surrounding the FCI/FPC shall ensure adverse land use impacts to Lilley Cornett Woods are avoided.

9. Utilities

(a) Development of the on-site water storage tank and distribution system shall follow applicable regulations with plans submitted to the Kentucky Department of Environmental

Protection, Division of Water for review and approval prior to construction.

(b) Development of the on-site wastewater collection system shall follow applicable regulations with plans submitted to the Kentucky Department of Environmental Protection, Division of Water for review and approval prior to construction.

(c) Extension of electric power shall follow applicable regulations while avoiding service disruptions and maintaining effective worker safety practices and procedures.

(d) Permanent closure, abandonment, and/or relocation of on-site oil/natural gas wells and associated infrastructure shall comply with applicable regulations of the Kentucky Department of Natural Resources, Division of Oil and Gas.

(e) Construction wastes shall be stored on-site and transported to facilities permitted to accept such wastes for recycling or disposal.

(f) Solid wastes generated during FCI/FPC operation shall be stored in enclosed dumpsters or roll off containers in accordance with institution policies and procedures until collected and transported for recycling or final disposal.

10. Transportation

(a) A Traffic Safety and Maintenance Plan shall be developed prior to construction. The plan shall identify optimum vehicle routing during construction including permissible traffic movements along KY 588 and KY 160, vehicle height and weight limitations, and the need for temporary detours or lane closures to avoid damaging roadways.

(b) Construction schedules and activities shall be communicated and coordinated with the appropriate Commonwealth of Kentucky and Letcher County law enforcement and transportation agencies so traffic safety is maintained and any disruptions to normal traffic operations are minimized.

11. Air Quality

(a) Best management practices shall be implemented during construction including covering and/or periodically wetting exposed soil, material stockpiles, and other unpaved surfaces; providing dust control measures during weekends, after hours, and prior to daily start-up of construction activities; operating equipment in accordance with manufacturer's specifications; and limiting unnecessary idling of diesel-powered engines among other measures.

(b) Design and construction shall follow applicable regulations with permit(s) obtained from the Kentucky

Department for Environmental Protection, Division for Air Quality for air emission sources.

(c) Electric charging stations shall be provided for dedicated on-site government vehicles with additional infrastructure installed for future charging stations for employee and visitor electric powered vehicles.

(d) Design and construction of facilities shall apply the appropriate codes and incorporate features to minimize the potential for radon to accumulate in concentrations exceeding U.S. Environmental Protection Agency action levels.

12. Noise

(a) Construction activities shall be confined to normal working hours to the extent feasible.

(b) Construction equipment shall be equipped with appropriate noise attenuation devices and be maintained and operated in accordance with manufacturers specifications.

(c) Material and equipment staging areas and haul routes would be placed away from property boundaries to minimize potential for off-site noise impacts.

13. Climate

(a) FBOP shall pursue the sustainable green building certification program Leadership in Energy and Environmental Design including use of low volatile organic compound (VOC) materials, elimination of ozone depleting gases, and other conservation measures.

(b) FBOP shall consider Executive Order 13693, Planning for Federal Sustainability in the Next Decade, Executive Order 14057, Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability, Council on Environmental Quality's Final NEPA Guidance on Consideration of the Effects of Climate Change and Greenhouse Gas Emissions and other applicable executive orders and regulations during FCI/FPC design and construction.

VI. Decision

Based on consultations with federal, Commonwealth of Kentucky, and local regulatory agencies; consideration of potential environmental consequences; current operational, security, and management needs for the Mid-Atlantic Region; public comments on the 2024 DEIS and FEIS; and having been apprised of the material and information contained in previous technical studies, the FBOP has decided to select development of a new FCI and FPC at the Roxana Site in Letcher County as the

Preferred Alternative as summarized above and described in detail within the 2024 FEIS. Development of the proposed project at the Roxana Site in Letcher County is contingent on the availability of funding sufficient to proceed.

VII. Rationale

The FBOP's decision is based on the following:

The condition of facilities, infrastructure, and equipment is critical to effective correctional facility operation and security. As a result of their continuous use, facilities, infrastructure, and equipment require frequent maintenance and repairs, large-scale upgrades and renovations, and in select cases, complete replacement. With over 50 percent of all federal correctional facilities developed prior to 1991, and many facing a substantial backlog of Modernization and Repair (M&R) work, the challenge confronting the FBOP to continue achieving its mission with aging and obsolete institutions is formidable.

Coinciding with the need for modern facilities and infrastructure, Congress directed the FBOP to conduct investigations leading to development of a new federal correctional facility in Letcher County, Kentucky. The decision to develop a new FCI and FPC at the Roxana Site in Letcher County is based on the many detailed investigations conducted by the FBOP and demonstrates compliance with Congress' directive while best meeting the FBOP's goals and objectives. Because implementation of this alternative would have fewer adverse impacts on the human and natural environments, the FBOP considers it to be the Preferred Alternative.

Construction of the proposed FCI/FPC at the Roxana Site will result in short-term, temporary impacts including increased noise levels, fugitive dust emissions, soil erosion, traffic volumes, and fuel consumption with the associated air emissions. Permanent and significant impacts to topography, geology and soils would also occur from construction with permanent and less than significant impacts anticipated to land use, community facilities and services, transportation and traffic, visual and aesthetic resources, air quality, cultural resources, noise, utility services, water resources, biological resources, and hazardous materials, as defined by NEPA.

While construction and operation of the proposed FCI/FPC at the Roxana Site will cause unavoidable impacts, activities involving construction and operation shall comply with applicable

federal statutes, implementing regulations, Executive Orders, and other consultation, review, and permit requirements. Unavoidable adverse impacts to natural and manmade resources will be controlled, reduced, or eliminated by the avoidance, minimization, and mitigation measures identified in Section V (Avoidance, Minimization, and Mitigation Measures) of this ROD.

The FBOP will implement a Monitoring and Enforcement Program (MEP) to ensure that the proposed avoidance, minimization, and mitigation measures documented within this ROD are implemented. The MEP will identify the timing, responsibility, and method of implementation of the proposed measures, as well as any required monitoring and enforcement activities. As part of the program, each project contractor will be required to implement the mitigation measures arising from its project activities with the FBOP or its authorized agencies overseeing, inspecting and monitoring the measures to ensure compliance. The FBOP will be responsible for any mitigation measures required as part of FCI/FPC operation. The FBOP will maintain the MEP throughout project implementation and will include the MEP in the project administrative record. Any on-going obligations will be the responsibility of the FBOP.

Development of the proposed FCI/FPC at the Roxana Site will result in beneficial impacts by adding a modern new correctional facility to the federal prison system. In doing so, the local and regional economies will benefit from the addition of 325 permanent workers and new annual wages and salaries of \$43 million along with \$14 million in annual expenditures for supplies, equipment, utilities, and other goods and services necessary for operation. The estimated \$57 million annual operating budget is also expected to indirectly support additional private sector employment in Letcher County and throughout southeastern Kentucky. The region has experienced declining populations and slow or no economic growth which makes development of the proposed FCI/FPC attractive and consistent with the socioeconomic goals and objectives expressed by Letcher County leaders and representatives.

The FBOP will rely upon the Letcher County Water and Sewer District for the provision of water supply and wastewater treatment services along with other providers for electric power, natural gas, telecommunications, and solid waste collection services. Positive economic benefits will also accrue to those utility providers from supplying

such services. The necessity for utility service upgrades, extensions and related improvements will be communicated and coordinated with all appropriate agencies.

Prior to making this decision, the FBOP carefully considered comments received following the publication of the 2024 DEIS and FEIS. The comments and responses thereto are hereby acknowledged and measures to avoid, minimize, and mitigate potential adverse impacts are documented within Section V of this ROD. The FBOP has also carefully considered potential environmental justice impacts of the Proposed Action as discussed in the 2024 FEIS, together with comments concerning environmental justice submitted during the DEIS and FEIS process. As documented in the 2024 FEIS, the FBOP has determined that the Proposed Action will not result in either a disparate or significantly adverse impact to low-income or minority populations to which Executive Order 12898 is applicable.

VIII. Conclusion

After consulting with FBOP staff and being appraised of material in the 2024 DEIS and FEIS and visiting Letcher County in August 2024, it is the decision of the undersigned that the FBOP select the Roxana Site for land acquisition and the development of a FCI and FPC in Letcher County.

Colette S. Peters,

Director, Federal Bureau of Prisons.

[FR Doc. 2024-24948 Filed 10-25-24; 8:45 am]

BILLING CODE P

MERIT SYSTEMS PROTECTION BOARD

Performance Review Board Membership

AGENCY: Merit Systems Protection Board.

ACTION: Notice.

SUMMARY: The Merit Systems Protection Board announces the appointment of the members of its Senior Executive Service Performance Review Board. This notice supersedes all previous notices regarding the Performance Review Board membership.

DATES: These appointments are effective October 28, 2024.

FOR FURTHER INFORMATION CONTACT:

Pervis Lee, Director of Human Resources, Merit Systems Protection Board, 1615 M Street NW, Washington, DC 20419; telephone: (771) 210-1492; or email: pervis.lee@mspb.gov.

SUPPLEMENTARY INFORMATION: The Merit Systems Protection Board (MSPB) is publishing the names of the current members of its Performance Review Board (PRB) as required by 5 U.S.C. 4314(c)(4) and 5 CFR 430.311. Laura M. Alborno, MSPB, serves as Chair of the PRB. Susan M. Swafford, MSPB; Gina K. Grippando, MSPB; and David S. Eddy III, Federal Labor Relations Authority, serve as members of the PRB.

Gina K. Grippando,
Clerk of the Board.

[FR Doc. 2024-24936 Filed 10-25-24; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

[EA-23-140; NRC-2024-0162]

In the Matter of Glow Rhino LLC; Confirmatory Order

AGENCY: Nuclear Regulatory Commission.

ACTION: Order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) issued a Confirmatory Order to Glow Rhino, LLC (Glow Rhino) to document commitments made as part of a settlement agreement between the NRC and Glow Rhino following an alternative dispute resolution mediation session held on July 18, 2024. The mediation addressed two apparent violations involving the possession and distribution of devices containing radioactive materials without the appropriate NRC licenses. Glow Rhino has committed to corrective actions in the following areas: return of unapproved models in Glow Rhino possession, establishing and maintaining written documentation and procedures, and training. The Confirmatory Order became effective upon issuance.

DATES: The Confirmatory Order was issued on October 16, 2024.

ADDRESSES: Please refer to Docket ID NRC-2024-0162 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2024-0162. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301-415-0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed

in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Document collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. The Confirmatory Order is available in ADAMS under Accession No. ML24250A125.

- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Leelavathi Sreenivas, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-287-9249; email: Leelavathi.Sreenivas@nrc.gov.

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated: October 21, 2024.

For the Nuclear Regulatory Commission.

David L. Pelton,

Director, Office of Enforcement.

Attachment—Glow Rhino, LLC—ADR Confirmatory Order

United States of America

Nuclear Regulatory Commission

In the Matter of: Glow Rhino, LLC,
Dearborn, Michigan, EA-23-140

Confirmatory Order Effective Upon Issuance

I

Glow Rhino, LLC. (Glow Rhino) is a limited liability company and a commercial seller of consumer products that contain tritium it purchases and receives from initial distributors that have been licensed by NRC. This Confirmatory Order (CO) is the result of an agreement reached during an Alternative Dispute Resolution (ADR) mediation session conducted on July 18, 2024, in Rockville, Maryland, to address two apparent violations.

II

On November 15, 2022, the NRC's Office of Investigations (OI) opened an

investigation (OI Case No. 3-2023-003). The purpose of the investigation was to determine whether Glow Rhino was in compliance with NRC's regulatory requirements related to Glow Rhino's possession and distribution of products containing radioactive material.

Based on the conclusions of the investigation, the NRC issued two apparent violations that were documented in an NRC letter, dated April 11, 2024,

(Agencywide Documents Access and Management System (ADAMS) Accession No. ML24102A272). The NRC letter identified two apparent violations of Title 10 of the *Code of Federal Regulations* (10 CFR) 30.3, "Activities requiring license". The violations are related to the possession and distribution of products containing radioactive material without the appropriate licenses or authorizations from the NRC.

10 CFR 30.3(a), "Activities requiring license" states, in part, that no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter.

The investigation identified that between approximately January 6, 2021, to October 4, 2023, Glow Rhino possessed a number of consumer products that contained licensable quantities of byproduct material (tritium) that was not authorized by a specific or general license. Specifically, Glow Rhino possessed products containing tritium that were not authorized by a possession license and were not exempt from the requirements for a possession license. In addition, the investigation identified that between approximately January 6, 2021, to October 4, 2023, Glow Rhino transferred products containing byproduct material to persons not possessing a license, without having been evaluated by the NRC and registered in the Sealed Source and Device Registry (SSDR) or authorized for distribution by a license issued pursuant to 10 CFR 30.3(a). The NRC has determined that certain consumer product models possessed and distributed by Glow Rhino did not match the description and information in the SSDR. The models identified in the apparent violations were: Tritium Pry Bar, Tritium Glow Fob, Tritium Keybar, Ember Fob, Griffin Pocket Tool, Spyderco Paramilitary 3, G10 Scales, Tritium Benchmade Thumbstud—Glow Rhino, Tritium Benchmade Bugout Axis Lockbar, G10 Tritium Scales for the Benchmade Bugout, Tritium Benchmade Griptilian Axis Lockbar,

and Tritium Mini Benchmade Griptilian Axis Lockbar. Subsequently, NRC approved two of the models, authorizing possession and distribution of those models as of the approval date. On March 1, 2023, NRC approved the Tritium Pry Bar model included in the apparent violation. On October 4, 2023, NRC approved the Tritium Glow Fob with the exoskeleton included in the apparent violation.

When issuing the apparent violations, the NRC provided Glow Rhino an opportunity to respond in writing, attend a pre-decisional enforcement conference or participate in an ADR mediation session to resolve these concerns. In response, Glow Rhino requested the use of the NRC's ADR process. On July 18, 2024, the NRC and Glow Rhino conducted an ADR session mediated by a professional mediator, arranged through Cornell University's Scheinman Institute on Conflict Resolution. The ADR process is one in which a neutral mediator, with no decision-making authority, assists the parties in reaching an agreement to resolve any differences regarding the dispute. This Confirmatory Order is issued pursuant to the agreement reached during the ADR process.

III

NRC and Glow Rhino reached a preliminary settlement agreement during a full-day mediation session that was conducted on July 18, 2024. The elements of the agreement include the following:

1. The Confirmatory Order will acknowledge the following actions have been completed:

- Glow Rhino ceased distribution, of all the models in the apparent violation (AV), except glow fob and pry bar, from 9/9/23 to present.

- Glow Rhino ceased distribution of glow fob 9/21/22–10/4/23 and pry bar 10/13/22–3/1/23. Glow Rhino resumed distribution after the models were authorized by NRC.

- Glow Rhino recalled available products back in from third-party vendors.

2. NRC and Glow Rhino agree to disagree on the issue of whether the models referenced in NRC letter dated 4/11/24 letter are authorized or not.

3. Glow Rhino will provide access to NRC for inspection to allow NRC independent verification that Confirmatory Order conditions have been satisfied. The inspection will be an announced inspection.

4. Within 90 days, Glow Rhino will provide written confirmation to NRC that it has returned all units for models specifically listed in AV1 to the supplier

(or another entity licensed to possess tritium). The written confirmation will include, for each model listed in AV1: the Glow Rhino model number, the number of units in Glow Rhino's possession, the number of units transferred, the name and license number of the entity it was transferred to, and the date of transfer. Glow Rhino will obtain written documentation of transfer from the licensee(s) that they transferred the material to. Glow Rhino will provide a copy of that documentation to NRC.

5. Glow Rhino will establish and maintain a crosswalk.

- Within 45 days, Glow Rhino will provide a list of all Glow Rhino models still in Glow Rhino possession that contain radioactive material. The list will include the Glow Rhino model number.

- Within 90 days, for each model in the list, Glow Rhino will:

- (A) establish and maintain a written crosswalk. The crosswalk will list all models possessed by Glow Rhino. For each model, the crosswalk will list: the supplier's name, the supplier exempt license number, the supplier registered model number, and written confirmation from the supplier that the model is an authorized model (*i.e.*, has been distributed under an exempt distribution license and is registered in accordance with 10 CFR 32.210). The crosswalk will be updated to include any changed or new models prior to Glow Rhino distribution of those models.

- or (B) For any model not included on the crosswalk in (A), Glow Rhino will provide written documentation that Glow Rhino has returned all units of that model to the supplier.

- Within 90 days, Glow Rhino will provide to NRC,

- (A) the initial copy of the written crosswalk of models in Glow Rhino possession

- and (B) a copy of the written documentation of returned models.

- Glow Rhino will maintain the crosswalk in (A) for a minimum of 3 years.

- A copy of the crosswalk will be maintained on site available for NRC review. A copy will be provided to NRC upon request.

6. Within 90 days, Glow Rhino will establish and implement a written procedure to verify that Glow Rhino only possesses authorized models.

- The procedure will include instructions for:

- the development and maintenance of the crosswalk

- how the crosswalk is used to verify only authorized models are ordered

- updating the crosswalk to include any changed or new models prior to Glow Rhino distribution of those models.

- A copy of the procedure will be maintained on site available for NRC review. A copy will be provided to NRC upon request.

7. Within 120 days, all Glow Rhino individuals involved in the tritium product verification and acquisition will be trained in the applicable Glow Rhino procedures/processes, as applicable for their role.

- Training will include reading the procedures established within this Agreement in Principle.

- Training for management will also include: reading the NRC letter dated 4/11/24 and reading the NRC Confirmatory Order.

- Glow Rhino will provide training to new individuals involved in tritium product verification and acquisition and will do annual refresher training for a minimum 3 years.

- Training will be documented, and the documentation will include the date, names, and a summary of content.

- A copy will be maintained on site available for NRC review. A copy will be provided to NRC upon request.

The NRC considers the actions discussed above to be appropriately prompt and comprehensive.

The NRC agrees to not issue a separate Notice of Violation to Glow Rhino.

The NRC agrees to not impose a civil penalty.

The NRC agrees not to pursue any further enforcement action in connection with the NRC's April 11, 2024, letter to Glow Rhino (EA–23–140).

Unless otherwise specified, all dates are from the date of issuance of the Confirmatory Order.

Unless otherwise specified, all documents required to be submitted to the NRC will be sent to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852–2738, with a copy to the Director, Materials Safety, Security, State, and Tribal Programs, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852–2738.

This agreement is binding upon successors and assigns of Glow Rhino. In the event of the transfer of the ownership of Glow Rhino to another entity, the terms and conditions set forth hereunder shall continue to apply and accordingly survive any transfer of ownership.

Based on the completed (and planned) actions described above, and the commitments described in Section V below, the NRC agrees to not pursue any

further enforcement action based on the apparent violations identified in NRC's April 11, 2024, letter (see Section II).

On October 08, 2024, Glow Rhino consented to issuing this Confirmatory Order with the commitments, as described in Section V below. Glow Rhino further agreed that this Confirmatory Order is to be effective upon issuance, and that the agreement memorialized in this Confirmatory Order settles the matter between the parties, and Glow Rhino has waived its right to a hearing.

IV

I find that the actions completed or planned by Glow Rhino, as described in Section III above, combined with the commitments as set forth in Section V, are acceptable and necessary, and conclude that public health and safety are reasonably assured with these completed actions and commitments. In view of the foregoing, I have determined that public health and safety require that Glow Rhino's commitments be confirmed by this Order. Based on the above and Glow Rhino's consent, this Confirmatory Order is effective upon issuance.

V

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR part 30, as applicable, *it is hereby ordered, effective upon issuance, that:*

1. NRC and Glow Rhino agree to disagree on the issue of whether the models referenced in NRC letter dated April 11, 2024, are authorized or not. However, Glow Rhino accepts the NRC determination for the purposes of restoring compliance and addressing corrective actions.

2. The following actions have been completed, based on the NRC determination that the models in the apparent violations in NRC letter dated April 11, 2024, were not authorized:

a. Glow Rhino ceased distribution, of all the models in the apparent violations (AV), except glow fob and pry bar, from September 9, 2023, to present. The models identified in the AVs were: Tritium Pry Bar, Tritium Glow Fob, Tritium Keybar, Ember Fob, Griffin Pocket Tool, Spyderco Paramilitary 3, G10 Scales, Tritium Benchmade Thumbstud—Glow Rhino, Tritium Benchmade Bugout Axis Lockbar, G10 Tritium Scales for the Benchmade Bugout, Tritium Benchmade Griptilian Axis Lockbar, and Tritium Mini Benchmade Griptilian Axis Lockbar.

b. Glow Rhino ceased distribution of Tritium Glow Fob from September 21, 2022, to October 4, 2023, and Tritium Pry Bar from October 13, 2022, to March 1, 2023. Glow Rhino resumed distribution after the models were authorized by NRC.

c. Glow Rhino recalled available product back in from third-party vendors.

3. Glow Rhino will provide access to NRC for inspection to allow NRC independent verification that Confirmatory Order conditions have been satisfied. The inspection will be an announced inspection.

4. Within 90 days, Glow Rhino will provide written confirmation to NRC that it has returned all units for models specifically listed in AV1 to the supplier (or another entity licensed to possess the radioactive material). The written confirmation will include, for each model listed in AV1: the Glow Rhino model number, the number of units in Glow Rhino's possession, the number of units transferred, the name and license# of the entity it was transferred to, and the date of transfer. The written confirmation will also include written documentation of receipt from the licensee(s) that Glow Rhino transferred the material to.

5. Glow Rhino will establish and maintain a crosswalk.

a. Within 45 days, Glow Rhino will provide in writing to NRC a list of all Glow Rhino models still in Glow Rhino's possession that contain radioactive material. The list will include the Glow Rhino model number.

b. Within 90 days, for each model in the list, Glow Rhino will:

(A) establish and maintain a written crosswalk. The crosswalk will list all models possessed by Glow Rhino. For each model, the crosswalk will list: the supplier's name, the supplier exempt license number, the supplier registered model number, and written confirmation from the supplier that the model is an authorized model (*i.e.*, it has been distributed under an exempt distribution license and is registered in accordance with 10 CFR 32.210). The crosswalk will be updated to include any changed or new models prior to Glow Rhino distribution of those models, and

(B) For any model not included on the crosswalk in (A), Glow Rhino will provide written confirmation to NRC that Glow Rhino has returned all units of that model to the supplier. The written confirmation will include, for each model: the Glow Rhino model number, the number of units in Glow Rhino's possession, the number of units transferred, the name and license# of

the entity it was transferred to, and the date of transfer. The written confirmation will also include written documentation of receipt from the licensee(s) (or other entity licensed to possess the radioactive material) to which Glow Rhino transferred the material.

c. Within 90 days, Glow Rhino will provide to NRC,

(A) the initial copy of the written crosswalk of models in Glow Rhino possession and (B) a copy of the written documentation of returned models.

d. Glow Rhino will maintain the written crosswalk in (A) for a minimum of 3 years.

e. A copy the crosswalk will be maintained on site available for NRC review. A copy will be provided to NRC upon request.

6. Within 90 days, Glow Rhino will establish and implement a written procedure to verify that Glow Rhino only possesses authorized models. Authorized models are models that have been authorized by NRC for distribution under an exempt distribution license.

a. The procedure will include instructions for:

1. the development and maintenance of the crosswalk required by Condition 5,
2. how the crosswalk is used to verify that only authorized models are ordered
3. and, updating the crosswalk to include any changed or new models prior to Glow Rhino's distribution of those models.

b. Glow Rhino will maintain and implement the written procedure for a minimum of 5 years.

c. A copy of the procedure will be maintained on site available for NRC review. A copy will be provided to NRC upon request.

7. Within 120 days, all Glow Rhino individuals involved in the tritium product verification and acquisition will be trained in the applicable Glow Rhino procedures/processes, as applicable for their role.

a. Training will include reading the procedures established through this Confirmatory Order.

b. Training for management will also include: reading the NRC letter dated April 11, 2024, and reading this Confirmatory Order.

c. Glow Rhino will provide training to new individuals involved in tritium product verification and acquisition. This training will be provided prior to the new individual engaging in activities involving tritium product verification and acquisition.

d. Glow Rhino will do annual refresher training for all individuals for a minimum of 3 years.

e. Training will be documented and include date, names of the individuals trained, name of the individual conducting the training, and a summary of the content.

f. Glow Rhino will maintain the training documentation for a minimum of 5 years.

g. A copy of training records will be maintained on site available for NRC review. A copy will be provided to NRC upon request.

The NRC considers the actions discussed above to be appropriately prompt and comprehensive.

The NRC agrees to not issue a separate Notice of Violation to Glow Rhino.

The NRC agrees to not impose a civil penalty.

The NRC agrees not to pursue any further enforcement action in connection with the NRC's April 11, 2024, letter to Glow Rhino (EA-23-140).

Unless otherwise specified, all documents required to be submitted to the NRC will be sent to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Director, Materials Safety, Security, State, and Tribal Programs, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738.

This agreement is binding upon successors and assigns of Glow Rhino. In the event of the transfer of the ownership of Glow Rhino to another entity, the terms and conditions set forth hereunder shall continue to apply and accordingly survive any transfer of ownership.

The Director, Office of Enforcement, may, in writing, relax, rescind, or withdraw any of the above conditions upon demonstration by Glow Rhino or its successors of good cause.

VI

In accordance with 10 CFR 2.202 and 10 CFR 2.309, any person adversely affected by this CO, other than Glow Rhino, may request a hearing within 30 calendar days of the date of issuance of this CO. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a

petition, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on making electronic submissions may be found in the "Guidance for Electronic Submissions to the NRC" (ADAMS Accession No. ML13031A056) and on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals/getting-started.html>. Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at <https://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time (ET) on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the

document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>, by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, excluding Federal government holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)-(d). Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at <https://adams.nrc.gov/ehd>, unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click "cancel" when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such

information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

The Commission will issue a notice or order granting or denying a petition, designating the issues for any hearing that will be held, and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

If a person (other than Glow Rhino) requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this CO and shall address the criteria set forth in 10 CFR 2.309(d) and (f). If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an order designating the time and place of any hearings. If a hearing is held, the issue to be considered at such hearing shall be whether this CO should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 30 days from the date of this CO without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

For the Nuclear Regulatory Commission.
David L. Pelton, Director
/RA/
Office of Enforcement

Dated this 16th day of October 2024

[FR Doc. 2024-24829 Filed 10-25-24; 8:45 am]

BILLING CODE 7590-01-P

OFFICE OF PERSONNEL MANAGEMENT

Federal Prevailing Rate Advisory Committee Virtual Public Meeting

AGENCY: Office of Personnel
Management.

ACTION: Notice.

SUMMARY: According to the provisions of section 10 of the Federal Advisory Committee Act, notice is hereby given that a virtual meeting of the Federal Prevailing Rate Advisory Committee will be held on Thursday, November 21,

2024. There will be no in-person gathering for this meeting.

DATES: The virtual meeting will be held on November 21, 2024, beginning at 10:00 a.m. (ET).

ADDRESSES: The meeting will convene virtually.

FOR FURTHER INFORMATION CONTACT: Ana Paunoiu, 202-606-2858, or email pay_policy@opm.gov.

SUPPLEMENTARY INFORMATION: The Federal Prevailing Rate Advisory Committee is composed of a Chair, five representatives from labor unions holding exclusive bargaining rights for Federal prevailing rate employees, and five representatives from Federal agencies. Entitlement to membership on the Committee is provided for in 5 U.S.C. 5347.

The Committee's primary responsibility is to review the Prevailing Rate System and other matters pertinent to establishing prevailing rates under subchapter IV, chapter 53, 5 U.S.C., as amended, and from time to time advise the Office of Personnel Management.

Annually, the Chair compiles a report of pay issues discussed and concluded recommendations. These reports are available to the public. Reports for calendar years 2008 to 2023 are posted at <http://www.opm.gov/fprac>. Previous reports are also available, upon written request to the Committee.

The public is invited to submit material in writing to the Chair on Federal Wage System pay matters felt to be deserving of the Committee's attention. Additional information on these meetings may be obtained by contacting the Committee at Office of Personnel Management, Federal Prevailing Rate Advisory Committee, Room 7H31, 1900 E Street NW, Washington, DC 20415, (202) 606-2858.

This meeting is open to the public, with an audio option for listening. This notice sets forth the participation guidelines for the meeting.

Meeting Agenda. The committee meets to discuss various agenda items related to the determination of prevailing wage rates for the Federal Wage System. The committee's agenda is approved one week prior to the public meeting and will be available upon request at that time.

Public Participation: The November 21, 2024, meeting of the Federal Prevailing Rate Advisory Committee is open to the public through advance registration. Public participation is available for the meeting. All individuals who plan to attend the virtual public meeting to listen must register by sending an email to paypolicy@opm.gov with the subject

line "November 21, 2024" no later than Tuesday, November 19, 2024.

The following information must be provided when registering:

- Name.
- Agency and duty station.
- Email address.
- Your topic of interest.

Members of the press, in addition to registering for this event, must also RSVP to media@opm.gov by November 19, 2024.

A confirmation email will be sent upon receipt of the registration. Audio teleconference information for participation will be sent to registrants the morning of the virtual meeting.

Office of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

[FR Doc. 2024-25016 Filed 10-25-24; 8:45 am]

BILLING CODE 6325-39-P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2025-115 and K2025-113; MC2025-117 and K2025-115; MC2025-118 and K2025-116; MC2025-119 and K2025-117; MC2025-120 and K2025-118; MC2025-121 and K2025-119; MC2025-122 and K2025-120; MC2025-123 and K2025-121; MC2025-124 and K2025-122]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* October 29, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. Public Proceeding(s)
- III. Summary Proceeding(s)

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal

Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. See 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR

3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s)*: MC2025–115 and K2025–113; *Filing Title*: USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 498 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: October 21, 2024; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Kenneth R. Moeller; *Comments Due*: October 29, 2024.

2. *Docket No(s)*: MC2025–117 and K2025–115; *Filing Title*: USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 500 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: October 21, 2024; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Jennaca D. Upperman; *Comments Due*: October 29, 2024.

3. *Docket No(s)*: MC2025–118 and K2025–116; *Filing Title*: USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 501 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: October 21, 2024; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Christopher C. Mohr; *Comments Due*: October 29, 2024.

4. *Docket No(s)*: MC2025–119 and K2025–117; *Filing Title*: USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 502 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: October 21, 2024; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Gregory S. Stanton; *Comments Due*: October 29, 2024.

5. *Docket No(s)*: MC2025–120 and K2025–118; *Filing Title*: USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 503 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: October 21, 2024; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Gregory S. Stanton; *Comments Due*: October 29, 2024.

6. *Docket No(s)*: MC2025–121 and K2025–119; *Filing Title*: USPS Request to Add Priority Mail Express, Priority

Mail & USPS Ground Advantage Contract 504 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: October 21, 2024; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Almaroof Agoro; *Comments Due*: October 29, 2024.

7. *Docket No(s)*: MC2025–122 and K2025–120; *Filing Title*: USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 505 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: October 21, 2024; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Almaroof Agoro; *Comments Due*: October 29, 2024.

8. *Docket No(s)*: MC2025–123 and K2025–121; *Filing Title*: USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 506 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: October 21, 2024; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Madison Lichtenstein; *Comments Due*: October 29, 2024.

9. *Docket No(s)*: MC2025–124 and K2025–122; *Filing Title*: USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 507 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: October 21, 2024; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Madison Lichtenstein; *Comments Due*: October 29, 2024.

III. Summary Proceeding(s)

None. See Section II for public proceedings.

This Notice will be published in the **Federal Register**.

Erica A. Barker,
Secretary.

[FR Doc. 2024–24946 Filed 10–25–24; 8:45 am]

BILLING CODE 7710–FW–P

¹ See Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2025–125 and K2025–123; MC2025–126 and K2025–124; MC2025–127 and K2025–125; MC2025–128 and K2025–126; MC2025–129 and K2025–127; MC2025–130 and K2025–128; MC2025–131 and K2025–129; MC2025–132 and K2025–130; MC2025–133 and K2025–131; MC2025–134 and K2025–132; MC2025–135 and K2025–133; MC2025–136 and K2025–134; MC2025–137 and K2025–135; MC2025–138 and K2025–136; MC2025–139 and K2025–137; MC2025–140 and K2025–138; MC2025–141 and K2025–139; MC2025–142 and K2025–140]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* October 30, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

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The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance

with the requirements of 39 CFR 3011.301.¹

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. See 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s):* MC2025–125 and K2025–123; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 508 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39

CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* October 30, 2024.

2. *Docket No(s):* MC2025–126 and K2025–124; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 509 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* October 30, 2024.

3. *Docket No(s):* MC2025–127 and K2025–125; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 510 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* October 30, 2024.

4. *Docket No(s):* MC2025–128 and K2025–126; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 511 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Gregory S. Stanton; *Comments Due:* October 30, 2024.

5. *Docket No(s):* MC2025–129 and K2025–127; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 512 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Gregory S. Stanton; *Comments Due:* October 30, 2024.

6. *Docket No(s):* MC2025–130 and K2025–128; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 403 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth R. Moeller; *Comments Due:* October 30, 2024.

7. *Docket No(s):* MC2025–131 and K2025–129; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 404 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024;

¹ See Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

Filing Authority: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth R. Moeller; *Comments Due:* October 30, 2024.

8. *Docket No(s).*: MC2025–132 and K2025–130; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 513 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Madison Lichtenstein; *Comments Due:* October 30, 2024.

9. *Docket No(s).*: MC2025–133 and K2025–131; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 405 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jennaca D. Upperman; *Comments Due:* October 30, 2024.

10. *Docket No(s).*: MC2025–134 and K2025–132; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 406 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jennaca D. Upperman; *Comments Due:* October 30, 2024.

11. *Docket No(s).*: MC2025–135 and K2025–133; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 514 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Madison Lichtenstein; *Comments Due:* October 30, 2024.

12. *Docket No(s).*: MC2025–136 and K2025–134; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 515 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Madison Lichtenstein; *Comments Due:* October 30, 2024.

13. *Docket No(s).*: MC2025–137 and K2025–135; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 516 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:*

October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Samuel Robinson; *Comments Due:* October 30, 2024.

14. *Docket No(s).*: MC2025–138 and K2025–136; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 407 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Samuel Robinson; *Comments Due:* October 30, 2024.

15. *Docket No(s).*: MC2025–139 and K2025–137; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 517 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Samuel Robinson; *Comments Due:* October 30, 2024.

16. *Docket No(s).*: MC2025–140 and K2025–138; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 518 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* October 30, 2024.

17. *Docket No(s).*: MC2025–141 and K2025–139; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 519 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* October 30, 2024.

18. *Docket No(s).*: MC2025–142 and K2025–140; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 520 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 22, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* October 30, 2024.

III. Summary Proceeding(s)

None. See Section II for public proceedings.

This notice will be published in the **Federal Register**.

Erica A. Barker,
Secretary.

[FR Doc. 2024–25010 Filed 10–25–24; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, October 31, 2024.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at <https://www.sec.gov>.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION:

For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: October 24, 2024.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024-25077 Filed 10-24-24; 11:15 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101402; File No. SR-NYSE-2024-47]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend Section 102.01 of the NYSE Listed Company Manual To Provide That the Distribution Standard Therein Will Be Calculated on a Worldwide Basis

October 22, 2024.

On August 22, 2024, New York Stock Exchange LLC (“NYSE”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b-4 thereunder,² a proposed rule change to amend Section 102.01 of the NYSE Listed Company Manual to provide that the distribution standard therein will be calculated on a worldwide basis. The proposed rule change was published for comment in the **Federal Register** on September 10, 2024.³ The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act⁴ provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission will either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is October 25, 2024. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change, so that it has sufficient time

to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,⁵ designates December 9, 2024, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR-NYSE-2024-47).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-24939 Filed 10-25-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101406; File No. SR-CboeBZX-2024-097]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Company Listing Fees in BZX Rule 14.13

October 22, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 9, 2024, Cboe BZX Exchange, Inc. (“Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (“BZX” or the “Exchange”) is filing with the Securities and Exchange Commission (“Commission” or “SEC”) a proposed rule change to amend the fees applicable to securities listed on the Exchange, which are set forth in BZX Rule 14.13, Company Listing Fees. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange’s website (http://markets.cboe.com/us/equities/regulation/rule_filings/BZX/), at the Exchange’s Office of the

Secretary, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On January 1, 2019, the Exchange adopted an entry fee for exchange-traded products (“ETPs”)³ that are not “Generically-Listed ETPs”.⁴ The entry fee adopted in the Original Entry Fee Filing imposed a maximum entry fee on an issuer basis of \$22,500 per calendar year. Now, the Exchange proposes to eliminate the yearly \$22,500 maximum entry fee (the “entry fee cap”) applied to issuers. The Exchange also proposes to amend Rule 14.13 in order to adopt a separate fee of \$3,500 per ETP for Companies⁵ that make a change to a product already approved for listing and trading on the Exchange that requires a proposed rule change pursuant to Section 19(b) of the Exchange Act (an “Exchange Rule Filing Amendment”).⁶

³ As defined in Rule 11.8(e)(1)(A), the term “ETP” means any security listed pursuant to Exchange Rule 14.11.

⁴ “Generically-Listed ETPs” refers to all ETPs, with the exception of Index Fund Shares, Portfolio Depository Receipts, Managed Fund Shares, Linked Securities, Currency Trust Shares, and Exchange-Traded Fund Shares that are listed on the Exchange pursuant to Rule 19b-4(e) under the Exchange Act and for which a proposed rule change pursuant to Section 19(b) of the Exchange Act is not required to be filed with the Commission. See Exchange Rule 14.13(b)(1)(B)(v)(a). See Securities Exchange Act No. 83597 (July 5, 2018) 83 FR 32164 (July 11, 2018) (SR-CboeBZX-2018-046) (the “Original Entry Fee Filing”).

⁵ See Exchange Rule 14.1(a)(3).

⁶ The Exchange initially filed the proposed fee change on September 12, 2024 (SR-CboeBZX-2024-086). On September 19, 2024, the Exchange withdrew that filing and submitted SR-CboeBZX-2024-090. On September 30, 2024, the Exchange withdrew that filing and submitted SR-CboeBZX-2024-095. On October 9, 2024, the Exchange withdrew that filing and submitted this proposal.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 100918 (September 4, 2024), 89 FR 73463 (September 10, 2024) (SR-NYSE-2024-47).

⁴ 15 U.S.C. 78s(b)(2).

⁵ 15 U.S.C. 78s(b)(2).

⁶ 17 CFR 200.30-3(a)(31).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Entry Fee Cap

Rule 14.13(b)(1)(B)(v) sets forth the entry fees applicable to ETPs, which charge an entry fee of \$7,500 per ETP that is not a Generically-Listed ETP. Specifically, ETPs that are not Generically-Listed ETPs require an Exchange Rule Filing⁷ to list and trade the ETP on the Exchange, and thus require significantly more time and Exchange resources to bring to market than Generically-Listed ETPs. Rule 14.13(b)(1)(B)(v)(a)(2) also provides that each issuer will be subject to an aggregate maximum entry fee of \$22,500 per calendar year. Therefore, an issuer is only required to pay an entry fee for a maximum of three new ETPs that are not Generically Listed ETPs per year.

Now, the Exchange proposes to eliminate the yearly \$22,500 entry fee cap applied to ETP issuers. The Exchange believes that eliminating the entry fee cap would address the costs associated with preparing more than three Exchange Rule Filings for an issuer on an annual basis.

The Exchange also proposes to combine the text of existing Exchange Rule 14.13(b)(1)(B)(v)(a)(1) and Exchange Rule 14.13(b)(1)(B)(v)(a) and to correspondingly delete the (1) from the Rulebook.

Exchange Rule Filing Amendment Fee

The Exchange also proposes to adopt Rule 14.13(b)(4) which would provide for an Exchange Rule Filing Amendment fee of \$3,500 per ETP. The proposed Exchange Rule Filing Amendment fee would apply to a Company that makes a change to a product already approved for listing and trading on the Exchange that would require the Exchange to prepare an Exchange Rule Filing Amendment. In general, any change that requires a new or amended representation from the initial Exchange Rule Filing would require an Exchange Rule Filing Amendment. Such a fee would be used to address the costs associated with preparing and submitting an Exchange Rule Filing Amendment when Companies make a change that would require such an amendment. The Exchange notes that Companies making multiple changes that are addressed in the same Exchange Rule Filing Amendment would only be charged \$3,500 total and would not be charged for each individual change in the

⁷ An initial Exchange Rule Filing refers to the proposed rule change filed pursuant to Section 19(b) of the Exchange Act required to initially list and trade an ETP on the Exchange. See Exchange Rule 14.13(b)(1)(B)(v)(a).

Exchange Rule Filing Amendment.⁸ The Exchange will charge for each Exchange Rule Filing Amendment unless it is in furtherance of the same continuous effort. Specifically, similar to existing Rule 14.13(b)(1)(B)(v)(a)(1), proposed Rule 14.13(b)(4) would provide that an Exchange Rule Filing Amendment will be considered in furtherance of the same continuous effort if: the Exchange Rule Filing Amendment is required for ministerial purposes related to another previously filed Exchange Rule Filing Amendment,⁹ or if the Exchange Rule Filing Amendment is withdrawn and refiled within 30 calendar days.¹⁰

The Exchange proposes to implement the proposed fees effective September 10, 2024.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.¹¹ Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹² requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers as well as Section 6(b)(4)¹³ as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities.

The Exchange believes that proposed Rules 14.13(b)(1)(B)(v)(a) and

⁸ An Exchange Rule Filing Amendment that modified representations across multiple ETPs in the same Exchange Rule Filing Amendment would be charged the fee for each individual ETP.

⁹ Specifically, the Exchange would not assess an additional fee to an ETP in the event that an Exchange Rule Filing Amendment was submitted to the Commission, rejected by the Commission, and shortly thereafter resubmitted. Instances where Exchange Rule Filing Amendments are either rejected or withdrawn and refiled shortly thereafter often involve minor or ministerial errors that are in furtherance of the same continuous effort.

¹⁰ The proposed fee would not be applicable to an amendment to an open Exchange Rule Filing Amendment. For example, assume the Exchange has already made an Exchange Rule Filing Amendment to amend a representation in the initial filing to list and trade the ETP. If another Exchange Rule Filing Amendment (e.g., amendment no. 2 to the previously filed Exchange Rule Filing Amendment) is necessary, the Exchange would not charge an additional Exchange Rule Filing Amendment fee. As another example, if a partial amendment no. 3 is needed to that Exchange Rule Filing Amendment, the Exchange would not charge an additional Exchange Rule Filing Amendment Fee for that partial amendment. Stated differently, the proposed fee would not be applicable to an amendment to an open Exchange Rule Filing Amendment.

¹¹ 15 U.S.C. 78f(b).

¹² *Id.*

¹³ 15 U.S.C. 78f(b)(4).

14.13(b)(4), which are both designed to address the Exchange's costs in preparing and filing Exchange Rule Filings and Exchange Rule Filing Amendments, are reasonable, fair and equitable, and not an unfairly discriminatory allocation of fees and other charges because they would apply equally to all Companies. Specifically, the Exchange's proposal to eliminate the entry fee cap for ETPs would only impact Companies that require more than three Exchange Rule Filings in a given calendar year. As each Exchange Rule Filing requires significant Exchange resources on an individual basis, and because there is no reduced cost to the Exchange for preparing multiple Exchange Rule Filings for a single Company, the Exchange believes it reasonable to address the Exchange's cost in preparing such Exchange Rule Filings even if they exceed three in a given year for a given Company. The Exchange also believes its proposal to adopt an Exchange Rule Filing Amendment fee is reasonable given the additional resources required by the Exchange in connection with ETPs requiring an Exchange Rule Filing Amendment pursuant to Section 19(b), specifically the significant additional time and extensive legal and business resources required by Exchange staff to prepare and review such filings and to communicate with issuers and the Commission regarding such filings.

The Exchange believes the technical change to combine Rule 14.13(b)(1)(B)(v)(a) and Rule 14.13(b)(1)(B)(v)(a)(1) is consistent with Section 6(b)(1)¹⁴ because it will allow Members of the Exchange to more easily interpret Exchange Rules.

Furthermore, the marketplace for listings is extremely competitive and there are several other national securities exchanges that offer ETP listings. Transfers between listing venues occur frequently for numerous reasons, including listing fees. The proposed rule change reflects a competitive pricing structure, which the Exchange believes will enhance competition both among ETP issuers and listing venues, to the benefit of investors.

Based on the foregoing, the Exchange believes that the proposed rule changes are consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance

¹⁴ 15 U.S.C. 78f(b)(1).

of the purposes of the Act. With respect to the proposal to eliminate the entry fee cap for ETPs and adopt a new fee for each Exchange Rule Filing Amendment, the Exchange does not believe that the changes burden competition, but instead, enhance competition, as they are intended to address the costs associated with preparing an Exchange Rule Filing and Exchange Rule Filing Amendment when Companies require such filings. As such, the proposal is a competitive proposal designed to enhance pricing competition among listing venues and implement pricing for such rule filings that better reflects expenses associated with listing ETPs on the Exchange. The Exchange does not believe the proposed amendment would burden intramarket competition as the proposed fee would be assessed to all issuers uniformly that require more than three Exchange Rule Filings in a given year or an Exchange Rule Filing Amendment.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁵ and paragraph (f) of Rule 19b-4¹⁶ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (https://www.sec.gov/rules/sro.shtml); or
• Send an email to rule-comments@sec.gov. Please include file number SR-CboeBZX-2024-097 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-CboeBZX-2024-097. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (https://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-CboeBZX-2024-097 and should be submitted on or before November 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

Sherry R. Haywood, Assistant Secretary.

[FR Doc. 2024-24940 Filed 10-25-24; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20813 and #20814; NEBRASKA Disaster Number NE-20009]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Nebraska

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Nebraska (FEMA-4838-DR), dated 10/21/2024.

Incident: Severe Storms, Straight-line Winds, Tornadoes, and Flooding.

Incident Period: 07/31/2024.

DATES: Issued on 10/21/2024.

Physical Loan Application Deadline Date: 12/20/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 07/21/2025.

ADDRESSES: Visit the MySBA Loan Portal at https://lending.sba.gov to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President’s major disaster declaration on 10/21/2024, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal https://lending.sba.gov or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1-800-659-2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Cass, Douglas, Lancaster, Sarpy, Saunders.

The Interest Rates are:

Table with 2 columns: Description and Percent. Rows include For Physical Damage: Non-Profit Organizations with Credit Available Elsewhere ... (3.250) and For Economic Injury: Non-Profit Organizations without Credit Available Elsewhere ... (3.250).

The number assigned to this disaster for physical damage is 20813B and for economic injury is 208140.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek, Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024-24973 Filed 10-25-24; 8:45 am]

BILLING CODE 8026-09-P

¹⁵ 15 U.S.C. 78s(b)(3)(A).

¹⁶ 17 CFR 240.19b-4(f).

¹⁷ 17 CFR 200.30-3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20795 and #20796; NORTH CAROLINA Disaster Number NC-20011]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of North Carolina

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of North Carolina (FEMA-4837-DR), dated 10/19/2024.

Incident: Potential Tropical Cyclone Eight.

Incident Period: 09/16/2024 through 09/20/2024.

DATES: Issued on 10/19/2024.

Physical Loan Application Deadline Date: 12/18/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 07/21/2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 10/19/2024, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal <https://lending.sba.gov> or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1-800-659-2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Brunswick, Carteret, New Hanover, Onslow.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Non-Profit Organizations with Credit Available Elsewhere ...	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
<i>For Economic Injury:</i>	

	Percent
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 207958 and for economic injury is 207960.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,
Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024-24931 Filed 10-25-24; 8:45 am]

BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20459 and #20460; SAN CARLOS APACHE TRIBE Disaster Number AZ-20005]

Presidential Declaration Amendment of a Major Disaster for the San Carlos Apache Tribe

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the San Carlos Apache Tribe (FEMA-4833-DR), dated 10/04/2024.

Incident: Watch Fire.
Incident Period: 07/10/2024 through 07/17/2024.

DATES: Issued on 10/21/2024.

Physical Loan Application Deadline Date: 12/16/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 07/07/2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the San Carlos Apache Tribe, dated 10/04/2024, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 12/16/2024.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,
Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024-24915 Filed 10-25-24; 8:45 am]

BILLING CODE 8026-09-P

DEPARTMENT OF STATE

[Public Notice: 12571]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: “Qi Baishi: Inspiration in Ink” Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to an agreement with their foreign owner or custodian for temporary display in the exhibition “Qi Baishi: Inspiration in Ink” at the Asian Art Museum, San Francisco, California; the Museum of Fine Arts, Boston, in Boston, Massachusetts; and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA-5), Suite 5H03, Washington, DC 20522-0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Nicole L. Elkon,
Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2024-24944 Filed 10-25-24; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF STATE

[Public Notice: 12569]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: “Pirouette: Turning Points in Design” Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition “Pirouette: Turning Points in Design” at The Museum of Modern Art, New York, New York, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Nicole L. Elkon,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2024–24942 Filed 10–25–24; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 12570]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: “Franz Kafka” Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition “Franz Kafka” at The Morgan Library & Museum, New York, New York, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Nicole L. Elkon,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2024–24943 Filed 10–25–24; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–2024–0017]

Surface Transportation Project Delivery Program; Arizona Department of Transportation Draft FHWA Audit Four Report

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Notice; request for comment.

SUMMARY: The Moving Ahead for Progress in the 21st Century Act (MAP–21) established the Surface Transportation Project Delivery Program that allows a State to assume FHWA’s environmental responsibilities for environmental review, consultation, and compliance under the National Environmental Policy Act (NEPA) for Federal highway projects. When a State assumes these Federal responsibilities, the State becomes solely responsible and liable for carrying out the responsibilities it has assumed, in lieu of FHWA. This program mandates annual audits during each of the first 4 years of State participation to ensure compliance with program requirements. This is the fourth audit of the responsibilities assigned to the Arizona Department of Transportation (ADOT) under the Surface Transportation Project Delivery Program (NEPA Assignment Program). This notice announces and solicits comments on the fourth audit report for ADOT.

DATES: Comments must be received on or before November 27, 2024.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit all comments by only one of the following means:

- **Federal eRulemaking Portal:** Go to www.regulations.gov and follow the online instructions for submitting comments.
- **Mail:** Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590.
- **Hand Delivery:** West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.
- **Instructions:** You must include the agency name and docket number at the beginning of your comments. All comments received will be posted without change to www.regulations.gov, including any personal information provided.

FOR FURTHER INFORMATION CONTACT:

Owen Lindauer, Ph.D., RPA, Office of Project Development and Environmental Review, (202) 633-0356, owen.lindauer@dot.gov, Federal Highway Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, or Mr. Silvio J. Morales, Office of the Chief Counsel, (202) 366-1345, silvio.morales@dot.gov, Federal Highway Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 8:00 a.m. to 4:30 p.m., EST, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:**Electronic Access**

An electronic copy of this notice may be downloaded from the specific docket page at www.regulations.gov.

Background

The Surface Transportation Project Delivery Program, codified at 23 United States Code (U.S.C.) 327, commonly known as the NEPA Assignment Program, allows a State to assume FHWA's environmental responsibilities for review, consultation, and compliance for Federal-aid highway projects. When a State assumes these Federal responsibilities, the State becomes solely liable for carrying out the responsibilities it has assumed, in lieu of FHWA. The ADOT published its application for NEPA assumption on June 29, 2018, and solicited public comment. After considering public comments, ADOT submitted its application to FHWA on November 16, 2018. The application served as the basis for developing a memorandum of understanding (MOU) that identifies the responsibilities and obligations that ADOT would assume. The FHWA published a notice of the draft MOU in the **Federal Register** on February 11, 2019, at 84 FR 3275, with a 30-day comment period to solicit the views of the public and Federal Agencies. After the close of the comment period, FHWA and ADOT considered comments and proceeded to execute the MOU. Effective April 16, 2019, ADOT assumed FHWA's responsibilities under NEPA, and the responsibilities for other Federal environmental laws described in the MOU.

Section 327(g) of title 23, U.S.C., requires the Secretary to conduct annual audits to ensure compliance with the MOU during each of the first 4 years of State participation and, after the fourth year, monitor compliance. The FHWA must make the results of each audit available for public comment. The audit

report reflects the findings at the time of the review and does not capture specific actions taken after the review. This notice announces and solicits comments on the fourth audit report for ADOT.

Authority: Section 1313 of Public Law 112-141; section 6005 of Public Law 109-59; 23 U.S.C. 327; 23 CFR 773.

Kristin R. White,

Acting Administrator, Federal Highway Administration.

Surface Transportation Project Delivery Program Draft FHWA Audit #4 of the Arizona Department of Transportation**Executive Summary**

This is Audit #4 of the Arizona Department of Transportation's (ADOT) assumption of National Environmental Policy Act (NEPA) responsibilities under the Surface Transportation Project Delivery Program. Under the authority of 23 U.S.C. 327, ADOT and the Federal Highway Administration (FHWA) executed a memorandum of understanding (MOU) on April 16, 2019, to define ADOT's NEPA responsibilities and liabilities for Federal-aid highway projects and other related environmental reviews for highway projects in Arizona. This MOU covers environmental review responsibilities for projects that require the preparation of environmental assessments (EA), environmental impact statements (EIS), and unlisted (identified as individual by ADOT) categorical exclusions (CE).

The FHWA conducted the fourth audit of ADOT's performance according to the terms of the MOU from March 27 to March 31, 2023. Prior to the audit, the FHWA audit team reviewed ADOT's environmental manuals and procedures, NEPA project files, ADOT's response to FHWA's pre-audit information request (PAIR), and ADOT's NEPA Assignment Self-Assessment Report. During the fourth audit, the audit team conducted interviews with staff from ADOT's Office of Environmental Planning (EP), Civil Rights Office (CRO), Construction Districts, Right-of-Way, Alternative Delivery Group, and the Deputy Director, as well as the Salt River Pima-Maricopa Indian Community Tribal Historic Preservation Office (THPO), the Arizona State Historic Preservation Officer (SHPO), and the Arizona Attorney General's Office (AGO) and prepared preliminary audit results. The audit team presented these preliminary results to ADOT EP leadership on March 30, 2023, and to ADOT leadership on April 7, 2023.

The audit team found that ADOT has carried out the responsibilities it assumed consistent with the terms of the MOU and ADOT's application. The ADOT continues to develop, revise, and implement procedures and processes required to deliver its NEPA Assignment Program. This report describes several general observations and successful practices, as well as identified non-compliance observations where ADOT must implement corrective actions pursuant to MOU Part 13.2.2. This report concludes with the status of FHWA's observations from the third audit review. After the fourth year of ADOT's participation in the program, FHWA

will continue to monitor ADOT's compliance with the terms of this MOU, in accordance with 23 U.S.C. 327(h).

Background

The purpose of the audits performed under the authority of 23 U.S.C. 327 is to assess a State's compliance with the provisions of the MOU as well as all applicable Federal statutes, regulations, policies, and guidance. The FHWA's review and oversight obligation entails the need to collect information to evaluate the success of the NEPA Assignment Program; to evaluate a State's progress toward achieving its performance measures as specified in the MOU; and to collect information for the administration of the NEPA Assignment Program. This report summarizes the results of the fourth audit in Arizona and ADOT's progress towards meeting the program review objectives identified in the MOU.

Scope and Methodology

The overall scope of this audit review is defined both in statute (23 U.S.C. 327) and the MOU (Part 11). The definition of an audit is one where an independent, unbiased body makes an official and careful examination and verification of accounts and records. Auditors who have special training with regard to accounts or financial records may follow a prescribed process or methodology in conducting an audit of those processes or methods. The FHWA considers its review to meet the definition of an audit because it is an unbiased, independent, official, and careful examination and verification of records and information about ADOT's assumption of environmental responsibilities.

The audit team consisted of NEPA subject matter experts from FHWA Headquarters, Resource Center, Office of the Chief Counsel, and staff from FHWA's Arizona Division. This audit is an unbiased official action taken by FHWA, which included an audit team of diverse composition, and followed an established process for developing the review report and publishing it in the **Federal Register**.

The audit team reviewed six NEPA Assignment Program elements: program management; documentation and records management; quality assurance/quality control (QA/QC); performance measures; legal sufficiency; and training. The audit team considered four additional focus areas for this review: the procedures contained in 40 CFR 93 for project-level conformity; the procedures for environmental justice evaluations (Environmental Justice per Executive Order (E.O.) 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations); the Section 106 consultation procedures contained in the National Historic Preservation Act of 1966, 36 CFR 800 *et seq.*; and ADOT's environmental commitment tracking and implementation process. This report concludes with a status update for FHWA's observations from the second and third audit reports.

The audit team conducted a careful examination of ADOT policies, guidance, and manuals pertaining to NEPA responsibilities,

as well as a representative sample of the ADOT project files. Other documents, such as ADOT's PAIR responses and ADOT's Self-Assessment Report, also informed this review. In addition, the audit team interviewed ADOT, the Arizona AGO and Tribal THPO staff, as well as the Arizona SHPO in person and via videoconference.

The timeframe defined for this fourth audit includes highway project environmental approvals completed between January 1 and December 31, 2022. During this timeframe, ADOT completed NEPA approvals and documented NEPA decision points for seven projects. Due to the small sample size, the audit team reviewed all seven projects. This consisted of three EA re-evaluations, one EA with a Finding of No Significant Impact, one draft EA that completed the public hearing and review process, and two unlisted CEs. The FHWA also reviewed information pertaining to project tracking and mitigation commitment compliance for all projects that have been processed by ADOT since the initiation of the NEPA Assignment Program.

The PAIR submitted to ADOT contained 25 questions covering all 6 NEPA Assignment Program elements. The audit team developed specific follow-up questions for the interviews with ADOT staff and others based on ADOT responses to the PAIR. The audit team conducted a total of 18 interviews. Interview participants included staff from ADOT, a Tribal THPO and the Arizona AGO, as well as the Arizona SHPO.

The audit team compared ADOT manuals and procedures to the information obtained during interviews and project file reviews to determine if ADOT's performance of its MOU responsibilities is in accordance with ADOT procedures and Federal requirements. The audit team documented individual observations and successful practices during the interviews and reviews and combined these under the six NEPA Assignment Program elements. The audit results are described below by program element.

Overall Audit Opinion

The audit team found that ADOT has carried out the responsibilities it has assumed consistent with the terms of the MOU. The FHWA is notifying ADOT of three non-compliance observations identified in this audit that require ADOT to take corrective action. The ADOT must address these non-compliance observations per MOU Part 13.2.2 and continue making progress on non-compliance observations in the previous audits as a section of the 327 MOU renewal process. Future monitoring reviews will continue to report on ADOT's corrective actions. By addressing the observations cited in this report, ADOT will continue to ensure a successful program.

Successful Practices and Observations

Successful practices are practices that the team believes are positive and encourages ADOT to consider continuing or expanding the use of those practices in the future. While not accounting for all the successful practices used by ADOT in implementing the NEPA Assignment Program, the audit team identified four successful practices in this report.

Observations are items the audit team would like to draw ADOT's attention to, which may improve processes, procedures, and/or outcomes. The audit team identified 13 general observations in this report.

Non-compliance observations are instances where the audit team finds the State is not in compliance or is deficient with regard to a Federal regulation, statute, guidance, policy, State procedure, or the MOU. Non-compliance may also include instances where the State has failed to secure or maintain adequate personnel and/or financial resources to carry out the responsibilities they have assumed. The FHWA expects the State to develop and implement corrective actions to address all non-compliance observations. The audit team identified three non-compliance observations in this report.

Program Management

Successful Practice #1

The ADOT EP meets monthly with the Arizona (AZ) Division. This has resulted in improved communication and contributes to the tracking and ultimate resolution of issues.

Successful Practice #2

The audit team acknowledges the efforts to address lessons learned on alternative delivery projects through the development of NEPA and Public Private Partnership Guidance. These include improving communication with ADOT EP and advancing environmental commitment activities earlier for more successful projects.

Successful Practice #3

The ADOT has taken steps over the past year to improve Tribal engagement. The ADOT EP sent letters to Tribes introducing the EP Tribal Liaison and offered to meet. The ADOT created and filled a Native Nations Ambassador for Infrastructure position in the State Engineer's Office to improve communication with the Tribes and be a point of contact for them regarding any issues. And finally, ADOT EP developed the first project-specific Tribal Environmental Engagement Plan which outlines communication protocols, outreach practices and points of contact for a project that crosses into Tribal land.

Observations

Non-compliance Observation #1: Incomplete Reporting to the Federal Infrastructure Permitting Dashboard

The ADOT is responsible for inputting project information for assigned projects into the Federal Infrastructure Permitting Dashboard (Dashboard), per MOU Part 8.5.1. During the time period covered by this audit, the audit team reviewed the Dashboard and found that it did not include all Federal permit and authorization information for the applicable projects assigned to ADOT. In addition, the audit team found that not all active projects were included, updates appeared in draft form or were not published. The audit team also found that milestone dependencies, which are milestone dates on the Permitting Dashboard that are contingent on the completion of another milestone found in the permitting timetable, were not identified and there were misidentifications

of Major Infrastructure Projects which no longer applied due to the rescission of E.O. 13807, Establishing Discipline and Accountability in the Environmental Review and Permitting Process for Infrastructure Projects. Per the Office of the Secretary of Transportation Dashboard reporting standards, ADOT is required to identify all Federal permits and authorizations that are anticipated to be needed for the project to complete construction, and to input target and actual milestone completion dates for those permits and authorizations. In accordance with the Office of the Secretary of Transportation Dashboard reporting standards, ADOT must take corrective action to address this issue.

Observation #1: Deficiencies and Gaps in ADOT's Manuals and Procedures

The audit team reviewed ADOT's manuals and procedures. Part 4.2.4 of the MOU specifies that ADOT must implement procedures to support appropriate environmental analysis and decisionmaking under NEPA and associated laws and regulations. The audit team identified the following deficiencies in ADOT's manuals and procedures which may result in incomplete project documentation or analysis and increase the risk for non-compliance:

- The EA/EIS Manual and the CE Manual do not identify what the minimum requirements or procedures are for public involvement when there is a low-income or minority population in the project area, or when these populations have expressed an interest in the project.
- The ADOT manuals and procedures do not make a clear statement that the 23 U.S.C. 327 MOU disclosure language is required in the consultation that is completed as part of the NEPA process for Local Public Agency (LPA)/Certified Acceptance Agency (CAA) projects per MOU Parts 3.1.2 and 3.2.6.
- The ADOT EA/EIS Manual should be updated to clearly indicate that a purpose and need statement should not include discussion of the build alternative nor use the build alternative as justification for the need to construct a transportation facility.

The FHWA recommends an update to the ADOT EA/EIS Manual related to the public involvement process for re-evaluations. While public circulation is not required for re-evaluations, FHWA recommends ADOT institute a review process for ADOT to determine if controversial or projects of public concern require public outreach or at a minimum, post the NEPA document for public and stakeholder review.

Observation #2: Improvements to Tribal Engagement Are Warranted

Interviews with ADOT staff, the SHPO and a THPO identified the need for ADOT to continue efforts to improve Tribal consultation practices and relationships with Tribes. The SHPO encourages ADOT to listen to Tribes, consult earlier and improve trust with Tribes, and identifies the need for more training of ADOT staff. The THPO expressed continued communication and transparency issues with ADOT, such as that ADOT lacked an understanding of what Tribal consultation should consist of, frustration with continued

violations of cultural commitments during construction, and continued lack of trust. The audit team acknowledges that ADOT seems to be attempting to work on some of these issues, but the actions are inconsistent. The FHWA recommends:

- ADOT seek input from THPOs and AZ SHPO on the specification developed to address cultural resource commitment non-compliance by construction contractors and advance the specification to implementation.
- ADOT improve transparency regarding project information for projects in Tribal land or of Tribal interest.
- ADOT build and maintain relationships with the Tribes.
- ADOT fully implement the FHWA/ADOT Tribal Consultation Letter Agreement executed on August 5, 2022.

Observation #3: Incomplete Identification and Reporting of Responsibilities Under the 327 MOU Assigned to Additional Divisions Independent of ADOT EP

During Audit #3, the previous audit team identified that ADOT divisions outside of EP have NEPA responsibilities and these divisions have not been identified or addressed in the ADOT EP procedures; nor were they included in the ADOT documentation and reporting. Based on interviews of ADOT staff, the PAIR responses and review of ADOT's manuals for this audit, ADOT has not taken corrective actions to develop or implement procedures to apply the 327 MOU provisions to all divisions of ADOT in accordance with MOU Part 1.1.2. In addition, the audit team identified a lack of training and awareness of NEPA assignment and MOU responsibilities within the other divisions, in particular at management levels. The ADOT should identify methods to ensure future compliance.

Non-Compliance Observation #2: Inadequate or Incomplete Documentation and Implementation of Environmental Commitments

The ADOT is obligated to implement all committed environmental impact mitigation measures (23 CFR 771.109(b)(2)) for projects funded with Federal-aid. Therefore, it is also responsible for environmental commitment tracking. The ADOT does not have a process manual or consolidated report which documents the tracking of all environmental commitments made during the environmental review process. Based on the ADOT interviews, ADOT has taken steps to establish some tracking mechanisms to cover environmental commitments which are the responsibility of ADOT EP or the contractors. This includes official use of the Environmental, Permits, Issues, and Commitments (EPIC) Tracking sheet. The ADOT Districts are inconsistent in how they describe tracking commitments, and reporting whether they prepare documentation demonstrating implementation of the remaining types of environmental commitments. These gaps include commitment tracking that are the responsibility of other divisions of ADOT, LPA/CAA, and those covered by a standard specification. Project file reviews indicated that environmental commitments were not clearly stated or if they were identified in

environmental documentation, ADOT's record keeping did not demonstrate how, when, and who is responsible for environmental commitment documentation. The ADOT will need to take corrective actions to address the lack of documentation, implementation and tracking of environmental commitments and mitigation compliance.

Documentation and Records Management

Observations

Observation #4: Incomplete Project File Submission Based on a FHWA Request for Information and Standard Folder Structure Issues

For this audit, FHWA requested all project files pertaining to the NEPA approvals and documented NEPA decision points completed during the audit review period. The audit review team received project file information from ADOT, but this information was found to be incomplete with attachments or other supporting information missing. The FHWA worked with ADOT Information Technology (IT) Group to ensure that project file issues were not due to technology challenges resulting from the transfer of electronic files between ADOT and FHWA. While FHWA had fewer issues when attempting to access the files ADOT provided for the audit than in past years, the audit team still found several inconsistencies between ADOT's procedures for maintaining project files and the project file documentation provided to FHWA. Examples of missing documentation included: public involvement plan (PIP); public involvement summary report; signed noise analysis form; Section 404 and 408 documentation; Section 106 Closeout Memorandum; 327 air quality EA/EIS checklist; authorization letters/NEPA certification approval; Statewide Transportation Improvement Program/Transportation Improvement Program verification; and email communication. In addition, there were instances of missing or incomplete QC reviews, and environmental commitments resulting from technical analysis or consultation that were not included in the NEPA document. In these instances, the determinations were not adequately supported by the project file. The audit review team could not reconcile information about project file completeness and QC provided through interviews with the content of project files supplied by ADOT. It may also be the case that there is a shortfall in ADOT filing practices performed by an individual developing a project file to ensure a project file is complete. By this observation the audit review team is making ADOT aware that both by (1) implementing sound internal controls related to project filing and records retention, and (2) improving QCs, fewer ADOT files would contain errors or omissions once the reviews are complete.

Observation #5: Deficiencies in Section 4(f) Analyses

The ADOT has a number of manuals and procedures that describe the requirements for Section 4(f) analyses, consultation, and documentation. Based on those requirements, the review team found some of the project files to be deficient. Observations based on

project file reviews included: (1) no Section 4(f) form or memorandum; (2) lack of documented communication with the official with jurisdiction; (3) no research documentation to support the determinations; (4) an empty Section 4(f) file folder; (5) a Section 4(f) resource that was not accounted for in the project documentation; and (6) one instance where the consultation letter did not determine whether the Section 4(f) archeological resource had value for preservation in place. The FHWA recommends that ADOT personnel who have Section 4(f) training identified as a requirement for their position take the training within a year and that ADOT EP updates the Section 4(f) manual to increase reviews and oversight of decisions made.

Observation #6: Continuing Issues With Air Quality Conformity Analysis

While ADOT has made progress regarding the level of communication and coordination with FHWA and EPA on project-level air quality conformity analysis, the audit team identified areas in need of improvement. Per MOU Part 3.2.4, FHWA retained responsibilities for conformity determinations. This authority includes whether a conformity determination remains valid under 40 CFR 93.104(d). The ADOT does not include FHWA in the decisionmaking process when it determines that project level conformity determinations remain valid for re-evaluations, which conflicts with FHWA authority under 40 CFR 93.104(d). In addition, no interagency consultation is conducted by ADOT for those decisions. Re-evaluations should be shared with interagency consultation partners as early as possible so their input can inform the FHWA determination of whether a conformity determination remains valid. The FHWA also recommends that for interagency consultation, when a consultation period ends, ADOT summarizes who responded, who did not, and what follow-up ADOT did with those agencies that did not provide a response. The ADOT should continue to build on the progress made with the air quality conformity process and maintain communication amongst all the interagency consultation partners.

Observation #7: Inconsistent Use and Absence of the 327 MOU Disclosure Statement

Part 3.1.3 of the MOU specifies that ADOT shall include a disclosure statement to the public, Tribes and agencies as part of agency outreach and public involvement procedures. The audit team project file reviews found the absence of the statement in agency correspondence and technical reports, and public involvement materials, as well as the wrong MOU reference when the statement was present. The audit team found no consistent process or procedure for inclusion of the 327 MOU disclosure statement in the current ADOT manuals or guidance as required by MOU Part 3.1.3. The ADOT should strive to achieve consistency in the placement of disclosure statements in documents. The audit team acknowledges that the new ADOT PIP has updated requirements and details to prevent instances in future public involvement materials.

Non-Compliance Observation #3: Inconsistencies and Deficiencies in Analysis of Environmental Impacts on Low-Income and Minority Populations (Environmental Justice Populations)

During Audit #3, the audit team identified deficiencies in ADOT's procedures and analyses of environmental impacts on low-income and minority populations. In response, ADOT drafted new procedures, a checklist and process flowcharts which were provided to FHWA as part of the PAIR response to this audit. In addition, FHWA provided a National Highway Institute Environmental Justice training course for ADOT in December 2022. The audit team for this audit identified inconsistencies in ADOT's new procedures, EA/EIS Manual, CE Manual, PAIR response, and interview responses regarding how ADOT completes environmental justice analyses. The procedural guidance is still not fully compliant with the MOU and the U.S. Department of Transportation environmental justice responsibilities because of incorrect definitions of environmental justice populations. The review team could not assess compliance for several project files because they lacked supporting documentation for the identification, presence/absence of the populations, and meaningful public involvement. In addition, ADOT EP's coordination with the ADOT CRO was inconsistent with the ADOT procedures according to the interviews. Information presented in the CE Manual and ADOT's PAIR response, indicates that the CRO is to be consulted on all environmental justice analyses. The ADOT must take corrective action to ensure that environmental justice analysis and assessments comply with E.O. 12898, DOT Order 5610.2C and FHWA policy and guidance in advance of or as part of the 327 MOU renewal application. This can be done by obtaining FHWA review of the updated environmental procedures prior to ADOT approval.

Observation #8: Deficiencies in Re-Evaluation Analyses and Documentation

The ADOT has an EA/EIS Guidance manual that contains EA re-evaluation procedures. The manual states, "the re-evaluation should consider the entire project analyzed in the original NEPA document. All environmental sections require re-evaluation to review whether impacts have changed as compared with the previous NEPA document and whether any impact changes result in new or significant impacts Documentation should be appropriate to the project changes, environmental impacts from the changes, potential for controversy, and length of time since the last NEPA document was completed." Observations based on project file reviews included (1) lack of supporting documentation in the project files for all analyses summarized in EA re-evaluation errata that support the outcome of the re-evaluation, and (2) two project files with purpose and need statements that changed from the original EA and did not document whether that change affected the validity of the re-evaluation conclusion. Based on the required procedures, the review

team found some of the project files to be deficient.

Observation #9: Inappropriate Purpose and Need Statement

The review team found that a draft EA purpose and need statement contained a discussion of the build alternative throughout. The purpose and need statement had a figure with the build alternative in it, travel demand data that included the build alternative, and the connectivity discussion referenced the build alternative. The purpose and need statement serves as the basis for the alternatives analysis and should not discuss alternatives. The alternatives analysis is the section of the document to explain how the considered range of alternatives meet the purpose and need. In addition, the purpose section of the draft EA used population and employment growth as a justification but presented no data.

Quality Assurance/Quality Control

Observations

Observation #10: QA/QC Procedures Lack Assessment of Compliance

The ADOT has procedures in place for QA/QC which are described in the ADOT QA/QC Plan and the ADOT Project Development Procedures. When implemented, ADOT focuses on the completeness of the project files, not the accuracy or technical merits of the decisions documented by those files. The ADOT does not appear to have an adequate process to review and confirm compliance of the decisionmaking according to its own procedures and it is therefore unclear how the project-level QC reviews inform the program. These observations were also found with Audits #1, #2, and #3, and no updates were made to the ADOT QA/QC procedures in response. The ADOT does not appear to have a process in place for assessing the effectiveness of its QA/QC procedures to identify opportunities to improve the processes and procedures in its program, in ways that could help ensure improved compliance with MOU requirements.

Performance Measures

Observations

Observation #11: Incomplete Development and Implementation of Performance Measures To Evaluate the Quality of ADOT's Program

The audit team reviewed ADOT's development and implementation of performance measures to evaluate their program as required in the MOU (Part 10.2.1). The ADOT's QA/QC Plan, PAIR response, and self-assessment report identified several performance measures and reported the data for the review period. The ADOT's reporting data primarily dealt with increasing efficiencies and reducing project delivery schedules rather than measuring the quality of relationships with agencies and the general public, and decisions made during the NEPA process. The metrics ADOT has developed are not being used to provide a meaningful or comprehensive evaluation of the overall program. This observation was made in Audits #1, #2, and #3. The FHWA recommends the creation of new

performance measures in the 327 renewal MOU that ADOT would use to evaluate and improve their program.

Legal Sufficiency

During the audit period, ADOT had no formal legal sufficiency reviews of assigned environmental documents. This is based on the information provided by ADOT and interviews of the Assistant Attorneys General (AAG) assigned to ADOT's NEPA Assignment Program. Currently, ADOT retains the services of two AAGs for NEPA Assignment reviews and related matters. The assigned AAGs have received formal and informal training in environmental law matters and participated in a legal sufficiency training conducted by FHWA Office of Chief Counsel in May 2023. The ADOT and the AGO also have the option to procure outside counsel in accordance with 23 U.S.C. 327(a)(2)(G), but this was not necessary during the audit period.

Successful Practice #4

Through the interviews, the audit team learned ADOT seeks to involve lawyers early in the environmental review phase, with AAGs participating in project coordination team meetings and reviews of early drafts of environmental documents. The AAGs will provide legal guidance at any time ADOT requests it throughout the project development process. For formal legal sufficiency reviews, the process includes a submittal package from ADOT's NEPA program manager containing a request for legal sufficiency review. Various ADOT manuals set forth legal sufficiency review periods, which typically involve a 30-day review period, and the AAGs coordinate with ADOT to ensure timely completion of legal sufficiency reviews. For this audit period, the AAGs both cited an emphasis on environmental justice compliance. In addition, the AAGs regularly notify ADOT of relevant changes in Federal law and guidance applicable to the NEPA Assignment Program.

Observations

Observation #12: Assertion of Attorney-Client Privilege Limits NEPA Assignment Program Assessment

Since FHWA began auditing ADOT in 2020, the AGO has regularly cited attorney-client privilege when answering interview questions posed by FHWA Office of Chief Counsel (HCC) staff about the legal sufficiency process it employs when reviewing ADOT NEPA documents. The ADOT's position is unique as compared to its peer NEPA Assignment States in the West. The FHWA's HCC interviewers have consistently affirmed that they seek only to understand the role of the AGO in implementing ADOT's NEPA Assignment Program and do not seek privileged communications or advice. Nevertheless, the AGO has maintained that disclosing any specific information about its role in advising on legal issues would constitute a waiver of attorney-client privilege under the State's open records act and could present legal risks to their clients. As a result, FHWA interviews of the AAG's have produced a somewhat informative, but limited and incomplete

understanding of the AGO's role in NEPA Assignment matters in AZ.

Training

Observation #13: Training Gaps

The audit team reviewed ADOT's 2023 Training Plan, interview responses, and ADOT's PAIR responses pertaining to its training program. The ADOT's EP staff training matrix indicates that many staff have not taken the required training. In addition, there is no data regarding training from the other divisions within ADOT who have 327 MOU responsibilities. The ADOT made no changes to the ADOT training plan in response to FHWA's previous training gap observations.

Status of Previous General Observations and Non-Compliance Observations From the Audit #3 Report

This section describes the actions ADOT has taken or is taking in response to observations made during the third audit. The ADOT was provided the third audit draft report for review and provided comments to FHWA on November 17, 2022.

Non-Compliance Observation #1: Incomplete Reporting to the Federal Infrastructure Permitting Dashboard

During Audit #3, the audit team identified deficiencies in the information ADOT is required to post on the Dashboard. The ADOT did post some of the additional projects and missing project information to the Dashboard but not until the week before audit week. The ADOT needs to establish a consistent and ongoing process to maintain the project information required to be inputted into the Dashboard.

Observation #1: Deficiencies and Gaps in ADOT's Manuals and Procedures

During Audit #3, the audit team identified deficiencies in ADOT's manuals and procedures which may result in incomplete project documentation or analysis and increase the risk for non-compliance. The first was in the ADOT CE Checklist Manual and the EA/EIS Manual, specifically the process for re-evaluations for EAs and EISs was not well-defined. The other was that neither the ADOT EA/EIS Manual nor the current 2017 ADOT PIP approved prior to NEPA assignment contained procedures detailing the criteria ADOT uses to make the determination on when to hold public hearings for EA-level projects and what criteria will be used to make determinations on whether to hold a public hearing when one is requested, as specified in 23 CFR 771.111(h)(2)(iii). The ADOT EA/EIS Manual was not updated to address this deficiency and the updated PIP was not approved at the time of the audit. The deficiencies identified in Audit #3 were not addressed by ADOT, and additional related issues were identified by the audit team in Audit #4.

Observation #2: Improvements to Tribal Engagement Are Warranted

The audit team observed in Audit #3 the need for improved engagement with the Tribes for ADOT to develop procedures that identify its responsibilities to coordinate and consult with Tribes in all phases of project

development, and implementation of the FHWA/ADOT Tribal Consultation Letter Agreement executed on August 5, 2022. The deficiencies identified in Audit #3 were not completely addressed by ADOT, as the Letter Agreement was not fully implemented, and continued issues were identified by the audit team in Audit #4. The ADOT staff participated in the Section 106 and Tribal Consultation Training given by the Advisory Council on Historic Preservation and FHWA staff on June 13 and June 14, 2023.

Non-Compliance Observation #2: Responsibilities Under the 327 MOU Assigned to Additional Divisions Independent of ADOT EP

During Audit #3, the team identified ADOT divisions outside of EP that have responsibilities under NEPA Assignment. These divisions have not been identified by ADOT EP during the past review processes or addressed in the ADOT EP procedures, manuals, or plans. The ADOT was directed to develop and implement procedures to apply the 327 MOU provisions to all divisions of ADOT who have responsibilities under the 327 MOU. The current audit team did not observe any progress on this corrective action.

Non-Compliance Observation #3: Deficiencies in Environmental Commitment Tracking

During Audit #3, ADOT was unable to provide FHWA with a process manual or consolidated report documenting the tracking of environmental commitments made during the environmental review process. The ADOT was unable to identify a meaningful tracking and monitoring system for environmental commitments and mitigation compliance. Since the last audit, ADOT has developed a spreadsheet for EP responsibilities and has rolled out the EPIC Tracking sheet process which covers the Contractor responsibilities—non-standard specification commitments only. There is still no process manual or consolidated reporting of all environmental commitments required for each project.

Non-Compliance Observation #4: Incomplete Project File Submission and Standard Folder Structure Issues

As was observed in previous audits, during Audit #3, the audit team found several inconsistencies between ADOT's procedures for maintaining project files and the project file documentation provided to FHWA. Since that audit, ADOT's IT Group worked with the AZ Division to resolve the project file issue on the technological side. The ADOT IT Group determined that the electronic transfer process is working and is therefore not the cause of the incomplete project file submissions.

Observation #3: Minor Edits Needed To Resolve Deficiency in Section 4(f) Evaluation of Archaeological Resources

During Audit #1 and #2, FHWA identified inconsistencies with ADOT's Section 4(f) evaluation and documentation of archaeological sites. In response to the Audit #2 finding, ADOT updated their Section 106 Federal-aid Programmatic Agreement Manual with new preservation in place language and

in Audit #3 FHWA recommended edits to the new language. The ADOT has made the recommended edits.

Observation #5: Inconsistent Use and Absence of the 327 MOU Disclosure Statement

During Audit #3, the audit team project file reviews found inconsistent use of the disclosures statement on agency correspondence and technical reports, as well as absence of the statement in public involvement materials. The audit team found no consistent process or procedure for inclusion of the 327 MOU disclosure statement in the ADOT manuals and guidance as required by MOU Part 3.1.3. The ADOT has drafted a new PIP that contains disclosure statement guidance, but no updates were found in the ADOT EP manuals.

Non-Compliance Observation #5: Deficiencies in Analysis of Environmental Impacts on Low-Income and Minority Populations (Environmental Justice)

The Audit #3 team identified inconsistencies in ADOT's manuals, PAIR response, and interview responses regarding how ADOT completes environmental justice analyses. The methodology described by ADOT is not in compliance with FHWA policy and guidance and the CE Manual infers a default position that there will be no disproportionately high and adverse impacts on low-income or minority populations with CE-level projects. The audit team observed similar inconsistencies during the project file reviews for this audit and identified the same environmental justice analysis procedural deficiencies in the project documentation, as well as project files with little or no analysis documentation. Since Audit #3, ADOT participated in a FHWA-led pilot environmental justice training and drafted some new environmental justice guidance materials.

Observation #6: QA/QC Procedures Lack Assessment of Compliance and Observation #8: QA/QC Procedures Do Not Inform the Performance Measures

The audit team identified continuing issues with ADOT's QA/QC procedures, including the fact that ADOT does not check for compliance of the decisionmaking and it is therefore unclear how the project-level QC reviews inform the program. These observations were also found with Audits #1, #2, and #3. In addition, it is unclear how the QA/QC procedures, such as the use of QC checklists, are informing ADOT about the technical adequacy of the environmental analyses conducted for projects and thereby inform the performance measures. No updates to the ADOT QA/QC procedures were made.

Observation #8: Incomplete Development and Implementation of Performance Measures

During Audit #2 and #3, the audit team reviewed ADOT's performance measures and reporting data submitted for the review period and concluded that ADOT had made progress toward developing and implementing its performance measures. For Audit #4, FHWA continues to identify this

program objective as an area of concern, described in the observations above, and will continue to evaluate this area in subsequent audits.

Observation #9: Training Gaps

The audit team reviewed ADOT's 2021 training plan and ADOT's PAIR responses pertaining to its training program. The ADOT's EP staff training matrix indicates that while ADOT identifies the availability of staff training, many staff have not taken advantage of the opportunity for training, including other ADOT divisions subject to the 327 MOU provisions. The ADOT's training plan identifies that the training interval for some topics, such as the NEPA Assignment Program, is only once per staff member regardless of the period of time since the previous round of training. Staff may benefit from regular "refresher" type training, especially as regulatory requirements and policy may change over time. No changes in response to this observation were made to the 2023 training plan.

Finalizing This Report

The FHWA provided a draft of the audit report to ADOT for a 14-day review and comment period pursuant to Part 11.4.1 of the MOU, as well as notification of the non-compliance observations. The ADOT provided comments which the audit team considered in finalizing this draft audit report. The audit team acknowledges that ADOT has begun to address some of the observations identified in this report and recognizes ADOT's efforts toward improving their program. This includes an action plan defined by ADOT and the AZ Division Office to address non-compliance observations identified in the AZ Program reviews to date. The FHWA is publishing this notice in the **Federal Register** for a 30-day comment period in accordance with 23 U.S.C. 327(g). No later than 60 days after the close of the comment period, FHWA will address all comments submitted to finalize this draft audit report pursuant to 23 U.S.C. 327(g)(2)(B). Subsequently, FHWA will publish the final audit report in the **Federal Register**.

[FR Doc. 2024-24981 Filed 10-25-24; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2024-0014]

Agency Information Collection Activity Under OMB Review: Survey of FTA Stakeholders

AGENCY: Federal Transit Administration, Department of Transportation (DOT).

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Requirements (ICRs) abstracted below have been forwarded to the Office of Management and Budget

(OMB) for review and comment. The ICR describe the nature of the information collection and their expected burdens.

DATES: Comments must be submitted on or before November 27, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function.

Comments Are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Tia Swain, Office of Administration, Management Planning Division, 1200 New Jersey Avenue SE, Mail Stop TAD-10, Washington, DC 20590 (202) 366-0354 or tia.swain@dot.gov.

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), Public Law 104-13, Section 2, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501-3520), and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. 44 U.S.C. 3506, 3507; 5 CFR 1320.5, 1320.8(d)(1), 1320.12. On August 12, 2024, FTA published a 60-day notice (89 FR 65707) in the **Federal Register** soliciting comments on the ICR that the agency was seeking OMB approval. FTA received no comments after issuing this 60-day notice. Accordingly, DOT announces that these information collection activities have been re-evaluated and certified under 5 CFR 1320.5(a) and forwarded to OMB for review and approval pursuant to 5 CFR 1320.12(c).

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for

public comment. 44 U.S.C. 3507(b); 5 CFR 1320.12(d). Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507 (b)-(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983. OMB believes that the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect. 5 CFR 1320.12(c); *see also* 60 FR 44983.

The summaries below describe the nature of the information collection requirements (ICRs) and the expected burden. The requirements are being submitted for clearance by OMB as required by the PRA.

Title: Survey of FTA Stakeholders.

OMB Control Number: 2132-0564.

Background: The Federal Transit Administration (FTA) is requesting an extension without change to the customer service survey of its stakeholders. FTA is required to identify its stakeholders and address how the agency will provide services in a manner that seeks to streamline service delivery and improve the experience of its customers. FTA is seeking a three-year approval of an existing information collection that will allow FTA to collect data from transit agencies, states, tribal governments, and metropolitan planning organizations. FTA will utilize the survey to assess how its services are perceived by its customers, learn about opportunities for improvement and establish goals to measure results. The data captured from the survey will provide this information and enable FTA to make improvements where necessary. The survey will be limited to data collections that solicit voluntary opinions and will not involve information that is required by regulations. Respondents are split into two groups. Group A includes Chief Executive Officers (CEOs) and other executive leaders of transit agencies, state DOTs, and other FTA stakeholders. Group B includes unit supervisors and professional staff such as engineers, urban planners and budget analysts from the same organizations. FTA will utilize the survey to assess how its services are perceived by its customers, learn about opportunities for improvement and establish goals to measure results. The information obtained from the survey will provide insights into customer or stakeholder perceptions, experiences and

expectations; provide an early warning of issues with service; or focus attention on areas where communication, training or changes in operations might improve delivery of products or services.

Respondents: State Departments of Transportation (DOTs), Metropolitan Planning Organizations (MPOs), Transit Authorities, States, and Local Government Units, Indian Tribes.

Estimated Total Number of Respondents: 8,177.

Estimated Total Number of Responses: 8,177.

Estimated Total Annual Burden: 1,022.

Frequency: Biennial.

Kusum Dhyani,

Director, Office of Management Planning.

[FR Doc. 2024-25003 Filed 10-25-24; 8:45 am]

BILLING CODE 4910-57-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2024-0141]

Request for Comments on the Renewal of a Previously Approved Collection: Approval of Underwriters for Marine Hull Insurance

AGENCY: Maritime Administration, DOT.
ACTION: Notice.

SUMMARY: The Maritime Administration (MARAD) invites public comments on our intention to request the Office of Management and Budget (OMB) approval to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 2133-0517 (Approval of Underwriters for Marine Hull Insurance) is used to provide approval of foreign underwriters on the basis of an assessment of their financial condition, the regulatory regime under which they operate, and a statement attesting to a lack of discrimination in their country against U.S. hull insurers. The regulations also require that American underwriters be given an

opportunity to compete for every placement, thereby necessitating in some cases certification that such opportunity was offered. We are required to publish this notice in the **Federal Register** to obtain comments from the public and affected agencies.

ADDRESSES: Written comments and recommendations for the proposed information collections should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Cameryn Miller, (202) 366-0907, Office of Marine Insurance, Maritime Administration, U.S. Department of Transportation, 1200 New Jersey Ave SE, Washington, DC 20590, Email: cameryn.miller@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: Approval of Underwriters for Marine Hull Insurance.

OMB Control Number: 2133-0517.

Type of Request: Extension without change of a currently approved information collection.

Abstract: This collection of information involves the approval of marine hull underwriters to insure MARAD program vessels. Applicants will be required to submit financial data upon which MARAD approval would be based. This information is needed in order that MARAD officials can evaluate the underwriters and determine their suitability for providing marine hull insurance on MARAD vessels.

Respondents: Marine Insurance Underwriters and Brokers.

Affected Public: Businesses or other for profit.

Estimated Number of Respondents: 66.

Estimated Number of Responses: 66.

Estimated Hours per Response: .5–1 hour.

Annual Estimated Total Annual Burden Hours: 49.

Frequency of Response: Once Annually.

A 60-day **Federal Register** Notice soliciting comments on this information collection was published on August 8, 2024 (89 FR 65011).

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2024-24974 Filed 10-25-24; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF THE TREASURY

United States Mint

2024 Pricing of Numismatic Gold, Commemorative Gold, Platinum, and Palladium Products Grid

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

The United States Mint announces 2024 revisions within the Numismatic Gold, Commemorative Gold, Platinum, and Palladium Products Grid to include pricing for the Flowing Hair 24K gold proof coin.

A draft of the grid with price range for the Flowing Hair 24K One-Ounce Gold Proof Coin appears in the table below.

The complete 2024 Pricing of Numismatic Gold, Commemorative Gold, Platinum, and Palladium Products Grid will be available at <https://www.usmint.gov/content/dam/usmint/shop/Pricing-Grid.pdf>.

Pricing can vary weekly dependent upon the London Bullion Market Association gold, platinum, and palladium prices weekly average. The pricing for all United States Mint numismatic gold, platinum, and palladium products is evaluated every Wednesday and modified as necessary.

BILLING CODE 4810-37-P

2024 Pricing of Numismatic Gold, Commemorative Gold, Platinum, and Palladium Products

Average Price per Ounce	American Buffalo 1 oz 24K Gold Proof	American Eagle 1 oz Gold Uncirculated	American Eagle 1 oz Gold Proof	American Eagle 1/2 oz Gold Proof	American Eagle 1/4 oz Gold Proof	American Eagle 1/10 oz Gold Proof	American Eagle 4-Coin Gold Proof Set	American Eagle 1 oz Palladium	American Eagle 4 oz Platinum Proof	American Liberty 1/10 oz 24K Gold	American Liberty 1/10 oz 24K Gold	Commemorative Gold Proof*	Commemorative Gold Uncirculated*	First Spouse Gold Proof Coin	First Spouse Gold Uncirculated Coin	Liberty & Bellanca Intl. Collaboration 4 oz 24K Gold	Flowing Hair 1 oz 24K Gold
\$500.00 to \$549.99	\$1,440.00	\$1,370.00	\$380.00	\$183.00	\$2,650.00	\$1,450.00	\$1,450.00	\$1,450.00	\$1,095.00	\$1,465.00	\$210.00	\$468.75	\$955.50	\$755.00	\$735.00	\$1,520.00	\$1,540.00
\$550.00 to \$599.99	\$1,490.00	\$1,420.00	\$402.50	\$190.00	\$2,742.50	\$1,500.00	\$1,500.00	\$1,500.00	\$1,145.00	\$1,515.00	\$215.00	\$481.00	\$977.75	\$780.00	\$760.00	\$1,570.00	\$1,590.00
\$600.00 to \$649.99	\$1,540.00	\$1,470.00	\$415.00	\$195.00	\$2,835.00	\$1,550.00	\$1,550.00	\$1,550.00	\$1,195.00	\$1,565.00	\$220.00	\$493.75	\$990.00	\$805.00	\$785.00	\$1,620.00	\$1,640.00
\$650.00 to \$699.99	\$1,590.00	\$1,520.00	\$427.50	\$200.00	\$2,927.50	\$1,600.00	\$1,600.00	\$1,600.00	\$1,245.00	\$1,615.00	\$225.00	\$505.50	\$992.25	\$820.00	\$810.00	\$1,670.00	\$1,690.00
\$700.00 to \$749.99	\$1,640.00	\$1,570.00	\$440.00	\$205.00	\$3,020.00	\$1,650.00	\$1,650.00	\$1,650.00	\$1,295.00	\$1,665.00	\$230.00	\$517.75	\$994.50	\$835.00	\$835.00	\$1,720.00	\$1,740.00
\$750.00 to \$799.99	\$1,690.00	\$1,620.00	\$452.50	\$210.00	\$3,112.50	\$1,700.00	\$1,700.00	\$1,700.00	\$1,345.00	\$1,715.00	\$235.00	\$530.00	\$996.75	\$860.00	\$860.00	\$1,770.00	\$1,790.00
\$800.00 to \$849.99	\$1,740.00	\$1,670.00	\$465.00	\$215.00	\$3,205.00	\$1,750.00	\$1,750.00	\$1,750.00	\$1,395.00	\$1,765.00	\$240.00	\$542.25	\$999.00	\$905.00	\$885.00	\$1,820.00	\$1,840.00
\$850.00 to \$899.99	\$1,790.00	\$1,720.00	\$477.50	\$220.00	\$3,297.50	\$1,800.00	\$1,800.00	\$1,800.00	\$1,445.00	\$1,815.00	\$245.00	\$554.50	\$991.25	\$930.00	\$910.00	\$1,870.00	\$1,890.00
\$900.00 to \$949.99	\$1,840.00	\$1,770.00	\$490.00	\$225.00	\$3,390.00	\$1,850.00	\$1,850.00	\$1,850.00	\$1,495.00	\$1,865.00	\$250.00	\$566.75	\$993.50	\$955.00	\$935.00	\$1,920.00	\$1,940.00

*Data are subject to 35-business-day preliminary period.

FOR FURTHER INFORMATION CONTACT:
Derrick Griffin; Sales and Marketing

Directorate; United States Mint; 801 9th

Street NW, Washington, DC 20220; or
call 202-354-7579.

Authority: 31 U.S.C. 5111, 5112, & 9701.

Eric Anderson,

Executive Secretary, United States Mint.

[FR Doc. 2024-24989 Filed 10-25-24; 8:45 am]

BILLING CODE 4810-37-C

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0903]

Agency Information Collection Activity: Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion, and Specially Adaptive Housing Assistive Technology Grants Criteria and Responses

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before December 27, 2024.

ADDRESSES: Comments must be submitted through www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Program-Specific information: Nancy Kessinger, 202-632-8924, Nancy.Kessinger@va.gov.

VA PRA information: Maribel Aponte, 202-461-8900, vacopaperworkreductact@va.gov.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Agency Information Collection Activity under OMB Review: VA Form 26-0967, Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion, and VA Form 26-0967a, Specially Adaptive Housing Assistive Technology Grants Criteria and Responses.

OMB Control Number: 2900-0903.
<https://www.reginfo.gov/public/do/>

PRA Search (Once at this link, you can enter the OMB Control Number to find the historical versions of this Information Collection).

Type of Review: Extension without change of a currently approved collection.

Abstract: The proposed regulations would require applicants to submit VA Form 26-0967, Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion. These regulations would also require applicants to provide statements addressing six scoring criteria for grant awards as part of their application. The information will be used by Loan Guaranty personnel in deciding whether an applicant meets the requirements and satisfies the scoring criteria for award of an SAH Assistive Technology grant under 38 U.S.C. 2108. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Affected Public: Individuals and households.

Estimated Annual Burden: 40 hours.

Estimated Average Burden per Respondent: 120 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 20.

Authority: 44 U.S.C. 3501 *et seq.*

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024-24941 Filed 10-25-24; 8:45 am]

BILLING CODE 8320-01-P



FEDERAL REGISTER

Vol. 89

Monday,

No. 208

October 28, 2024

Part II

Department of Transportation

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 107, 171, 172, et al.

Hazardous Materials: Advancing Safety of Highway, Rail, and Vessel Transportation; Proposed Rule

DEPARTMENT OF TRANSPORTATION**Pipeline and Hazardous Materials Safety Administration**

49 CFR Parts 107, 171, 172, 173, 174, 176, 177, 178, 179, and 180

[Docket No. PHMSA–2018–0080 (HM–265)]

RIN 2137–AF41

Hazardous Materials: Advancing Safety of Highway, Rail, and Vessel Transportation

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: PHMSA proposes to revise the Hazardous Materials Regulations to adopt several modal-specific amendments that would enhance the safe transportation of hazardous materials in commerce. PHMSA, in consultation with the Federal Motor Carrier Safety Administration, the Federal Railroad Administration, and the United States Coast Guard, proposes amendments identified during Departmental review and from industry petitions for rulemaking.

DATES: Comments must be received by January 27, 2025. To the extent possible, PHMSA will consider late-filed comments as a final rule is developed.

ADDRESSES: You may submit comments identified by the Docket Number PHMSA–2018–0080 (HM–265) by any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 1–202–493–2251.

- *Mail:* Docket Management System; U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, Routing Symbol M–30, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* Docket Management System; Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays.

Instructions: All submissions must include the agency name and Docket Number (PHMSA–2018–0080) or Regulation Identifier Number (RIN) (2137–AF41) for this rulemaking at the beginning of the comment. To avoid duplication, please use only one of these four methods. All comments received will be posted without change

to the Federal Docket Management System (FDMS) and will include any personal information you provide.

Docket: For access to the dockets to read background documents or comments received, go to <http://www.regulations.gov> or DOT's Docket Operations Office (*see ADDRESSES*).

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." Submissions containing CBI should be sent to Eamonn Patrick, Office of Hazardous Materials Safety, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590–0001. Any commentary that PHMSA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

FOR FURTHER INFORMATION CONTACT: Eamonn Patrick, Standards and Rulemaking Division, 202–366–8553, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

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I. Executive Summary

The Pipeline and Hazardous Materials Safety Administration (PHMSA) proposes to amend the requirements for the transportation of hazardous materials set out in the Hazardous Materials Regulations (HMR) (49 Code of Federal Regulations (CFR) parts 171 to 180) and 49 CFR part 107. This rulemaking aims to amend provisions specific to the highway, rail, and vessel transportation of hazardous materials.

In this notice of proposed rulemaking (NPRM), PHMSA proposes to reform modal specific requirements in the HMR. PHMSA expects that the adoption of these proposals will maintain or enhance the safe transportation of hazardous materials while increasing the clarity of the HMR, and therefore decreasing compliance burdens. The proposed amendments also reflect changing conditions and trends that affect the safe transportation of hazardous materials while still maintaining or enhancing safety. The following are some of the more noteworthy subjects covered by proposed revisions:

- Rail tank car use requirements as recommended by the Rail Safety Advisory Committee (RSAC);

- Rail tank car and service equipment design approval requirements;
- Highway cargo tank specifications and requalification requirements; and
- Marking requirements for cargo tanks that contain multiple petroleum distillate fuels.

In this rulemaking, PHMSA solicits comment from the public and regulated community on these proposed amendments, specifically pertaining to the need for, benefits, and costs of the proposed amendments; impact on safety; public interest; and any other relevant concerns. In its preliminary regulatory impact analysis (PRIA), PHMSA concluded that the aggregate benefits of the proposed amendments justify their aggregate costs. PHMSA estimates annualized net benefits at a two percent discount rate of approximately \$97.3 million per year. Details on the estimated cost savings and benefits of this rulemaking can be found in the PRIA, which is available in the public docket for this rulemaking.

II. Background

The Federal Hazardous Materials Transportation Act (HMTA; 49 U.S.C. 5101 *et seq.*) at 49 U.S.C. 5103 gives the Secretary general authority to issue regulations for the safe transportation of hazardous materials in commerce. The Secretary delegates the above statutory authorities to PHMSA at 49 CFR 1.97.

A. Railroad Safety Advisory Committee

RSAC is a Federal Advisory Committee established by the U.S. Secretary of Transportation in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2) to provide information, advice, and recommendations to the Federal Railroad Administration (FRA) Administrator on matters relating to railroad safety. In 1996, FRA established RSAC to develop new regulatory standards, through a collaborative process, with all segments of the rail community working together to fashion mutually satisfactory solutions on safety regulatory issues. PHMSA participates in RSAC when issues related to hazardous material transportation are discussed, and participated in the development of the proposed recommendations in this rulemaking. On November 5, 2015, the RSAC accepted Task No. 15–04: “Hazardous Materials Issues,” which assigned the Hazardous Materials Issues Working Group (HMIWG) to consider several revisions to the HMR to enhance the safety of hazardous materials

transported by rail.¹ Consensus-approved regulatory change proposals were developed by the HMIWG and forwarded to the RSAC for consideration. On May 25, 2017, the RSAC voted and approved HMIWG’s consensus recommendations of changes to the HMR (hereafter referred to as the consensus recommendations) and submitted the suggested revisions to FRA. FRA subsequently recommended that PHMSA initiate a rulemaking to propose and adopt the consensus recommendations. In this rulemaking, PHMSA proposes to adopt the RSAC consensus recommendations with some modifications. Note that not all of the consensus recommendations are proposed as received. Rather, this rulemaking includes some revisions to the recommendations to better fit the construction of the HMR; to provide more appropriate amendatory instruction to the Office of the Federal Register; and to address some technical issues discovered during detailed review of the proposed regulatory text that was provided in the recommendation.

The consensus recommendations propose to make amendments to update, clarify, or remove existing requirements that are outdated or unnecessary. They propose the following changes, among others: (1) require tank car facilities to apply for and receive a DOT registration letter from PHMSA assigning a registration number prior to qualifying tank cars for service; (2) incorporate by reference updated versions of certain industry standards, including the Association of American Railroads (AAR) Manual of Standards and Recommended Practices Section C–III Specifications for Tank Cars (M–1002); and (3) revise the requirements for One-Time Movement Approvals (OTMAs). These changes are discussed in greater detail later in “Section IV. Section-by-Section Review.”

On August 27 and 28, 2013, FRA held a public meeting² to invite stakeholders and the public to participate in a comprehensive review of part 174 of the HMR, to improve the safety of railroad transportation of hazardous materials. Specifically, FRA sought comment on identifying provisions of part 174—Carriage by Rail—that are outdated, unclear, no longer necessary, present an undue economic burden on the regulated community, are inconsistent

with other North American standards and regulations (such as those issued by the AAR and Transport Canada), do not sufficiently address modern safety concerns, or do not sufficiently address technological advancements and procedural changes in the railroad operating environment. FRA included specific requests for comment on the public meeting agenda for a review of definitions and abbreviations (§ 171.8); notice to train crews (§ 174.24); nonconforming or leaking packages (§ 174.50); packagings, cargo tanks, and multi-unit tank car tanks in Tank-on-Flatcar (TOFC) and Container-on-Flatcar (COFC) service (§§ 174.61 and 174.63), tank car unloading (§ 174.67); switching placarded railcars, transport vehicles, freight containers and bulk packagings (§ 174.83); position of railcars (§ 174.85); as well as an open discussion on part 174. In its consensus recommendations, the RSAC addressed many of the issues identified and discussed during this public meeting. See “Section IV. Section-by-Section Review” for discussion of specific proposed changes because of the public meeting comments and RSAC deliberations.

B. AAR Authority To Approve the Design of Tank Cars and Quality Assurance Programs

1. Introduction

The design, construction, maintenance, and qualification of tank cars used to transport hazardous materials are complex regulatory topics. Tank cars are the largest type of hazardous materials packaging in use in surface transportation, and the consequence of failure during transportation can be—and has been—catastrophic. The HMR currently delegate tank car and service equipment design approval and tank car facility Quality Assurance Program (QAP) approval to the AAR Tank Car Committee (TCC). The AAR TCC is a body of representatives drawn from the railroads, tank car shippers, and the tank car manufacturing, maintenance, and repair industry. The AAR TCC approves tank car designs and manages QAP approval, as well as develops its own standards for the design and operation of tank cars. PHMSA and FRA provide regulatory oversight to the AAR TCC approval process to ensure the committee is operating within the HMR’s purview. The process by which the AAR TCC approves tank car and service equipment designs, materials, and construction, and conversion or alteration, is not specified in § 179.3; however, typically the committee votes on the proposed designs, materials, and

¹ More information about the RSAC, including HMIWG meeting minutes and other supporting documents can be found at: <https://rsac.fra.dot.gov/>.

² Comments from various associations and members of the public can be found at: <https://www.regulations.gov/docket?D=FRA-2013-0067>.

construction, and conversion or alteration based on AAR TCC staff review of design drawings and/or service trial results. The approval of QAPs is handled similarly via a vote of the AAR TCC after the facility has been audited by AAR Bureau of Explosives auditors. Audit scheduling, procedure, and recommendation for approval or denial is conducted wholly at the discretion of the AAR.

The HMR require each tank car facility to maintain a QAP that meets the requirements of § 179.7, with the intent that a properly implemented QAP will:

- Ensure the qualified tank car conforms to the requirements of the applicable specification and regulations;
- Identify any defects in the tank car manufacturing, repair, inspection, testing, and qualification or maintenance program; and
- Prevent any non-conformity from recurring.

Specifically, tank car facility QAPs must—at a minimum—address the elements in § 179.7(b)–(e), including verification of construction materials, monitoring and control of processes, and qualification of personnel.

PHMSA and FRA initiated a review of the current regulations in part 179—Specifications for Tank Cars—that require both tank car design and tank car facility QAPs to be approved by the AAR TCC. Additionally, PHMSA and FRA recognize that the scope of the definition of *tank car facility* has created confusion among tank car shippers and in the tank car manufacturing and maintenance industry. In this rulemaking, PHMSA proposes to revise the definition of *tank car facility* to reduce confusion and uncertainty in the regulated community. In conjunction with the other rail-specific changes proposed in this rule, this change will improve safety of rail transportation through increased awareness of who qualifies as a tank car facility and who specifically must comply with the HMR requirements for that facility (see “Section II.B.4 Tank Car Facility Definition” for further discussion on this issue).

PHMSA and FRA have determined that the current system requiring AAR approval for tank car facility QAPs and tank car designs creates a regulatory bottleneck without commensurate safety benefits for the regulated industry. As such, PHMSA proposes revisions to the current system to relieve confusion and increase the efficiency of the approval process (see “Section II.B.2 Tank Car Design Approval” and “Section II.B.3 Tank Car Facility Quality Assurance Program” for further discussion of these

issues). The proposed revisions are intended to increase the efficiency of the tank car design and QAP approval process, without compromising safety, by increasing governmental oversight of regulated entities through a registration program. The following is a brief summary of proposed changes to the approval processes and the definition of *tank car facility* which PHMSA discusses in greater detail later in this section:

A. Remove the requirement for tank car and service equipment designs to be approved solely by the AAR TCC and replace it with a requirement for tank car designs to be approved by a tank car Design Certifying Engineer (DCE) registered with PHMSA. This proposed requirement closely mirrors the process for highway cargo tank design review and approval.

B. Remove the requirement for tank car facilities to have a QAP approved by the AAR and replace it with a requirement for tank car facilities to register with PHMSA, maintain a QAP, and certify that it meets the § 179.7 quality assurance program requirements.

C. Revise the definition of *tank car facility* to clarify that the definition applies to facilities that qualify a tank car for service, and to clarify what activities require qualification of a tank car.

D. Add a registration program for tank car DCEs and tank car facilities.

E. Revise the incorporation by reference (IBR) of specific chapters and appendices of the 2014 edition of the *AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M–1002* (i.e., *AAR Specifications for Tank Cars*) to correspond to the above proposals (i.e., removing the requirement to comply with the specific sections of M–1002 that require AAR approval).

F. Revise the requirements for coating and lining inspection of tank cars to clarify what is expected.

G. Revise § 180.513—Repairs, alterations, conversions, and modifications—to clarify that tank car facilities must include the tank car owner’s qualification and maintenance program into their QAP to correct an incorrect reference to including the tank car owner’s QAP. Generally, a tank car owner is not subject to QAP requirements.

2. Tank Car Design Approval

Federal hazardous material transportation regulations have delegated the authority to approve tank car and service equipment designs to

the AAR—and various predecessor organizations—since at least 1927. As provided in § 179.3, the AAR TCC has authority to approve tank car designs, materials and construction, conversion, or alteration of tank car tanks under the specifications of part 179. By way of example, § 179.100–12(a) requires that manway nozzles must be of approved design of forged or rolled steel for steel tanks. In this context, pursuant to the definition in § 179.2, “approved” refers to approval by the AAR TCC.

Although PHMSA has delegated the authority to approve tank car designs, the current state of the AAR’s autonomous approval process presents inefficiencies when insufficient resources are available to process approval applications, resulting in unnecessary delays and increased costs for the tank car design and manufacturing community. As such, PHMSA and FRA propose to remove the requirement that tank car and service equipment designs receive approval solely through the AAR TCC before they are used in hazardous materials (hazmat) service. PHMSA and FRA propose to replace AAR TCC design approval with alternative approval by a tank car DCE, similar to the design approval structure for highway cargo tanks. The proposed tank car DCE requirement will include registration with PHMSA, and registrations will be subject to termination for cause, with the intent to create a more transparent, accountable tank car design approval system without any impact on the safety of such approved tank cars. “Design certifying engineer” is a defined term in the HMR in § 171.8, and currently only applies to engineers who can determine that a cargo tank design meets applicable DOT specification standards. PHMSA and FRA propose to revise the definition of DCE to include persons able to determine that a tank car meets applicable DOT specification standards. PHMSA and FRA propose that a tank car DCE must:

- Have an engineering degree and at least one year of work experience in tank car structural or mechanical design; or
- Be registered currently as a professional engineer by an appropriate authority of a state of the United States or a province of Canada.

As proposed, a tank car DCE may not use their experience in cargo tank structural or mechanical design to meet the experience requirement for tank car design, and vice versa for a cargo tank DCE. Based on our knowledge of the cargo tank and tank car industries, PHMSA believes it is unlikely that a company would attempt to register a

single engineer as both a tank car and cargo tank DCE. In the event this does occur, PHMSA would allow a single engineer to be registered as both a tank car and cargo tank DCE; however, they will need to acquire separate registrations: a cargo tank DCE registration as specified in subpart F of part 107, and a tank car DCE registration as specified in the proposed new subpart J of part 107. PHMSA has determined that maintaining separate registrations in the event that a single person holds both will simplify recordkeeping and enforcement by preventing unintended administrative hang-ups if one registration is allowed to lapse or termination proceedings are initiated. PHMSA requests comments on this proposed registration process.

Currently, the tank car design approval process is managed by the AAR TCC (see § 179.3). PHMSA and FRA attend AAR TCC meetings and participate in AAR TCC working groups on specific issues; however, the agencies do not manage the day-to-day operations of the AAR TCC. PHMSA and FRA have no voting power in the committee and little involvement in the day-to-day process by which the AAR TCC reviews and approves tank car designs. PHMSA and FRA retain full authority to set tank car safety standards through the adoption of tank car design specification requirements in part 179, and tank car use requirements in part 173. To provide additional context, there are approximately 130 instances in part 179 where the HMR requires that a tank car design feature (*e.g.*, the manner in which a tank car tank is attached to the car structure)³ or item of service equipment (*e.g.*, a valve)⁴ be “approved.” This approval is issued by the AAR TCC when the Committee determines that tank car tank or equipment is in compliance with the requirements of the HMR.⁵ The AAR TCC is the only entity granted the authority to issue such approvals for tank car tanks and service equipment in the HMR.

PHMSA and FRA have determined that—based on experience participating in the current AAR TCC process—the process for tank car design approval is conducted in such a way that increases costs and delays to the regulated community, without a commensurate increase in safety that would justify these delays. The HMR create a single-source, prescriptive system, because only AAR TCC has the authority to approve an application for a tank car

design, material of construction, conversion, or alteration under part 179 specifications. The HMR requirements for the review of a tank car design are well understood and include compliance with part 179 and other considerations that a tank car design must take into account (*e.g.*, lading properties, material compatibility, operating temperatures, etc.). There is little doubt that there are many engineers in the United States with tank car structural or mechanical design experience who could review and certify that a tank car’s design meets the HMR requirements. Replacing AAR TCC approval with DCE approval as proposed will create a system that increases efficiency in the tank car design approval market by expanding the pool of authorized tank car design approval sources without impacting the safety of tank cars used to transport hazardous materials. The proposed system also includes documentation requirements for DCEs that will facilitate improved government oversight of the design approval process via periodic audits, and it would allow DCE registrations to be terminated for cause as further discussed below.

PHMSA and FRA expect that an individual with an engineering degree and tank car design experience or a registered professional engineer—thus meeting the § 171.8 definition of a tank car DCE—will be able to review the design of a tank car or service equipment and determine whether the design complies with the tank car specification requirements. This proposal will improve government oversight of the tank car approval process. Currently, PHMSA and FRA have limited ability to take enforcement action against the TCC for failures to comply with the requirements of the HMR. The current TCC design review procedures have allowed non-compliant tank cars to enter transportation, posing risks to lives and the environment. When non-compliant cars are discovered in transportation, FRA takes immediate action to protect rail workers and the public. This can include issuing a railworthiness directive to address the non-compliance. Audits of the TCC tank car design review process conducted by the Department have revealed systemic operational and processing issues within the TCC—specifically—that the TCC utilizes, approves, and certifies Independent Third Party (ITP) individuals for reviewing and verifying that the application meets all AAR and DOT design requirements. These audit findings still have not been addressed to date. Additionally, in the recent past,

the TCC elected not to review and approve new designs for DOT–106 and DOT–110 multi-unit tank car tanks (commonly known as “ton tanks”). The TCC’s decision not to review and approve DOT–106 and DOT–110 designs created significant disruption for a packaging manufacturer and their customers. As a result, PHMSA expended resources to develop and issue a Special Permit⁶ to allow the construction and use of these packagings to avoid disruption to commercial activities caused by the TCC’s decision not to complete the role assigned to them in § 179.3. PHMSA and FRA are also concerned that the current system allows TCC to regulate entry to the market by controlling the approval process. Major tank car and service equipment (*e.g.*, valve) manufacturers are represented on the TCC. This creates a potential conflict of interest for the TCC when considering approval applications from firms that compete with companies its members represent. PHMSA and FRA have determined that due to unaddressed issues in the AAR TCC approval process, a recent history of a decision not to perform the role assigned in the HMR, and the potential for incumbent tank car industrial concerns to impact entry of competitors into the marketplace, we can no longer justify delegating authority for tank car design approval to the AAR TCC.

PHMSA and FRA expect that costs for reviewing and approving tank car designs will decrease by removing the single-source approval and the barriers of entry to the business of tank car design approval. The implementation of the proposed tank car DCE program will maintain at least an equivalent level of safety of tank car design by ensuring tank car DCEs maintain and adhere to a detailed written procedure to evaluate the compliance of a tank car design with the HMR’s tank car specification and usage requirements. PHMSA and FRA will be able to exert substantially greater oversight over tank car DCEs than the AAR TCC, both through the modification, suspension, and termination procedures proposed in this NPRM, as well as through the civil and criminal penalty procedures applicable to all persons who perform activities subject to the HMR through 49 CFR parts 107, 109, and 49 U.S.C. 5123–5124.

PHMSA, in conjunction with our highway modal partner FMCSA, has experience overseeing a DCE program for the design approval of bulk

³ See § 179.10.

⁴ See § 179.200–16(b).

⁵ See § 179.3.

⁶ <https://www.phmsa.dot.gov/hazmat/documents/offer/SP14437.pdf/offerserver/SP14437>.

hazardous materials packages intended for highway transportation through the existing cargo tank DCE program. This experience makes us confident that private sector engineers, operating under governmental oversight through a registration program, can safely and effectively review a package (*i.e.*, a tank design and ensure it complies in all respects with the relevant design requirements of the HMR. PHMSA and FRA intend to maintain direct oversight on the tank car design process through regular audits of tank car DCEs and reserve the right to terminate a tank car DCE registration for cause. Causes for registration termination include: (1) because of a change in circumstances the registration is no longer needed or would no longer be granted if applied for; (2) the application contained inaccurate or incomplete information and it would not have been granted had accurate and complete information been provided; (3) the application contained deliberately inaccurate or incomplete information; or (4) the registration holder knowingly violated the terms of the registration or an applicable requirement of 49 CFR Chapter I in a manner demonstrating lack of fitness to conduct the activity for which the registration is required. PHMSA emphasizes that criteria (4) can be used to bring enforcement action and potential modification, suspension, or termination proceedings against a tank car DCE who fails to maintain and follow an adequate written procedure that is used to verify conformance with the requirements of the HMR. *See* “Section IV. Section 107.911” for additional information on the termination of a tank car DCE registration.

By clearly describing the processes and procedures that the DCE must follow to approve a tank car design, PHMSA and FRA expect a high level of safety for tank car designs will be maintained. PHMSA proposes to require the DCE to review the same information and drawings currently required in the AAR Form 4–2. This commonality with existing design records is intended to minimize disruption during the transitional period and maximize tank car and service equipment manufacturer and DCE familiarity with the required documentation. The requirements proposed in §§ 179.3 and 179.5 are intended to create an accountable, auditable, criteria-based tank car design approval system that is more transparent to government oversight than the current system. The proposed requirements in §§ 179.3 and 179.5 are primarily based on the requirement for

a tank car DCE to develop, maintain, and adhere to a written procedure describing the process used to verify a tank car or service equipment’s design with the requirements of the HMR. This detailed procedure must include acceptance and rejection criteria for each tank car or service equipment design element approved by the DCE, which demonstrate the tank car or service equipment will meet the requirements of part 179 and retain the hazardous contents of the packaging in all normal conditions of transportation for the designed life of the packaging. PHMSA and FRA investigators and engineers will evaluate the detailed procedures during periodic audits to ensure the procedures adequately maintain compliance with part 179, and that the DCE is following the procedures. These general procedural requirements proposed in §§ 179.3 and 179.5 will allow tank car DCEs to determine the most efficient workflow for their business needs, while providing a clear basis for evaluation of a tank car DCE’s procedures. These standards also provide a clear framework for PHMSA and FRA to conduct audits and determine whether lapses in a tank car DCE’s performance warrant the issuance of a Notice of Probable Violation, or, in serious cases, initiation of modification, suspension, or termination proceedings.

The DCE registration program also may facilitate greater technological advancements in tank car and service equipment designs by facilitating greater access to tank car and service equipment design certification services. The proposed rule would enable other entities to approve tank car designs, potentially leading to more processing of innovative designs that meet the existing performance standards and their subsequent use in the transportation arena. In addition, opening these services up to other entities—rather than maintain the design approval process solely with AAR TCC—may increase competition within the industry as additional DCEs are registered and begin to provide tank car design approvals. This competition is expected to result in potential cost reductions for the regulated community.

To adequately oversee tank car DCEs, PHMSA and FRA propose to require that each DCE register with PHMSA and provide information on the types of design reviews the DCE will conduct. This will allow PHMSA and FRA to audit DCEs to ensure they are properly reviewing each tank car or service equipment design and only issuing approvals to those designs that meet the requirements of part 179. Each DCE

must develop procedures, including acceptance and rejection criteria for the approval process, which demonstrate that the tank car or service equipment will meet the requirements of part 179 and the design level of reliability and safety for the hazardous materials service for which the tank car is intended. The registration requirement is necessary to assist PHMSA and FRA in performance of their oversight responsibilities to ensure all tank car DCEs are performing their design reviews with appropriate rigor, and thus that tank car designs are suitable for hazmat transportation. See discussion in section “Section II.B.5 Tank Car Facility and Design Certifying Engineer Registration” for additional details on the proposed registration program.

Therefore, PHMSA proposes to remove reference to AAR approval for tank car designs wherever it appears in the subchapter. A DCE registered with PHMSA would fill the tank car design approval role currently delegated to the AAR. Authorizing qualified individuals, registered with PHMSA, to review and certify tank car designs under PHMSA and FRA oversight will increase the level of safety provided by the HMR while increasing design review efficiency for the tank car design and manufacturing community. Finally, PHMSA notes this would not exclude the AAR staff or TCC members from registering as DCEs to continue to perform these approvals; however, it removes exclusive delegation and opens the market to all those who are qualified. AAR TCC may continue to provide approval services commercially, provided they register with PHMSA and follow the same requirements proposed in this NPRM that other tank car DCEs must follow.

3. Tank Car Facility Quality Assurance Program

Tank car facilities, as defined in § 179.2, are required to have a QAP that—among other items—has the means to detect non-conformities in the tank car manufacturing, repair, inspection, testing, and qualification or maintenance processes. Currently, each tank car facility’s QAP must meet the requirements of § 179.7, which requires that the QAP be approved by the AAR. In this rulemaking, PHMSA proposes to remove the requirement that AAR approve a tank car facility’s QAP. As a substitute, we propose to replace this requirement with a requirement that tank car facilities must register with PHMSA, certify that they maintain a QAP that meets the requirements of § 179.7, and include an executive summary of their QAP with their

registration statement. As proposed, the registration program will improve safety through increased PHMSA and FRA situational awareness of tank car facility activities and provide mechanisms to address non-compliance. PHMSA proposes to allow modification, suspension, or termination of a tank car facility registration for the following causes: (1) because of a change in circumstances, that the registration is no longer needed or would no longer be granted if applied for; (2) the application contained inaccurate or incomplete information and it would not have been granted had accurate and complete information been provided; (3) the application contained deliberately inaccurate or incomplete information; or (4) the registration holder knowingly violated the terms of the registration or an applicable requirement of 49 CFR Chapter I in a manner demonstrating lack of fitness to conduct the activity for which the registration is required. PHMSA emphasizes that criteria (4) above can be used to bring enforcement action and initiate modification, suspension, and termination proceedings against a tank car facility that fails to adhere to their QAP. A tank car facility's failure to adhere to a QAP could create unacceptable risks in the rail system and may cause unsafe tank cars to enter transportation.

The creation of the QAP requirement for tank car facilities was initiated based on a National Transportation Safety Board (NTSB) safety recommendation (R-88-63)⁷ issued in response to a September 8, 1987, incident involving the release of butadiene from a tank car in New Orleans, Louisiana. In 1993, the Research and Special Programs Administration (RSPA)—PHMSA's predecessor agency—proposed the creation of the QAP requirement and definition of *tank car facility* in an NPRM (HM-201).⁸ The primary intent of this requirement—as discussed in the preamble of HM-201—is to ensure each tank car manufacturing or repair facility has procedures in place to detect any nonconformity in the tank car manufacturing, maintenance, or repair process and has the means to prevent its recurrence.

In 1995, RSPA created the definition for the term “tank car facility” and a requirement for each tank car facility to maintain a QAP meeting the requirements of § 179.7 in final rule HM-175A and HM-201,⁹ and made

minor revisions to the requirements in a 1996 HM-175A and HM-201 corrections final rule.¹⁰ The requirements of § 179.7 have not been modified substantively since.

PHMSA and FRA have found that the requirement for only AAR to review and approve each tank car facility's QAP creates an undue cost burden on the facility and creates delays in approving facility operation that hinder commerce. Additionally, PHMSA and FRA's experience auditing tank car facilities with QAPs approved by AAR TCC have revealed significant compliance issues with the current QAP approval process. For example, PHMSA and FRA have knowledge that on at least one occasion—over the course of many months—AAR did not take action on a facility that failed AAR Bureau of Explosives QAP audits. These negative findings demonstrated the facility's failure to maintain an effective QAP and, therefore, the company's inability to safely perform their tank car qualification functions as required by the HMR. Specifically, AAR did not take action to remove the certification of a tank car facility in Shoshone, Wyoming, (Wasatch Railroad Contractors) that had failed multiple QAP audits. This inaction allowed the facility to continue to operate without an effective QAP. FRA and PHMSA raised concerns that AAR has not adopted procedural changes to prevent this type of failure (e.g., by immediately addressing findings) from recurring. Subsequently, on April 22, 2021, two employees were killed in an explosion while working inside a tank car.¹¹ FRA and PHMSA believe corrective action by AAR and the facility may have prevented such an incident by not allowing continued work on tank cars. In 2022, the owner of Wasatch Railroad Contractors was found guilty of five counts of wire fraud and one count of knowing endangerment for knowingly exposing employees to asbestos and placing them in imminent danger of death or serious bodily injury.¹²

Additionally, as part of AAR TCC's current QAP approval process, AAR requires that tank car facilities bear the expense on an initial certification audit and annual recertification audits thereafter. The initial certification process often takes several months, and the tank car facility has no recourse under the current HMR requirements but to accept AAR's timeline and fees.

Additionally, the audit process does not increase the level of safety commensurate with the costs and delays it imposes. FRA inspectors regularly find violations of the HMR at facilities that AAR authorizes to operate through the current QAP approval process. FRA issues findings, tickets, and notices of probable violation to tank car facilities when it discovers non-compliance. When violations are systemic or significant, FRA uses its railworthiness authority to address similarly situated cars or fleets of cars.

Therefore, PHMSA and FRA propose to remove the requirement that tank car facilities submit their QAPs for approval to AAR and replace it with a requirement that each tank car facility register with PHMSA and certify that it has created and is maintaining a QAP that meets the requirements of § 179.7. As part of the registration requirement, PHMSA and FRA propose that the registrant must submit an executive summary of its QAP, demonstrating compliance with the elements required in § 179.7(b). Facilities may submit certifications from outside organizations, such as an external auditor, to serve as the executive summary or submit their own executive summary documents. PHMSA will administer the registration program for facilities, and FRA—in conjunction with PHMSA—will oversee tank car facility QAPs through regular facility compliance audits. PHMSA and FRA have limited oversight and control over the current AAR approval process for tank car facility QAPs. However, the observations that have been conducted, coupled with our enforcement oversight of the tank car fleet, provide PHMSA and FRA with significant concerns that the current system of AAR audits provides limited safety benefits compared to the burdens imposed. PHMSA and FRA expect the registration program combined with regular compliance audits by government personnel will maintain an equivalent or greater level of safety to the current requirements while reducing administrative delays caused by the AAR process. PHMSA and FRA emphasize that adhering to a rigorous QAP is critical for a tank car facility to ensure that the tank cars qualified for service at the facility meet the requirements of the tank car's specification and regulations. See “Section II.B.5. Tank Car Facility and Design Certifying Engineer Registration” for additional details on the proposed registration program.

⁷ See NTSB Safety Recommendation R-88-063: https://www.ntsb.gov/investigations/AccidentReports/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=R-88-063.

⁸ 58 FR 48485 (Sep. 16, 1993).

⁹ 60 FR 49048 (Sep. 21, 1995).

¹⁰ 61 FR 33250 (Jun. 26, 1996).

¹¹ <https://apnews.com/article/explosions-business-1aa330c562c393a74421e4a90b9394db>.

¹² <https://www.justice.gov/usao-wy/pr/wasatch-railroad-contractors-and-its-chief-executive-officer-sentenced-wire-fraud-and>.

PHMSA recognizes that this topic is the subject of an open petition P-1770¹³ submitted by AAR on October 21, 2022. This petition requests the removal of the AAR approval requirement for QAPs in accordance with § 179.7. The AAR petition requests that PHMSA replace AAR approval of QAPs with a requirement for tank car facilities to comply with an industry standard known as “AAR M-1003—Specification for Quality Assurance.” As described above, PHMSA believes that a performance-based approach to QAPs—along with registration with the Department and self-certification—is the best option. Our proposal allows for the use of accepted industry standards for quality assurance programs to meet the proposed safety requirements, but does not mandate one standard over another. This allows tank car facilities to implement the performance elements in the most appropriate manner for their operations. Therefore, in this NPRM, PHMSA is not proposing to incorporate by reference AAR M-1003 into § 179.7. PHMSA will consider any comments on this topic with respect to this NPRM as it evaluates petition P-1770.

4. Tank Car Facility Definition

PHMSA and FRA are aware that there is uncertainty in the tank car community related to the scope of the definition of “tank car facility.” This uncertainty impacts both tank car shippers and tank car manufacturers (including service equipment manufacturers). On October 8, 2019, PHMSA, in conjunction with FRA, issued Letter of Interpretation Reference No. 19-0117¹⁴ addressing the definition of “tank car facility.” PHMSA proposes to revise the definition of “tank car facility” consistent with Letter of Interpretation Reference No. 19-0117 so that the definition applies only to the facility that qualifies the tank car for service. That is, for example, an equipment manufacturer of a pressure valve used in the construction of a tank car is not a tank car facility solely on the basis of manufacturing a component part of a specification tank car. The determining factor on the applicability of the “tank car facility” definition is whether the facility qualifies a tank car for service. The tank car facility that qualifies the tank car for service is responsible for ensuring the conformity of the entire tank car, including service equipment, with the approved

specification. Additionally, PHMSA proposes to revise the definition of “service equipment” in § 180.503 to clarify what constitutes “service equipment” consistent with our expectations in revising the definition of a tank car facility. Service equipment is pressure or lading retaining equipment. Examples include pressure relief devices, valves, manway covers, devices used for loading and unloading, interior heating coils, and vents.

To address the community of tank car shippers: PHMSA’s and FRA’s position, as reflected in the proposed definition, is that the removal of service equipment from the tank car and replacement or re-installation of the service equipment is a qualification event and triggers the need for a leakage pressure test (see § 180.509(j)) to verify the tank car is leak tight at the connection. These functions must be conducted by a tank car facility, as defined in part 179, because the service equipment requires a leakage pressure test to ensure the connection to the tank car is qualified for its intended service. A leakage pressure test is a qualification event and must be performed by a tank car facility. Any action that triggers a qualification event requires a tank car facility to perform the qualification prior to placing the tank car into transportation. However, to be clear, a facility that only operates service equipment for loading and unloading purposes is not a tank car facility.

To address the community of tank car component manufacturers, repair facilities and manufacturers: PHMSA’s and FRA’s position, as reflected in the proposed definition, is that a facility that only manufactures, maintains, or repairs service equipment is not a tank car facility. The facility that qualifies the completed tank car for service after installation of the service equipment is the tank car facility. The facility that qualifies the tank car for service is responsible for ensuring the compliance of the packaging with the requirements of part 179, even those functions that they did not directly perform (e.g., manufacturing a valve). The tank car facility’s QAP must encompass all work done on the tank car and its components prior to qualification of the tank car.

Tank car facilities that meet the proposed revised definition of tank car facility in § 179.2 must have the knowledge and skill to ensure appropriate conformance with the requirements of parts 179 and 180. As qualification is the final step in the tank car manufacturing or maintenance process, only requiring the facilities that qualify tank cars (i.e., facilities that have the “last touch”) to have a QAP reduces

this requirement to a small subset of the total number of facilities that perform work related to tank cars, while still maintaining the high level of safety under the HMR. PHMSA and FRA emphasize the scope of the definition of “qualification” remains unchanged. Therefore, as proposed, tank car shippers and component suppliers are not subject to the administrative burdens associated with the creation and maintenance of QAPs, unless they perform qualification activities (e.g., removal and replacement of a valve or other service equipment on a tank car). PHMSA and FRA emphasize that all facilities that perform a function subject to the HMR are responsible for performing it correctly and in conformance with all applicable requirements, regardless of whether they meet the definition of a “tank car facility.”

Tank car facilities are responsible for ensuring all material installed onto the tank car meets the requirements of the specification and the regulations at the time the tank car is qualified for service. PHMSA and FRA understand that long-standing policy in the tank car industry had required tank car component manufacturers to maintain AAR-approved QAPs. This policy was confirmed in previously issued (and since revoked) PHMSA Letters of Interpretation Reference Nos. 15-0124 and 18-0029. While these letters are no longer valid, and have not been valid since 2019, at the time they were written they aligned with generally accepted industry practice and addressed a safety issue created by production of valves and other tank car service equipment by unapproved subcontractors without adequate oversight. As proposed in this NPRM, the facility that qualifies the tank car for service is responsible for ensuring the tank car and all equipment necessary for the tank car’s operation meets the applicable requirements of the HMR and any other applicable standards.

5. Tank Car Facility and Design Certifying Engineer Registration

As previously discussed, PHMSA and FRA propose to require that tank car facilities and tank car DCEs register with PHMSA prior to conducting regulated activities. PHMSA and FRA expect that a registration program for both tank car facilities and tank car DCEs is a more efficient alternative for the tank car industry while providing at least an equivalent level of safety. Direct monitoring of registered tank car facilities and tank car DCEs through site visits and audits will maintain the

¹³ <https://www.regulations.gov/document/PHMSA-2022-0130-0001>.

¹⁴ See Letter of Interpretation Reference No. 19-0117: <https://www.phmsa.dot.gov/regulations/title49/interp/19-0117>.

existing safety standards established in the HMR.

Therefore, PHMSA, in conjunction with FRA, proposes to create subpart J in part 107 for tank car facility and tank car DCE registration. The creation of a tank car facility registration program was agreed to in the RSAC process; however, PHMSA proposes to implement the tank car facility registration program in a format different than what appears in the RSAC consensus recommendations. In the RSAC proposal, the tank car facility registration was added to the existing cargo tank facility registration subpart (*i.e.*, part 107, subpart F). After reviewing the RSAC proposal, PHMSA and FRA have determined that it would be confusing to both the cargo tank and tank car communities to attempt to insert tank car-specific facility and DCE registration language into part 107, subpart F. PHMSA proposes to place the tank car facility and tank car DCE registration requirements in a new subpart to reduce confusion and highlight the tank car-specific nature of these programs. However, some of the proposed language is similar to the part 107, subpart F requirements for cargo tanks and cargo tank motor vehicles.

For tank car facilities, PHMSA proposes to require that each facility, *i.e.* each separate physical location with a unique street address, submit a separate registration. This will allow PHMSA and FRA to oversee each facility that qualifies tank cars more effectively by establishing the physical addresses and activities of each facility. Each registration statement must be signed by a principal, officer, partner, or employee of the facility responsible for compliance with the applicable requirements of the HMR, certifying knowledge of those requirements. In their registration statement, each tank car facility must list the qualification functions the tank car facility will perform and identify the types of DOT specification or special permit tank cars they intend to qualify.

For DCEs, PHMSA proposes to require each person, as defined in § 171.8, who conducts review of a tank car or service equipment design must register with PHMSA. Each engineer employed to conduct the design reviews must be individually named in the registration and will receive a unique, separate identifier associated with the company's DCE registration. If an engineer is

employed as a DCE to conduct design reviews of tank cars or service equipment and begins operating as a DCE for another company, or as self-employed, then the engineer must inform PHMSA and will then receive a new registration number.

PHMSA also proposes the ability to modify, suspend, or terminate both tank car facility and tank car DCE registrations for cause in new § 107.911. Further, procedures for a tank car facility or DCE to follow to request reconsideration and appeal a decision to modify, suspend, or terminate a registration are proposed in new §§ 107.913 and 107.915, respectively. Modification, suspension, and termination determinations for tank car facility and DCE registrations will be made by the Associate Administrator for Safety, FRA. Similarly, requests for reconsideration must also be submitted to the Associate Administrator for Safety, FRA, and appeal of the reconsideration decision to the FRA Administrator.

6. AAR Specifications for Tank Cars Incorporation by Reference

The AAR has developed a comprehensive industry standard for the construction and maintenance of tank cars, the *AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification, M-1002 (AAR Specifications for Tank Cars)*. Currently, § 171.7 incorporates by reference the December 2000 edition of the AAR Specifications for Tank Cars throughout parts 173 (Shippers-General Requirements for Shipments and Packagings), 179 (Specifications for Tank Cars), and 180 (Continuing Qualification and Maintenance of Packagings). In many sections, especially in part 179, the HMR only references a specific section, such as an appendix, of the document. To clarify the IBR structure of M-1002, the RSAC agreed to separately list the individual chapters and appendices of the of AAR Specifications for Tank Cars in the HMR's consolidated IBR section (§ 171.7). This will clearly denote to the reader the relevant chapter or appendix of the document that applies in a particular section of the HMR. This change will also provide PHMSA and FRA greater flexibility when incorporating by reference future editions of the standard. For example, if

PHMSA and FRA do not concur on the content of a particular chapter or appendix, it would not prevent other chapters or appendices from being incorporated by reference.

The RSAC also agreed to update the standard from the December 2000 edition to the November 2014 edition. The 2014 edition of the AAR Specifications for Tank Cars also addresses NTSB Safety Recommendation R-12-007,¹⁵ issued on March 2, 2012. R-12-007 recommends that PHMSA adopt AAR's revised design standards for center sill and draft sill attachments. AAR redesigned center and draft sill attachments in response to NTSB Safety Recommendation R-12-009.¹⁶ Chapter 6 of the 2014 edition of the AAR Specifications for Tank Cars, which is proposed for adoption into § 179.10, includes the new sill attachment standards for newly built tank cars. Therefore, the proposed IBR update helps PHMSA address NTSB Safety Recommendation R-12-007.

This NPRM proposes to update the IBR of the AAR Specifications for Tank Cars to the 2014 edition and to incorporate by reference separately each relevant chapter and appendix, as agreed to in the RSAC process. Due to the proposed removal of AAR's sole process for review and approval of tank car designs, certain appendices and sections are no longer necessary to IBR. Several appendices and sections that require designs and QAPs to be sent to AAR for approval would no longer be relevant (*see* "Section II.B.2. Tank Car Design Approval). Therefore, PHMSA does not propose to IBR Appendix B, Appendix L, and Appendix U of the AAR Specifications for Tank Cars into the HMR.

Additionally, PHMSA proposes to update the edition of the AAR Manual of Standards and Recommended Practices, Section C—II Specifications for Design, Fabrication and Construction of Freight Cars, Chapter 5 to the 2011 edition from the 1988 edition, as agreed in RSAC.

¹⁵ See NTSB Safety Recommendation R-12-007: https://www.ntsb.gov/safety/safety-recs/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=R-12-007.

¹⁶ See NTSB Safety Recommendation R-12-009: https://www.ntsb.gov/safety/safety-recs/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=R-12-009.

PHMSA proposes to IBR the 2014 edition of the AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M–1002 (AAR Specifications for Tank Cars) Chapter 2, section 2.2.1.2 into § 179.102–3. This proposed amendment creates an HMR requirement for shell and head material Charpy impact testing at time of manufacture for pressure tank cars that transport poisonous-by-inhalation material. Because this requirement has been in place through AAR interchange standards since 2005, PHMSA expects there will be no additional burden placed on tank car manufacturers. This proposed IBR also addresses NTSB Safety Recommendation R–19–001, which requests that PHMSA promulgate a final standard for pressure tank cars used to transport poison inhalation hazard/toxic inhalation hazard materials that includes enhanced fracture toughness requirements for tank heads and shells.

PHMSA proposes to incorporate by reference the 2014 edition of the AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M–1002 (AAR Specifications for Tank Cars) Chapter 3, into §§ 173.241, 173.242, and 173.247. Chapter 3 contains the requirements for manufacturing AAR specification tank cars. Sections 173.241, 173.242, and 173.247 are the packaging sections that authorize the use of AAR specification tank cars. Currently, these sections reference specific AAR specification tank cars, but provide no information as to how these cars are constructed, or what version of the AAR Specifications for Tank Cars they must meet. Incorporating by reference only Chapter 3 into these sections ensures that AAR specification tank cars are manufactured to a standard that PHMSA and FRA have reviewed and determined is acceptable for hazardous materials transportation. If the specifications of the AAR tank cars referenced in §§ 173.241, 173.242, and 173.247 are ever changed in a future edition of the AAR Specifications for Tank Cars, PHMSA and FRA will need to review the revised specifications before authorizing the tank cars for hazardous material service. Incorporation by reference of a specific edition of the AAR Specifications for Tank Cars in §§ 173.241, 173.242, and 173.247 ensures PHMSA will be able to review any future changes to the construction specification prior to authorizing the new specification for hazardous materials transportation.

Finally, PHMSA proposes to correct an error in the HMR and RSAC's

proposed IBR text. Currently, the HMR incorporates by reference the AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M–1002 (AAR Specifications for Tank Cars), Chapter 6, November 2014 in § 179.400–6. This citation is incorrect; the correct IBR document for design loads of outer jackets is AAR Manual of Standards and Recommended Practices, Section C—II Specifications for Design, Fabrication and Construction of Freight Cars, Chapter 6. Therefore, PHMSA proposes to IBR Section C—II, Chapter 6 into § 179.400–6.

7. Tank Car Linings and Coatings

The HMR prescribes requirements for the inspection of tank car linings in § 180.509(i). On May 22, 2019, the Railway Supply Institute (RSI) requested a Letter of Interpretation on the applicability of the inspection requirements of § 180.509(i). Specifically, RSI asked whether linings and coatings solely used to protect product purity (*i.e.*, the lining or coating plays no role in protecting the tank from corrosion or reactivity) are subject to the inspection requirements of § 180.509(i).

In Letter of Interpretation Reference No. 19–0117,¹⁷ PHMSA and FRA provided clarification on inspection requirements for linings and coatings. Specifically, the requirements of § 180.509(i) apply only to internal tank car linings and coatings that are applied to protect the tank from a material that is corrosive or reactive to the tank. As noted in the preamble of the final rule HM–216B,¹⁸ PHMSA and FRA are aware of incidents where a material was loaded into a tank car with a defective or incompatible lining which caused a reaction with the tank car. In these instances, the tank lining owners expected the lining was there to protect product purity when in fact it served to protect the tank. It is the responsibility of the tank lining owner to determine whether the internal lining or coating is solely for product purity purposes.

To address confusion on the applicability of tank car lining and coating inspections, PHMSA proposes an editorial revision of the requirements of § 180.509(i)(1), adding the phrase “used to transport hazardous materials corrosive or reactive to the tank” to the second sentence of (i)(1). The proposed revision clearly indicates that tank car linings and coatings are only subject to the inspection requirements of part 180

if they are used to protect the tank from material corrosive or reactive to the tank. PHMSA expects that this clarification will improve compliance with this inspection requirement and therefore improve safety. PHMSA requests comment on this proposal.

8. Editorial Revisions to §§ 180.501 and 180.513

Section 180.501 contains the general requirements for the qualification and maintenance of tank cars. In this NPRM, PHMSA proposes to replace the phrase “owner’s qualification program” with “owner’s qualification and maintenance program” to maintain alignment with the scope of part 180, subpart F, and the existing references to “qualification and maintenance program” in §§ 179.7 and 180.513.

Section 180.513 provides the requirements to repair, alter, convert, and modify tank cars. PHMSA, in conjunction with FRA, adopted this section into the HMR in HM–216B. Section 180.513(b) outlines responsibilities of a tank car facility. The last sentence in § 180.513(b) contains wording that does not communicate the requirement accurately. Specifically, at the end of paragraph (b), it currently states, “a tank car facility must incorporate the owner’s Quality Assurance Program into their own Quality Assurance Program.” The sentence contains an incorrect reference to an equipment owner’s QAP. Tank car owners are not subject to the part 179 QAP requirements unless they also operate a tank car facility. The last sentence should make a general reference to a tank car owner’s qualification and maintenance program and not a QAP that is required of tank car facilities. The requirement should read, “a tank car facility must incorporate the owner’s qualification and maintenance program into their own Quality Assurance Program.” Therefore, PHMSA proposes to replace the first appearance of the phrase “Quality Assurance Program” in the last sentence of § 180.513(b) with the phrase “qualification and maintenance program.”

C. Cargo Tank Regulatory Amendments

PHMSA, in conjunction with the Federal Motor Carrier Safety Administration (FMCSA), developed proposed amendments specific to enhancing safe highway transportation of hazardous materials. A portion of the proposed items were initially identified during two technical information sessions sponsored by National Tank Truck Carriers, Inc. (NTTC) and Truck Trailer Manufacturer’s Association

¹⁷ See Letter of Interpretation Reference No. 19–0117: <https://www.phmsa.dot.gov/regulations/title49/interp/19-0117>.

¹⁸ 77 FR 37962 (Jun. 25, 2012).

(TTMA) in 2005. During these meetings, PHMSA and FMCSA began developing a list of issues, concerns, and requests for clarifications to be considered in a future rulemaking. Moreover, PHMSA and FMCSA have identified numerous advancements in industry practice, as well as potential safety incidents, over the course of the past 17 years. This rulemaking aims to address the safety concerns raised by industry stakeholders.

Additionally, PHMSA and FMCSA continue to review enforcement actions, letters of interpretation, and information received from cargo tank manufacturers and testing facilities, in efforts to identify appropriate revisions to the HMR.

D. Cargo Tank Marking for Petroleum Distillate Fuels

In an advance notice of proposed rulemaking (ANPRM) HM-213E,¹⁹ PHMSA addressed United Nations identification number (UN ID number) marking of cargo tank motor vehicles containing petroleum distillate fuels in response to a *Protecting our Infrastructure of Pipelines and Enhancing Safety Act of 2016 (PIPES Act of 2016)* Congressional mandate and two petitions for rulemaking (P-1667²⁰ and P-1668²¹). The PIPES Act of 2016 mandate stated that “[n]ot later than 90 days after the date of enactment of this Act, the Secretary of Transportation shall issue an [ANPRM] to take public comment on the petition for rulemaking

dated October 28, 2015, titled ‘Corrections to Title 49 CFR 172.336 Identification numbers; special provisions’ (P-1667).”

The central issue addressed in the HM-213E ANPRM was whether a cargo tank motor vehicle transporting different types of petroleum distillate fuels (e.g., gasoline, diesel fuel, kerosene, and fuel oil) over the course of multiple trips should be permitted to display the UN ID number of the fuel with the lowest flash point, even when that fuel is not being transported (e.g., display “1203”—the UN ID number for gasoline—when the cargo tank contains only diesel fuel).

As detailed in table 1, PHMSA received 14 sets of comments to the HM-213E ANPRM.

TABLE 1—HM-213E COMMENTERS AND ASSOCIATED COMMENT DOCKET NUMBERS

Commenter	Docket ID number
American Trucking Association (ATA)	PHMSA-2016-0079-0012
Anonymous	PHMSA-2016-0079-0003
Commercial Vehicle Safety Alliance (CVSA)	PHMSA-2016-0079-0009
Dangerous Goods Advisory Council (DGAC)	PHMSA-2016-0079-0010
International Association of Fire Chiefs (IAFC)	PHMSA-2016-0079-0008
International Association of Fire Fighters (IAFF)	PHMSA-2016-0079-0011
Josh Torrez	PHMSA-2016-0079-0002
Kansas Highway Patrol	PHMSA-2016-0079-0005
NTTC	PHMSA-2016-0079-0006
Patriot Tank Lines, Inc.	PHMSA-2016-0079-0004
Petroleum Marketers Association of America (PMAA)	PHMSA-2016-0079-0013; PHMSA-2016-0079-0014
Public Utilities Commission of Ohio	PHMSA-2016-0079-0007
Transportation Trades Department, American Federation of Labor and Congress of Industrial Organizations (AFL-CIO).	PHMSA-2016-0079-0015

ATA, CVSA, DGAC, Kansas Highway Patrol, Patriot Tank Lines, Inc., NTTC, and PMAA support allowing cargo tank motor vehicles that deliver multiple types of petroleum distillate fuels to display the UN ID number of the fuel with the lowest flash point, even when that fuel is not being transported. These organizations note that materials with a lower flash point generally have a higher flammability hazard, and therefore, conclude that marking the UN ID number of a lower flash point material would not increase risks in transportation. Additionally, these commenters note that the Emergency Response Guidebook (ERG) emergency response procedures are nearly identical for UN1203 (gasoline) and UN1202/NA1993 (diesel fuel, fuel oil), and marking of a cargo tank with “1203” even when it only contains diesel fuel has been a safe industry practice for decades. PHMSA also notes that for other petroleum distillate fuels—such as

UN1223 (kerosene)—the ERG also directs the reader to the same response procedures for UN1203 and UN1202/NA1993. Lastly, the commenters note that switching the UN ID number before every trip to reflect the material transported in the cargo tank at the time would increase the time per trip and costs for fuel distributors.

The IAFC, IAFF, Public Utilities Commission of Ohio, and Transportation Trades Department of the AFL-CIO do not support allowing cargo tank motor vehicles that deliver multiple types of petroleum distillate fuels to display the UN ID number of the fuel with the lowest flash point, even when that fuel is not being transported. These commenters state that emergency responders would treat an incident—including clean-up and spill mitigation—involving diesel fuel differently from gasoline, and the use of the gasoline “1203” marking in place of the diesel fuel “1202” or “1993”

increases confusion and decreases response effectiveness. Specifically, first responders may use the presence (or lack) of a fire and communicated hazard to determine the potential dangers of the fuel in the immediate aftermath of an accident. Because “1203” signifies a material with a lower flashpoint than “1202” or “1993” is present on the vehicle, the absence of a fire signifies that there may not be a fire hazard. However, when the higher flashpoint material is present, but only the lower flash point material is communicated on the vehicle, the absence of a fire may create a false sense of security for emergency responders, as they would be unaware that the fuel in the tank or spilled on the ground had not yet reached the higher flash temperature for diesel fuel.

PHMSA conducted a thorough review of the regulatory history related to the UN ID number marking requirements for petroleum distillate fuels in cargo tanks

¹⁹ 81 FR 83190 (Nov. 21, 2016).

²⁰ See petition for rulemaking P-1667: <https://www.regulations.gov/document?D=PHMSA-2015-0219-0001>.

²¹ See petition for rulemaking P-1668: <https://www.regulations.gov/document?D=PHMSA-2015-0251-0001>.

and concludes the origin of the confusion on this issue dates to final rule HM-118.²² In HM-118, RSPA added new hazard marking sections including § 172.332 for requirements on the display of UN ID numbers, § 172.334 for the prohibited display of UN ID numbers, and § 172.336 for special provisions and exceptions of UN ID numbers. In § 172.336, RSPA added two exceptions for the marking of UN ID numbers for a cargo tank transporting liquid distillate fuels, which read as follows:

(c) Identification numbers are not required

* * * * *

(4) For different liquid distillate fuels, including gasoline, in a compartmented cargo tank or tank car, if the identification number is displayed for the distillate fuel having the lowest flash point.

(5) For each of the different liquid distillate fuels, including gasoline, transported in a cargo tank, if the identification number displayed is for the liquid distillate fuel having the lowest flash point.

* * * * *

In the final rule preamble,²³ RSPA described the intent of the exception in § 172.336(c)(5) as:

Paragraph (c)(5) provides for display of the identification number of the liquid distillate fuel having the lowest flash point of any liquid distillate fuel carried in a cargo tank. This provision will eliminate the need for continuous changes in identification numbers in many operations where gasoline and fuel oil are transported in the same cargo tank on different trips during the same day.

While RSPA stated that the intent of this exception would address moving gasoline and other petroleum distillate fuels in the same cargo tank on different trips on the same day, this was not reflected in the regulatory text.

Although the time frame for use of this exception was not explicitly written in the regulatory text, the preamble language makes it clear that the exception in § 172.336(c)(5) was not limited to multi-compartmented tanks carrying multiple petroleum distillate fuels at the same time. Specifically, if § 172.336(c)(5) only applied to compartmented cargo tanks that transported multiple liquid distillate fuels at the same time, § 172.336(c)(4) would be duplicative. Therefore, PHMSA concludes that RSPA intended § 172.336(c)(5) to authorize a cargo tank to display the UN ID number of the petroleum distillate fuel with the lowest flash point transported in that cargo tank on different trips within the same

day, and not based on each individual trip.

Furthermore, RSPA's intent of this regulatory exception was reiterated in 1996 and 2000, with Letter of Interpretation Reference Nos. 96-0079 and 00-0208. In these interpretation letters, RSPA clearly stated that the exception in § 172.336(c)(5) allowed cargo tanks that previously transported gasoline (UN1203) and were subsequently transporting only diesel fuel (NA1993/UN1202) to be marked with "1203."

As discussed in the HM-213E ANPRM, § 172.336(c)(5) was updated in 1987 and 2008 to address specific concerns related to increased ethanol content in certain fuels that required different emergency response procedures, but the basic structure of the paragraph was not changed. Further, in 2013, PHMSA published final rule HM-219,²⁴ which amended the HMR in response to various petitions for rulemaking. In HM-219, PHMSA removed the reference to "gasohol" in § 172.336, as the Hazardous Materials Table (HMT) entry for this material was removed in 2008. In addition, PHMSA replaced §§ 172.336(c)(1)-(6) with a table to "more clearly indicate hazard communication requirements." In this new table, PHMSA added paragraphs (c)(1)-(3) and (c)(6) as individual entries but combined the language in paragraphs (c)(4) and (5) into a single entry. The impact of combining the provisions of paragraphs (c)(4) and (5) was that the historical context for the original meaning of paragraph (c)(5) was lost. As this revision in HM-219 was an attempt at clarification, it was not PHMSA's intent to change the exceptions substantively for marking of UN ID numbers on cargo tanks.

On June 26, 2015, PHMSA published an additional Letter of Interpretation Reference No. 14-0178.²⁵ In the incoming letter, the requester asserted that § 172.336(c) stated clearly that if a cargo tank is transporting multiple liquid petroleum distillate fuels, it may be marked with the UN ID number of the fuel with the lowest flash point. The requester asked if a cargo tank is transporting only diesel fuel (NA1993), is it authorized to continue displaying the UN ID number for gasoline (UN1203) even though gasoline was no longer present. As the regulations no longer clearly indicated that this continued to be an acceptable practice, in the response, PHMSA stated that a

cargo tank transporting only diesel fuel could not be marked with the UN ID number for gasoline because the gasoline was no longer present.

As previously discussed, in HM-219, it was not PHMSA's intent to remove the longstanding exception that allowed a cargo tank transporting more than one petroleum distillate fuel in different trips to display the UN ID number for the petroleum distillate fuel with the lowest flash point. Although, PHMSA recognizes that there may be safety concerns associated with this practice, as noted by commenters to the HM-213E ANPRM, PHMSA has not received specific information describing instances in which this marking exception has increased risks in transportation. Therefore, PHMSA proposes to revise the § 172.336(c) table, to authorize display of the UN ID number of the petroleum distillate fuel with the lowest flash point transported in a cargo tank in different trips on the previous or current business day. This proposal aligns with the original intent of § 172.336(c)(5), and addresses the operational concerns identified by commenters to the HM-213E ANPRM. In addition, this proposal generally aligns with the requirements of DOT-SP 21104,²⁶ which was issued on November 11, 2020, and further modified on February 26, 2021. DOT-SP 21104 currently allows for the transportation of gasoline, diesel fuel, kerosene, and fuel oil in a cargo tank motor vehicle marked with the UN ID number "1203" as long as gasoline had been transported in the cargo tank during the previous or current business day. PHMSA is unaware of any safety issues associated with DOT-SP 21104.

Although "different trips on the same day" was not defined in HM-118, PHMSA proposes that this provision apply when the petroleum distillate fuel with the lowest flash point is transported on the cargo tank motor vehicle during the previous or current business day. As previously mentioned, this proposal aligns with the time frame currently authorized in accordance with DOT-SP 21104. As proposed, PHMSA considers a "business day" to mean a day that the operator of the cargo tank motor vehicle is open and operating in commerce. Therefore, if a cargo tank carrying gasoline is unloaded and subsequently filled with a fuel with a higher flash point, "1203" may only continue to be displayed on the cargo tank for that day and the following day that the operator is open and operating.

²⁴ 78 FR 14702 (Mar. 7, 2013).

²⁵ See Letter of Interpretation Reference No. 14-0178: <https://www.phmsa.dot.gov/regulations/titled49/inter/14-0178>.

²⁶ See DOT-SP 21104: <https://www.phmsa.dot.gov/hazmat/documents/offer/SP21104.pdf/2021014464/SP21104>.

²² 45 FR 74640 (Nov. 10, 1980).

²³ 45 FR 74647 (Nov. 10, 1980).

To ensure compliance with this requirement, PHMSA anticipates the use of shipping paper records (see § 177.817(f)) to verify which petroleum distillates were transported in the cargo tank during the previous or current business day. PHMSA requests comment on the functionality of this proposed exception for the previous or current business day of petroleum distillate fuels.

In this new entry in the § 172.336(c) table, PHMSA also proposes to include specific requirements when transporting gasoline and alcohol fuel blends consisting of more than 10% ethanol. Specifically, due to different emergency response procedures for liquid petroleum distillate fuels containing more than 10% ethanol and as currently required in the fifth row in the § 172.336(c) table, PHMSA proposes that if the cargo tank contains gasoline and alcohol fuel blends consisting of more than 10% ethanol, the UN ID number “3475” or “1987,” as appropriate, must be displayed. Additionally, the UN ID numbers “3475” or “1987” may only be displayed if a gasoline and alcohol fuel blend consisting of more than 10% ethanol is present in the cargo tank during transportation. This means that “3475” or “1987” may not be displayed even if it is the lowest flash point petroleum distillate fuel and the cargo tank transported the fuel in a different trip on the previous or current business day. Therefore, if the lowest flash point liquid petroleum distillate fuel transported in the cargo tank in different trips on the previous or current business day is a gasoline and alcohol fuel blend consisting of more than 10% ethanol—and this material is not present in the cargo tank for that trip—the carrier must display the UN ID number of either the next lowest flash point liquid petroleum distillate fuel carried in a different trip on the previous or current business day or the liquid petroleum distillate fuel currently being transported in the cargo tank.

Additionally, as an accompanying amendment, PHMSA proposes to specify the fifth row of the § 172.336 table to specify that the exception provided in that row only apply to compartmented cargo tanks or compartmented tank cars. This proposed change distinguishes a compartmented cargo tank (or tank car) transporting more than one petroleum distillate fuel in the same trip (fifth row) from a cargo tank transporting more than one petroleum distillate fuel in different trips on the current or previous business day (sixth row). This clearly distinguishes the marking exception that applies to a compartmented tank

that transport multiple fuels of differing flashpoints at one time, and the exception that applies to a cargo tank (single or multi-compartment) that is used to transport fuels of differing flashing points during the course of business on current or previous business day.

PHMSA requests comments related to specific, articulable safety or cost concerns associated with this proposed amendment. PHMSA notes that for NA1993, UN1202, UN1203, UN1223, and other petroleum distillate fuels, the ERG directs the reader to the same guide page for initial emergency response measures, and PHMSA further requests information from emergency responders describing how emergency response would differ for an accident involving a cargo tank motor vehicle marked “1993,” “1202,” “1203,” “1223,” or another UN ID number associated with a petroleum distillate fuel. Finally, PHMSA requests information on any known incidents where emergency response was impacted negatively due to a cargo tank motor vehicle displaying “1203” when it was transporting a petroleum distillate fuel with a higher flash point.

E. P-1712

In petition for rulemaking P-1712,²⁷ the Chlorine Institute (CI) requested PHMSA delete § 173.315(i)(13) from the HMR. This change would remove the requirement to install Crosby pressure relief devices (PRDs) on chlorine cargo tanks, thus providing flexibility by authorizing the use of alternative PRDs meeting the requirements of § 173.315(i). The petition for rulemaking also outlined the current use of the Midland PRD on chlorine cargo tanks under the authority of DOT-SPs 9694 and SP-10457. CI noted that the Midland PRD meets the requirements in § 173.315(i) and is incorporated in CI's Pamphlet 49, “*Recommendation Practices for Handling Chlorine Bulk Highway Transporters*.” Furthermore, in their petition for rulemaking, CI notes that since the requirement was established in § 173.315(i), Midland Manufacturing entered the chlorine PRD market. This expanded market was reflected in CI Pamphlet 49, but it was not reciprocated in the HMR, except by special permit.

After reviewing this petition for rulemaking, PHMSA proposes to allow use of the Midland PRD under § 173.315(i) but does not propose to delete the specific limitations on the type of PRD authorized. PHMSA will

²⁷ See petition for rulemaking P-1712: <https://www.regulations.gov/docket?D=PHMSA-2018-0022>.

continue to work with CI to develop generally applicable specifications for PRDs used on cargo tanks transporting inhalation hazards. Therefore, for the purpose of this rulemaking, PHMSA only considered the inclusion of the PRD specifications that are already outlined in CI Pamphlet 49 and we do not propose the deletion of § 173.315(i)(13) in its entirety. Instead, PHMSA proposes to revise § 173.315(i) to specify that the PRD on a chlorine cargo tank must conform to one of the drawings in CI Pamphlet 49, which would allow for the use of the Midland PRD in addition to the Crosby PRD. PHMSA expects that this will provide for additional regulatory flexibility in selection of a PRD while maintaining the current level of safety.

F. P-1724

In petition for rulemaking P-1724,²⁸ the Greenbrier Companies requested PHMSA revise § 179.100-12 to allow for an alternative means of connecting the manway protection housing to the tank car. Currently, the HMR require the protective housing that shields the valves and fittings on top of pressure cars to be bolted to the manway cover. The petition for rulemaking asks that the connection be alternatively made between the protective housing and the manway reinforcing pad. This alternative allows the protective housing to be bolted to a flange connected to the manway reinforcing pad with not less than twenty 3/4-inch studs. After reviewing the petition for rulemaking, PHMSA agrees there is merit in making this proposed revision as it will provide regulatory flexibility without reducing the safety of attaching the manway protection housing to a tank car. This alternative method is currently only authorized in DOT-SPs 14832 and 20607. Therefore, PHMSA proposes to revise § 179.100-12 to permit the use of an alternative means of connecting the manway protection housing to the tank car.

G. P-1735

In petition for rulemaking P-1735,²⁹ TTMA requested PHMSA amend §§ 173.33(d)(3) and 180.405(h)(3) to remove requirements referring to the venting capacity of the original specification for the MC cargo tank motor vehicles with upgraded pressure relief valves.

After reviewing this petition for rulemaking, PHMSA agrees with the

²⁸ See petition for rulemaking P-1724: <https://www.regulations.gov/docket?D=PHMSA-2018-0111>.

²⁹ See petition for rulemaking P-1735: <https://www.regulations.gov/docket?D=PHMSA-2019-0132>.

position of the petitioner regarding the error made in the preamble in final rule HM-218H,³⁰ but does not agree that a regulatory change to §§ 173.33(d)(3) and 180.405(h)(3) is necessary. In final rule HM-218H, PHMSA responded to a number of appeals to the final rule. In the preamble, PHMSA incorrectly stated that the PRD set pressure must be to the original specification when upgrading or modifying the PRDs on a MC 300 series cargo tank motor vehicle. PHMSA has previously and subsequently addressed this issue via letters of interpretation and clarified that the upgraded or modified PRD on a MC 300 series cargo tank motor vehicle must meet all requirements of § 178.345-10, including set pressure (see Letters of Interpretation Reference Nos. 16-0183 and 18-0118). As such, while PHMSA agrees with the position of the petitioner, PHMSA finds that no amendments are necessary as the petition for rulemaking was predicated on the incorrect language included in the preamble to HM-218H.

III. Overview

A. Rail

PHMSA, in conjunction with FRA, proposes numerous revisions to the HMR related to transportation of hazardous materials by rail. These proposed revisions will provide greater clarity for hazardous materials rail carriage requirements and remove regulatory barriers to efficient operation without diminishing safety. PHMSA proposes the following amendments:

Related to the proposed amendments offered by RSAC (see “Section II.A. RSAC” for additional discussion), PHMSA proposes:

- In § 171.7, update the IBR of the AAR Manual of Standards and Recommended Practices, Section C—Part III, Specifications for Tank Cars, Specification M-1002, (AAR Specifications for Tank Cars), to the November 2014 edition from the 2000 edition;
- In § 171.7, separate the IBR of the AAR Manual of Standards and Recommended Practices, Section C—Part III, Specifications for Tank Cars, Specification M-1002 into its component chapters and appendices, except for Appendix B, Appendix L, and Appendix U, as discussed in “Section II.B.6. AAR Specifications for Tank Cars Incorporation by Reference”;
- In § 171.7, update the edition of the AAR Manual of Standards and Recommended Practices, Section C—II Specifications for Design, Fabrication

and Construction of Freight Cars, Chapter 5 to the 2011 edition from the 1988 edition;

- In § 172.101, editorially revise the description of Column 9A “Passenger aircraft/rail” to clarify the meaning for rail transportation;
- In § 172.820, add an exception for route planning for circumstances where no practicable alternative route exists;
- In § 173.31(d), add requirements for tank car closure instructions;
- In § 173.31(g), clarify securement requirements for tank car loading and unloading;
- In § 174.9, revise the safety and security inspection requirements;
- In § 174.14, add exceptions to the requirement for tank car movements to be expedited for certain unavoidable delays;
- Remove and reserve § 174.16, because the requirements for removal and disposition of certain explosives are obsolete;
- Remove and reserve § 174.20 because the reporting to the Bureau of Explosives for local and carrier restrictions is unnecessary;
- In § 174.24, clarify requirements for providing shipping papers to an authorized official;
- In § 174.50, revise the OTMA requirements to align with current FRA policy;
- In a new § 174.58, clarify the meaning of “extent practicable” as used in the § 171.8 definition of *residue*;
- In § 174.59, revise requirements for replacing lost placards;
- In § 174.63, make editorial revisions and expand the types of packages and materials eligible for COFC and TOFC service without an approval from FRA;
- In § 174.67, revise the transloading requirements to create a performance-based system, rather than the current prescriptive requirements;
- In Appendix B to part 179, revise the torch and pool fire testing provisions to improve industry understanding of the requirements; and
- In § 180.503, revise the definitions of *tank car owner*, *coating/lining owner*, and *service equipment owner* to more accurately reflect the complex business arrangements commonly in use.

Related to AAR delegated authority amendments (see “Section II.B. AAR Authority to Approve the Design of Tank Cars and Approve Quality Assurance Programs” for additional discussion), PHMSA proposes:

- In a new subpart J in part 107, add tank car facility and tank car DCE registration, with the ability to modify, suspend, or terminate the registration for cause;
- In §§ 107.1, 107.105, and 107.701, revise procedural requirements to

accommodate the proposed new subpart J;

- In § 171.7, incorporate by reference AAR Manual of Standards and Recommended Practices, Section C—Part III, Specifications for Tank Cars, Specification M-1002 Chapter 3 into §§ 173.241, 173.242, and 173.247;
- In § 171.8, revise the definition of *Design Certifying Engineer* to create a parallel definition for tank car DCEs;
- In § 179.2, revise the definitions for *approved* and *tank car facility* and add definitions for *component* and *tank car*;
- In § 179.2, add introductory text to indicate that terms defined in § 180.503 also apply to part 179 to address confusion with defined terms in these related regulatory parts;
- In § 179.3, remove the requirement for AAR TCC approval of tank car and service equipment designs, and replace it with approval by a DCE;
- In § 179.4, revise the process for designing and seeking approval of a design of a new tank car specification;
- In § 179.5, remove the tank car certification of construction requirement and replace it with a Design Approval Certificate (DAC). PHMSA also proposes to describe the information that must be included in a DAC for both tank cars and service equipment;
- In § 179.6, indicate that AAR approval is no longer required for repairs;
- In § 179.7, remove the requirement for AAR approval of the QAP and make revisions intended to clarify the intent of the applicability of the QAP requirement;
- In § 179.11, add a reference to AAR Specifications for Tank Cars in Appendix W, except section 1.2, for welding requirements;
- In § 179.24, remove reference to AAR Form 4-2 in conformance with the replacement of the certificate of construction with the DAC;
- Throughout the HMR, including §§ 172.102, 173.31, and 173.314, and parts 179-180, remove all references to approval by AAR and replace with a reference to an approval by a DCE;
- In part 179, indicate that compliance with paragraph 1.2 of Appendix W of the AAR Specifications for Tank Cars is not required;
- In §§ 179.100-9, 179.200-10, and 179.220-10, remove the sentence requiring that welding procedures, welders, and fabricators be approved;
- In §§ 179.220-15 and 179.400-13, remove the requirement for design approval for tank cushioning systems;
- In § 179.400-6, correct an editorial reference to the incorrect IBR material;
- In §§ 179.500-17 and 179.500-18, revise recordkeeping requirements to

³⁰ 83 FR 28162 (Jun. 18, 2018).

remove obsolete references to the Bureau of Explosives;

- In § 180.501, replace “owner’s qualification program” with “owner’s qualification and maintenance program” to maintain alignment with the scope of part 180, subpart F, and the other references to “qualification and maintenance program” in §§ 179.7 and 180.513;

- In § 180.503, revise the definitions for *maintenance*, *modification*, *qualification*, and *service equipment*;

- In § 180.509(i), clarify the inspection requirements for linings and coatings;

- In § 180.513, revise the responsibilities of tank car owners; and

- In § 180.517, revise the section to reflect the removal of the certificate of construction and its replacement with the DAC.

Related to PHMSA initiated editorial clarification, PHMSA proposes to:

- In § 174.81, revise explosive segregation requirements to align with current highway and vessel requirements.

Related to NTSB Safety

Recommendation R–19–001, PHMSA proposes to:

- In § 171.7, incorporate by reference AAR Specifications for Tank Cars Chapter 2, section 2.2.1.2 into § 179.102–3 to require Charpy impact testing for shell and head material of pressure tank cars used for poisonous-by-inhalation material.

Related to NTSB Safety

Recommendation R–12–007, PHMSA proposes to:

- In § 179.10, incorporate by reference AAR Specifications for Tank Cars Chapter 6, to require compliance with AAR’s redesigned center and draft sill attachment requirements.

B. Highway

PHMSA, in conjunction with FMCSA, proposes numerous revisions to the HMR related to transportation of hazardous materials by highway (*i.e.*, motor vehicle). PHMSA expects these proposed revisions to enhance the safe transportation of hazardous materials by highway while providing greater clarity and regulatory flexibility. In addition to various other revisions to the HMR, PHMSA proposes the following amendments:

- In part 107, subpart F, revise the registration requirements to allow for electronic submission procedures;

- In part 107 subpart F, create cargo tank facility modification, suspension, and termination procedures; reconsideration of modification, suspension, and termination procedures; and appeal of modification,

suspension, and termination procedures;

- In § 171.7, revise editorially the ASTM D 1838–64 IBR document to include reference to the 1968 reapproval date;

- In § 171.7, update the Compressed Gas Association (CGA) Technical Bulletin P–26 (formerly TB–2) IBR document to the 1997 edition;

- In § 171.7, replace current incorporation by reference of CI drawings with the entire CI Pamphlet 49, which would include the use of the Midland Type PRD for chlorine cargo tank in § 173.315;

- In the § 172.336(c) table, add a sixth row to specify that a cargo tank may display the UN ID number of the petroleum distillate fuel with the lowest flash point transported in different trips on the previous or current business day, except for gasoline and alcohol fuel blends with more than 10% ethanol;

- In §§ 173.150(f)(3)(viii) and 177.837(c), require bonding and grounding when preparing to transfer or transferring a combustible liquid, or a flammable liquid reclassified as a combustible liquid, from a cargo tank motor vehicle, in addition to the current requirements for flammable liquids;

- In § 177.816(c) and (d), clarify the use of tank vehicle endorsement or hazardous materials endorsement training to fulfill the hazardous materials training requirements of §§ 172.704 and 177.816;

- In § 177.835, clarify that a multipurpose bulk truck may not be used in combination with any cargo tank that is required to be marked or placarded under § 177.823;

- In § 177.840, clarify that the requirements apply to external self-closing stop valves in addition to the current requirement of internal self-closing stop valves;

- In § 178.320, revise definitions for *cargo tank*, *cargo tank motor vehicle*, and *minimum thickness* and add definitions for: *cargo tank motor vehicle certification date*, *component*, *flexible connector*, *lading retention system*, *lining*, *name plate*, *original test date*, *sacrificial device*, *shear section*, and *specification plate*;

- In § 178.337–1(d), allow the use of other external coverings besides paint;

- In §§ 178.337–8, 178.338–11, and 178.345–11, specify that mechanical means of remote closure for manual operation must not be obstructed to prevent access to or operation of remote means of closure in an emergency;

- In §§ 178.337–10 and 178.338–10, clarify that the exception in § 393.86 for wheels back vehicles does not apply;

- In §§ 178.337–17 and 178.338–18, revise the specification plate attachment requirement so that the specification plate must be permanently attached to the cargo tank or its integral supporting structure, instead of the cargo tank motor vehicle chassis rail;

- In §§ 178.337–18 and 178.338–19, specify that when the cargo tank motor vehicle is brought into full compliance, the specification plate is marked with the cargo tank motor vehicle certification date;

- In § 178.338–19, revise the certification language so that it more closely mirrors certification language for other DOT specification cargo tank motor vehicles;

- In § 178.345–1, remove definitions that are also defined in § 178.320;

- In § 178.345–14, clarify that when there is no limit for the maximum loading or unloading rate in gallons per minute, the specification mark may be marked “NONE” or “OPEN MH”;

- In § 180.403, add definitions for *cargo tank maintenance*, *certification plate*, *objectively reasonable and articulable belief*, and *set pressure*, and revise the definition of *repair*;

- In a new paragraph in § 180.405(b)(3), provide instruction on the replacement of cargo tank and cargo motor vehicle specification plates;

- In a new § 180.407(a)(7), specify that all equipment and instruments used to test cargo tanks must be calibrated, with appropriate documentation, in accordance with the manufacturer’s instructions;

- In a new § 180.407(a)(8), allow for the use of video cameras or video optics equipment for any inspection or test;

- In a new § 180.407(a)(9), require that cargo tank motor vehicle pressure tests conducted tested at a pressure higher than 50 psi be done with the hydrostatic method, except for DOT Specification MC 338 cargo tanks used to transport cryogenic liquid;

- In a new § 180.407(a)(10), require that the Registered Inspector consult with the owner or motor carrier, as appropriate, to determine if materials corrosive or reactive to the cargo tank or its components were transported in the cargo tank motor vehicle since the last test or inspection, and ensure that the proper tests and inspections, along with suitable safeguards, are used;

- In a new § 180.407(a)(11), require that all sources of spark, flame, or glowing heat within the area in which the tests and inspections are conducted are extinguished, made inoperable, or rendered explosion-proof prior to all functions that are performed;

- In § 180.407(b), include “bulges” in the list of conditions that may render a

cargo tank unsafe for hazardous materials service;

- In § 180.407(b)(5), replace “reasonable doubt” with “objectively reasonable and articulable belief” to create a more consistent standard describing those circumstances in which a cargo tank—or series of cargo tanks—may be required to be tested and inspected outside of the normal test and inspection interval;

- In § 180.407(d)(2)(i), specify that the tank shell and head must be evaluated in accordance with § 180.411 and that during inspection of the cargo tank shell and heads, all pad attachments on either the cargo tank shell or head shell shall be inspected for method of attachments;

- In §§ 180.407(d)(2)(ix) and (g)(1)(iii), add an exception that the upper coupler must be removed if there are obstructions immediately above the cargo tank shell that prevent the upper coupler from being directly inspected;

- In a new paragraph § 180.407(d)(7), add inspection and maintenance requirements for external ring stiffeners installed on a cargo tank motor vehicle constructed of metal other than mild steel or high-strength low-alloy steel;

- In a new paragraph § 180.407(d)(8), clarify inspection and verification requirements for welded repairs;

- In § 180.407(f)(2), add documentation requirements for linings from the lining manufacturer or installer;

- In § 180.407(f)(3), add a requirement that when the degraded or defective areas of the cargo tank lining are repaired or if the lining is replaced, it must comply with lining manufacturer or installer procedures;

- In § 180.407(h)(4), specify that the test pressure of the delivery hose assembly must be at least 80 percent of the Maximum Allowable Working Pressure (MAWP) of the cargo tank;

- In § 180.407(i)(4)(v), specify that thickness testing must be performed on areas around shell reinforcements, including evenly distributed areas around all ring stiffeners and those areas in the bottom half of the cargo tank;

- In § 180.407(i)(6)(i), specify that the supplemental Certificate of Compliance that includes the minimum thickness issued by the DCE must be provided to the CTMV owner;

- In a new § 180.409(a)(4), clarify that the person performing or witnessing the

inspections and tests must meet the training requirements of part 172 subpart H;

- In the § 180.411(b) list, include bulges as an additional condition requiring evaluation;

- In new § 180.411(h), specify conditions requiring removal from service and methods in which a cargo tank motor vehicle can be returned to service;

- In new § 180.411(i), specify that when required, emergency discharge control systems on a DOT Specification MC 330, MC 331, or a non-specification cargo tank motor vehicle operating under the provisions of § 173.315(k) must be present and functioning before passing any test or inspection; and

- In § 180.415(b), require that, unless already marked, the cargo tank registration number of the cargo tank facility performing the test or inspection must be marked on the cargo tank.

C. Vessel

PHMSA proposes several revisions to the requirements for transporting hazardous materials by vessel. These proposals are intended to increase transportation efficiency, increase harmonization with the International Maritime Dangerous Goods (IMDG) Code, and editorially revise the HMR while maintaining the high level of safety of vessel transport. The following proposals were developed in conjunction with the United States Coast Guard (USCG):

- In § 171.23(b)(5) and (b)(5)(iii), revise requirements for communicating the presence of hazardous substances by clarifying that only non-bulk packages are required to be marked with the letters “RQ” (to signify a reportable quantity), and the name of the hazardous substance, consistent with § 172.324;

- In new § 172.504(b)(2), remove the authorization to use the “DANGEROUS” placard for vessel transportation to reduce confusion and delays;

- In part 176, editorially revise the office identifier of the Coast Guard Commandant for Operating and Environmental Standards to the identifier for the Office of Design and Engineering Standards;

- In § 176.84(a), clarify editorially that hazardous materials transported in

accordance with a limited quantity exception are not subject to the stowage codes assigned by Column (10B) of the § 172.101 Table; and

- In § 176.905, add an exception for vehicles stored onshore incidental to vessel transportation to align with similar exceptions offered to highway and rail transportation of vehicles.

D. Multi-Modal

PHMSA proposes several revisions that affect multiple modes of transportation. These proposals enhance safe transportation of hazardous materials and were developed in conjunction with the FRA, FMCSA, and USCG. Proposals include:

- In § 171.22(f)(4), clarify requirements for providing hazardous material shipping paper information during inspections;

- In § 172.102, revise special provision 13 to identify more clearly that security plan requirements apply;

- In the § 172.336(c) table, more clearly identify that the exception in the fifth row of the table applies only to compartmented cargo tanks or tank cars carrying more than one petroleum distillate fuel;

- In § 172.704(e)(1), provide an exception (including an editorial correction) for hazmat employees who manufacture, repair, modify, recondition, or test packagings, and who do not perform any other function, from security awareness training requirements;

- In Appendix C to part 172, revise the recommended placard holder dimensions to be consistent with the current placard size requirements, and in § 172.516(d), clarify that the current placard holder is an authorized placard holder; and

- In § 173.159(e), clarify that wet batteries must be loaded or braced to secure the batteries against shifting while in transportation and require that the offeror ensure that persons loading the batteries have knowledge of the conditional provisions for exceptions from the general requirements of the HMR.

IV. Section-by-Section Review

The following table identifies the sections and mode(s) of transportation affected by the proposed changes in this NPRM.

TABLE 2—SECTIONS AFFECTED BY THIS NPRM

Section affected	Mode of transportation
§ 107.1	Rail.
§ 107.105	Rail.
§ 107.502	Highway.
§ 107.503	Highway.
§ 107.505	Highway.
§ 107.506	Highway.
§ 107.507	Highway.
§ 107.701	Rail.
§ 107.901	Rail.
§ 107.903	Rail.
§ 107.905	Rail.
§ 107.907	Rail.
§ 107.909	Rail.
§ 107.911	Rail.
§ 107.913	Rail.
§ 107.915	Rail.
§ 171.6	Multi-modal.
§ 171.7	Multi-modal.
§ 171.8	Multi-modal.
§ 171.22	Vessel.
§ 171.23	Vessel.
§ 172.101	Rail.
§ 172.102	Multi-modal.
§ 172.303	Multi-modal.
§ 172.328	Highway.
§ 172.336	Multi-modal.
§ 172.504	Vessel.
§ 172.516	Multi-modal.
§ 172.704	Multi-modal.
§ 172.820	Rail.
Appendix C to Part 172.	Multi-modal.
§ 173.31	Rail.
§ 173.150	Highway.
§ 173.159	Multi-modal.
§ 173.241	Rail.
§ 173.242	Rail.
§ 173.247	Rail.
§ 173.314	Rail.
§ 173.315	Highway.
§ 173.320	Multi-modal.
§ 174.9	Rail.
§ 174.14	Rail.
§ 174.16	Rail.
§ 174.20	Rail.
§ 174.24	Rail.
§ 174.50	Rail.
§ 174.58	Rail.
§ 174.59	Rail.
§ 174.63	Rail.
§ 174.67	Rail.
§ 174.81	Rail.
§ 176.2	Vessel.
§ 176.84	Vessel.
§ 176.340	Vessel.
§ 176.905	Vessel.
§ 177.801	Highway.
§ 177.804	Highway.
§ 177.816	Highway.
§ 177.835	Highway.
§ 177.837	Highway.
§ 177.840	Highway.
§ 177.841	Highway.
§ 178.320	Highway.
§ 178.337–1	Highway.
§ 178.337–2	Highway.
§ 178.337–3	Highway.
§ 178.337–8	Highway.
§ 178.337–9	Highway.
§ 178.337–10	Highway.

TABLE 2—SECTIONS AFFECTED BY THIS NPRM—Continued

Section affected	Mode of transportation
§ 178.337–17	Highway.
§ 178.337–18	Highway.
§ 178.338–3	Highway.
§ 178.338–10	Highway.
§ 178.338–11	Highway.
§ 178.338–18	Highway.
§ 178.338–19	Highway.
§ 178.345–1	Highway.
§ 178.345–3	Highway.
§ 178.345–8	Highway.
§ 178.345–11	Highway.
§ 178.345–13	Highway.
§ 178.345–14	Highway.
§ 178.345–15	Highway.
§ 178.348–1	Highway.
§ 179.2	Rail.
§ 179.3	Rail.
§ 179.4	Rail.
§ 179.5	Rail.
§ 179.6	Rail.
§ 179.7	Rail.
§ 179.10	Rail.
§ 179.11	Rail.
§ 179.24	Rail.
§ 179.100–9	Rail.
§ 179.100–10	Rail.
§ 179.100–12	Rail.
§ 179.100–18	Rail.
§ 179.102–3	Rail.
§ 179.103–5	Rail.
§ 179.200–7	Rail.
§ 179.200–10	Rail.
§ 179.200–11	Rail.
§ 179.200–17	Rail.
§ 179.200–22	Rail.
§ 179.220–10	Rail.
§ 179.220–11	Rail.
§ 179.220–15	Rail.
§ 179.220–18	Rail.
§ 179.300–9	Rail.
§ 179.300–10	Rail.
§ 179.400–5	Rail.
§ 179.400–6	Rail.
§ 179.400–11	Rail.
§ 179.400–12	Rail.
§ 179.400–13	Rail.
§ 179.400–15	Rail.
§ 179.400–18	Rail.
§ 179.400–19	Rail.
§ 179.500–17	Rail.
§ 179.500–18	Rail.
Appendix B to Part 179.	Rail.
§ 180.3	Multi-modal.
§ 180.403	Highway.
§ 180.405	Highway.
§ 180.407	Highway.
§ 180.409	Highway.
§ 180.411	Highway.
§ 180.413	Highway.
§ 180.415	Highway.
§ 180.416	Highway.
§ 180.501	Rail.
§ 180.503	Rail.
§ 180.509	Rail.
§ 180.513	Rail.
§ 180.517	Rail.
Appendix D to Part 180.	Rail.

The following is a section-by-section review of the proposed amendments:

Part 107

Section 107.1

Section 107.1 is the definition section for Part 107—“Hazardous Materials Programs Procedures.” The definition of “registration” currently states that, “For purposes of subparts A through E, “registration” does not include registration under subpart F or G of this part.” In this NPRM, we propose to add a reference to the new subpart J for tank car facility and tank car DCE registration to the existing references to subpart F or G. This will ensure that the registration requirements of subpart J for tank car facilities and DCEs are not confused or conflated with other registration requirements in Part 107. See also our discussion in “Section II.B.5 Tank Car Facility and Design Certifying Engineer Registration” for additional information.

Section 107.105

Section 107.105 contains the general information and supporting documentation requirements for special permit applications. Paragraph (a)(5) requires that special permit applicants who hold a registration under subparts F or G of Part 107 must include their registration number in their special permit application. PHMSA proposes to add a reference to the new subpart J to paragraph (a)(5), to require that tank car facilities or tank car DCEs who submit a special permit application to PHMSA include their registration number. This will allow PHMSA to more easily cross-reference tank car facility or DCE registration records with the special permit request. See also our discussion in “Section II.B.5 Tank Car Facility and Design Certifying Engineer Registration” for additional information.

Section 107.502

Section 107.502 details general registration requirements for persons who are engaged in the manufacture, assembly, inspection and testing, certification, or repair of a cargo tank or a cargo tank motor vehicle manufactured in accordance with a DOT specification or a special permit. Paragraph (a)(3) specifies reference citations to certain terms used in the HMR. PHMSA proposes to add a reference to the definition of *modification*, which is currently found in § 180.403. In addition—and as detailed later in this rulemaking—PHMSA proposes to add a definition of *component* to § 178.320(a) and a definition of *maintenance* to § 180.403, and PHMSA proposes to reference these

terms in paragraph (a)(3). Additionally, PHMSA proposes to add references to these definitions as they are all related to the cargo tank registration program and the references will provide greater understanding of the registration requirements. See “Section IV. Section-by-Section Review; Part 178; Section 178.320” and “Section IV. Section-by-Section Review; Part 180; Section 180.403” for further discussion of the proposed definitions.

PHMSA also proposes to add paragraphs (a)(4) through (a)(9) to specify definitions for *fixed test and inspection facility*, *FMCSA Agency Decisionmaker*, *FMCSA Agency Official*, *mobile tester*, *mobile testing* and *mobile test and inspection unit*. The definitions of *fixed test and inspection facility*, *mobile tester*, *mobile testing*, and *mobile test and inspection unit* are proposed to provide additional clarity and to help distinguish between fixed facilities and mobile testing units. As currently required, the registration statement must specify “whether the facility uses mobile testing/inspection equipment” (see § 107.503(a)(3)). However, the HMR does not include definitions to help distinguish these types of operations. Furthermore, the definitions for *FMCSA Agency Decisionmaker* and *FMCSA Agency Official* are being proposed as they are referenced in new §§ 107.505, 107.506, and 107.507, and they align with FMCSA’s organizational structure.

Paragraph (b) specifies that a person who is employed as a Registered Inspector or DCE is considered to be registered if the person’s employer is registered. PHMSA proposes minor editorial changes to specify that the “inspector” is a “Registered Inspector” and capitalize the term “Design Certifying Engineer.”

Paragraph (d) specifies submission information for registration statements. PHMSA proposes to revise this paragraph to include an electronic method for submitting registration statements. In addition, PHMSA proposes to make editorial revisions of an administrative nature to this paragraph, including revising the mailing address for FMCSA.

Paragraph (e) details the applicant’s receipt of registration statement. The first sentence specifies that a letter will be sent to the registrant and will assign the registrant with a registration number. The second sentence specifies that a separate registration number will be assigned for each cargo tank manufacturing, assembly, repair facility or other place of business identified by the registrant. PHMSA proposes to revise the first sentence of paragraph (e) to allow for the registrant letter to be

sent electronically instead of only in a hard copy. This will promote electronic correspondence with FMCSA, which is faster and more efficient for all parties. PHMSA also proposes to move the second sentence of paragraph (e) to a new paragraph (f), but the regulatory text within the second sentence will remain unchanged. The proposed change provides increased visibility and emphasis that a separate registration number will be assigned for each cargo tank manufacturing, assembly, or repair facility, or other place of business identified by the registrant.

Section 107.503

This section specifies the requirements pertaining to the registration statement for persons who are engaged in the manufacture, assembly, inspection and testing, certification, or repair of a cargo tank or a cargo tank motor vehicle manufactured in accordance with a DOT specification or a special permit. PHMSA proposes to revise paragraph (a)(2) to include an email address for the facility or place of business, if applicable (*i.e.*, if they have an email address). This will promote electronic correspondence with FMCSA which is faster and more efficient for all parties.

PHMSA proposes to revise the statement for compliance in paragraph (a)(4) to ensure that the person responsible for compliance certifies that hazmat employees meet the minimum qualification requirements set forth in § 171.8 for Registered Inspectors or DCEs, and that they are appropriately trained and knowledgeable of all the functions they are registered to perform. FMCSA notes that one of the top violations of employers is a lack of hazmat training of hazmat employees, including Registered Inspectors or DCEs. Therefore, the certification statement is revised to include reference to training to emphasize the requirement.

In paragraph (c), PHMSA proposes to remove the last sentence, as June 30, 1992, has passed and thus, this is an outdated requirement.

Lastly, PHMSA proposes to add paragraph (d) to require that each person who performs the wet fluorescent magnetic particle exam submit a copy of their ASME Code compliant training certificate. The training is required in both Section V (Non-Destructive Examinations) and Section VIII, Division 1 of the ASME Code. Requiring the certificate will ensure that FMCSA can verify that each person who performs the wet fluorescent magnetic particle exam has received the appropriate training.

Section 107.505

This proposed new section provides for the modification, suspension, or termination of a cargo tank facility registration. During 2019, FMCSA investigations of cargo tank facilities discovered 254 instances where the facilities had not been in compliance with the regulatory requirements, yet the Department does not have a codified process to modify, suspend, or terminate registrations to address lack of compliance. The proposal to allow the modification, suspension or termination of cargo tank facility registrations also addresses NTSB Safety Recommendation H-18-005,³¹ issued on January 30, 2018. This recommends that PHMSA revise the HMR to permit the suspension or termination of highway cargo tank registrations for failing to meet the requirements of the HMR. The safety recommendation was made after a March 11, 2016, incident where a cargo tank semitrailer separated from its truck-tractor and struck a rock. The impact with the rock breached the front head of the cargo tank, causing the lading to spill and a fire to occur. Although the investigation determined that the condition of the cargo tank was acceptable and its performance was consistent with its design, the investigation also discovered safety issues with inspection and testing of DOT Specification MC330 and MC331 cargo tanks and certification and training of cargo tank inspectors. The NTSB concluded that DOT needs to be able to suspend or terminate a cargo tank registration to ensure that when cargo tank facilities perform inadequate inspections, their authorization to do so can be terminated. Based on this safety recommendation, and additional recognition by FMCSA for the need of the ability to modify, suspend, or terminate a cargo tank registration, PHMSA proposes to add § 107.505 (along with § 107.506 for reconsideration and § 107.507 for appeal) to provide this authority. PHMSA proposes that this modification, suspension, or termination process in § 107.505 be consistent with existing FMCSA procedures for adjudicating motor carrier violations.

As proposed in paragraph (a), reasons for modification, suspension, or termination include: (1) that because of a change in circumstance, the registration is no longer needed or would not be granted if applied for; (2) that the application contained

³¹ See NTSB Safety Recommendation H-18-005: https://ntsb.gov/safety/safety-recs/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=H-18-005.

inaccurate or incomplete information and it would not have been granted had it included accurate and complete information; (3) that the application contained deliberately inaccurate or incomplete information; or (4) that the registration holder knowingly violated the terms of the registration or an applicable requirement of 49 CFR Chapter I in a manner demonstrating lack of fitness to conduct the activity for which the registration is required. Upon determination of this modification, suspension, or termination, and as proposed in paragraph (b), FMCSA will notify the registrant in writing or by electronic means of the proposed action and allow opportunity to show cause as to why the proposed action should not be taken. The registrant will then have 30 days from service of the notice to file a response to the notice. After consideration of the response, or after 30 days if no response has been filed, the FMCSA Agency Official will notify the registrant of a final decision with a brief statement of reasons and effective date of the action.

However, as proposed in paragraph (d), if a condition of imminent hazard exists, the FMCSA Agency Official may issue an immediately effective emergency order to the registration holder in accordance with § 109.17 of this subchapter.

As proposed in paragraph (c), the rules of practice for FMCSA proceedings for service and computation of time in §§ 386.6 and 386.8 of this title apply to this section, except that electronic service is permitted.

Section 107.506

This proposed new section provides for reconsideration of a registration that was modified, suspended, or terminated in accordance with proposed § 107.505. This proposed process is similar to existing FMCSA procedures. As proposed in paragraph (a), this request would be: (1) in writing or by electronic means and served within 20 days of service of the original decision; (2) state in detail any alleged errors of fact, law, or procedure; (3) state corrective actions taken, (4) enclose any additional information needed to support the request to reconsider; and (5) state in detail the modification of the final decision.

As proposed in paragraph (b), the decision issued under § 107.505 of this part remains effective pending a decision on reconsideration. The FMCSA Agency Official will consider requests to stay the decision using the criteria laid out in proposed § 107.507(b)(1)–(4). As proposed in paragraph (c), the FMCSA Agency

Official request may request additional information or documents and, to ensure that the deficiencies identified as the basis for the action have been corrected, may conduct additional investigation. Furthermore, paragraph (d) specifies that the FMCSA Agency Official will grant or deny, in whole or in part, the relief requested, and the notification will be made in writing or by electronic means. As proposed in paragraph (e), the rules for FMCSA proceedings for service and computation of time in §§ 386.6 and 386.8 of this title apply to this section, except that electronic service is permitted.

Section 107.507

This proposed new section provides for an appeal process for a cargo tank facility that has had its registration modified, suspended, or terminated by the Department in accordance with proposed § 107.505 and has been denied reconsideration in accordance with proposed § 107.506. This ensures that the registrant has been provided due process. As proposed, the appeal of the FMCSA Agency Official's decision is adjudicated by the FMCSA Agency Decisionmaker. Similar to §§ 107.505 and 107.506, the language in proposed § 107.507 is intended to reflect existing FMCSA procedures.

As proposed in paragraph (a), the appeal will be submitted to the FMCSA Agency Decisionmaker and must: (1) be in writing and served within 30 days of receipt of the FMCSA Agency Official's decision on the FMCSA Agency Decisionmaker at the mailing or email address provided and on all parties to the proceeding; (2) state in detail any alleged errors of fact, law, or procedure; (3) enclose any additional information needed to support the appeal; and (4) state in detail the modification of the final decision sought. Furthermore, as detailed in paragraph (b), the FMCSA Agency Official's action remains effective pending a decision on appeal, unless a stay is requested and the FMCSA Agency Decisionmaker determines:

- (1) There is a substantial likelihood that the requesting party will prevail on the merits;
- (2) The requesting party will suffer irreparable injury absent the stay;
- (3) The threatened injury outweighs whatever damage the stay may cause the opposing party; and
- (4) The stay will not harm the public interest.

As proposed in paragraph (c) the FMCSA Agency Official, who bears the burden of proof, will respond to the appeal within 30 days of service of the

appeal. Lastly, as proposed in paragraph (d), the FMCSA Agency Decisionmaker will grant or deny, in whole or in part, the relief requested. This decision is the final agency action.

As proposed, the rules for FMCSA proceedings for service and computation of time in §§ 386.6 and 386.8 of this title apply to this section, except that electronic service is permitted. This decision is the final administrative action.

Section 107.701

Section 107.701 contains the procedural requirements for the submission of registrations. PHMSA proposes to add an exception to paragraph (c) for the new subpart J. This exception will be applicable to tank car facilities and tank car DCE registrations. This aligns with the exception currently provided in paragraph (c) for subpart F, for cargo tank facilities and cargo tank DCEs. It allows tank car facility and tank car DCE registrations to be handled in the separate procedural manner outlined in the proposed subpart J, in which the registrations will be submitted to PHMSA, but subject to termination by FRA. See also our discussion in “Section II.B.5 Tank Car Facility and Design Certifying Engineer Registration” for additional information.

Part 107, Subpart J—“REGISTRATION OF TANK CAR FACILITIES AND DESIGN CERTIFYING ENGINEERS”

PHMSA proposes to create subpart J in part 107 (§§ 107.901–107.915) for tank car facility and tank car DCE registrations. The subpart includes definitions for terms used in the subpart, instructions for applying for registration for both tank car facilities and DCEs, and means of appeal if a registration is modified, suspended, or terminated. See also “Section II.B.5. Tank Car Facility and Design Certifying Engineer Registration” for additional details on the creation of this subpart.

Section 107.901

This proposed new section § 107.901 details the purpose and scope of new part 107 subpart J. Part 107 subpart J addresses the registration of tank car facilities and DCEs. Paragraph (b) details the threshold requirement that applicants for registration must be familiar with the HMR's requirements regarding specifications for tank cars (part 179) and the qualification and maintenance of tank cars (part 180, subpart F).

Section 107.903

This proposed new section § 107.903 details terms used in part 107, subpart

J and includes references to the location of their definition. The terms that PHMSA proposes to include in this section are *Design Certifying Engineer* (defined in § 171.8), *Qualification* (defined in § 180.503), *Tank car* (defined in § 179.2), *Tank car facility* (defined in § 179.2), and *Tank car tank* (defined in § 180.503). Additionally, PHMSA proposes to define *FRA Associate Administrator for Safety* and *FRA Administrator* as used in this subpart.

Section 107.905

This proposed new § 107.905 details the requirements for submitting a tank car facility registration, including the information required in the registration statement and where to send the information. This section requires all tank car facilities to register with PHMSA in order to legally qualify a DOT specification or special permit tank car.

In order to register with PHMSA, each tank car facility is required to provide a list of the qualification functions the tank car facility will perform, and identify the types of DOT specification or special permit tank cars that they intend to qualify. Paragraph (b) of this section prohibits tank car facilities from performing qualification functions that have not been identified in the registration. Each facility must also submit an executive summary of its current quality assurance program that is sufficient to demonstrate compliance with the requirements set out in § 179.7 in order to complete the registration process. PHMSA anticipates that this information will allow for effective oversight of registered tank car facilities.

Section 107.907

This proposed new § 107.907 details the requirements for submitting a tank car DCE registration. This section requires a DCE to be registered with PHMSA in order to legally approve the design of a DOT specification or DOT special permit tank car, as well as service equipment, and details the required information in the registration statement and where to send the information. Each registrant is required to provide a list of the specific design approval functions that the DCE will perform and identify the types of DOT specification and special permit tank cars and service equipment that the DCE will review. Paragraph (b) of this section prohibits design certifying engineers from performing design approval functions that have not been identified in the registration application. The registrant must also provide the name of each DCE, and a description of each

DCE's experience that shows that they meet the requirements set out in § 171.8. PHMSA anticipates that this information will allow for effective oversight of registered tank car facilities.

Section 107.909

This proposed new § 107.909 details the proposed administrative details of the tank car facility and tank car DCE registration, including renewal requirements, requirements to update PHMSA on changes in activity and personnel, and record retention. As proposed, DCE registrations must be renewed every six years, and registrants must keep PHMSA updated on changes in company name, address, ownership, personnel employed as tank car DCEs, and design approval activities performed by the registrant. PHMSA will inform FRA of these changes. PHMSA and FRA intend that this communication will increase our level of oversight on the activities of engineers who review and approve tank car and service equipment designs compared the existing AAR TCC closed system. Additionally, non-compliance with these requirements may create the basis for revocation of the registration. This will allow PHMSA and FRA greater enforcement ability than the current system, which will lead to an increased level of safety.

Section 107.911

This proposed new § 107.911 details the reasons for which FRA may modify, suspend, or terminate a tank car facility or DCE registration. As proposed in paragraph (a), reasons for modification, suspension, or termination include: (1) because of a change in circumstances, the registration is no longer needed or would no longer be granted if applied for; (2) that the application contained inaccurate or incomplete information and it would not have been granted if complete or accurate information was provided; (3) that the application contained deliberately inaccurate or incomplete information; or (4) that the registration holder knowingly violated the terms of the registration or an applicable requirement of 49 CFR Chapter I in a manner demonstrating lack of fitness to conduct the activity for which the registration is required. Upon determination of this modification, suspension, or termination, and as proposed in paragraph (b), FRA will notify the registrant in writing or by electronic means of the proposed action and allow opportunity to show cause as to why the proposed action should not be taken. The registrant will then have 30 days to file a response to the notice. After consideration of the response, or

after 30 days have elapsed with no response from the registrant, the Associate Administrator for Safety, FRA will notify the registrant of a final decision with a brief statement of reasons.

However, as proposed in paragraph (c), if it is necessary to avoid a risk of significant harm to persons or property, then the Associate Administrator for Safety, FRA may declare the proposed corrective action immediately effective.

Section 107.913

This proposed new § 107.913 details the proposed process for requesting reconsideration of FRA's decision to modify, suspend, or terminate a tank car facility or DCE registration. This proposed process is similar to the current special permit and approval reconsideration procedures in §§ 107.123 and 107.715, respectively. As proposed in paragraph (a), this request would be: (1) by electronic means and filed within 20 days of receipt of the decision; (2) state in detail any alleged errors of fact and law; (3) enclose any additional information needed to support the request to reconsider; and (4) state in detail the modification of the final decision.

As proposed in paragraph (b), newly submitted information will be considered if the registration holder can show that the information could have not been submitted when the application was processed. Furthermore, paragraph (c) specifies that the Associate Administrator for Safety, FRA will grant or deny, in whole or in part, the relief requested, and allows the Associate Administrator for Safety, FRA to notify the requesting party of the decision in writing or by electronic means.

Section 107.915

This proposed new § 107.915 details the process for requesting an appeal of FRA's decision on reconsideration regarding a modified, suspended, or terminated tank car facility or DCE registration. This will ensure that the registrant has been provided due process. The appeal of the Associate Administrator for Safety, FRA's decision will be adjudicated by the FRA Administrator. Similar to §§ 107.911 and 107.913, the language in § 107.915 mirrors the current appeal process for DOT special permits and approvals in §§ 107.125 and 107.717, respectively, except that the appeal is directed to FRA, rather than PHMSA.

As proposed in paragraph (a), the appeal will be submitted to the FRA Administrator and must: (1) be by electronic means and filed within 30

days of receipt of the Associate Administrator for Safety, FRA's decision; (2) state in detail any alleged errors of fact and law; (3) enclose any additional information needed to support the appeal; and (4) state in detail the modification of the final decision sought. Furthermore, as detailed in paragraph (b), the FRA Administrator may declare the Associate Administrator for Safety, FRA's action remain effective pending a decision on appeal, if it is necessary to avoid a risk of significant harm to persons or property. Lastly, as proposed in paragraph (c), the FRA Administrator will grant or deny, in whole or in part, the relief requested. This decision is the final administrative action.

Part 171

Section 171.6

Section 171.6 provides information on the Office of Management and Budget (OMB) control numbers assigned to information collection in the HMR under the Paperwork Reduction Act of 1995. The paragraph (b)(2) table lists all of the HMR sections associated with each OMB control number. As this NPRM proposes to add new information collection to the regulations, PHMSA proposes to revise the table to include the section references where this information collection request is specified. In addition, PHMSA proposes minor editorial revisions for grammatical consistency. For details on the affected OMB control numbers, see "Section V.G. Paperwork Reduction Act."

Section 171.7

This section details the IBR documents in the HMR. Paragraph (h) details IBR documents of the American Society of Testing and Materials (ASTM). In paragraph (h)(39), PHMSA proposes an editorial revision for standard method "ASTM D 1838-64 Copper Strip Corrosion by Liquefied Petroleum (LP) Gases, 1964" by adding the date "Reapproved 1968." The current IBR document for the 1964 edition of ASTM 1838-64 has a reapproved date of 1968, but it is not specified in § 171.7. Therefore, PHMSA proposes this editorial amendment to add this date to provide regulatory clarity without amending the actual IBR standard. This standard is available for purchase at the following online location: <https://webstore.ansi.org/>.

Paragraph (k) details IBR documents of the AAR. In paragraph (k), PHMSA proposes to revise editorially the AAR mailing address and website. As discussed in "Section II.A. Railroad

Safety Advisory Committee," PHMSA proposes to update the edition of and revise how the AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars) is incorporated by reference in the HMR. Specifically, PHMSA proposes to update the 2014 edition of the AAR Specifications for Tank Cars, divide it into its component chapters and appendices and incorporate by reference each chapter and appendix in the relevant section of the HMR, as agreed to by the RSAC. This revision provides more specificity on the relevant AAR chapters and appendices that are incorporated by reference throughout the HMR, instead of generally indicating the entire manual. Additionally, PHMSA proposes to update the edition of the AAR Manual of Standards and Recommended Practices, Section C—II, Specifications for Design, Fabrication and Construction of Freight Cars, Chapter 5 to the 2011 edition from the 1988 edition, as agreed to by the RSAC. This update also requires updating the title of the standard from "AAR Specifications for Design, Fabrication and Construction of Freight Cars," to "AAR Manual of Standards and Recommended Practices, Section C—II Specifications for Design, Fabrication and Construction of Freight Cars" and moving the IBR from § 171.7(k)(4) to paragraph (k)(1) to align with the numerical organization of this paragraph. PHMSA also proposes to incorporate by reference the updated 2016 edition of the AAR Manual of Standards and Recommended Practices, Section C, Car Construction Fundamentals and Details, Standard S-286, Free/Unrestricted Interchange for 286,000 lb Gross Rail Load Cars for rail cars weighing up to 286,000 lbs., as agreed in RSAC into § 179.13, and move the current S-286 IBR reference to § 171.7(k)(20). These revisions are intended to update the incorporated by reference versions of these industry standards to reflect the current state of the art.

There are several sections and appendices from the AAR Specifications for Tank Cars that were recommended by the RSAC but are not proposed. This is because, based on the proposal to remove AAR as the sole approval for tank car designs, the incorporation by reference of these sections and appendices is not needed in the HMR at this time. As such, PHMSA does not propose to IBR Appendix B, Appendix L, and Appendix U of the AAR Specifications for Tank Cars into the

HMR. As a matter of amendatory instructions, in § 171.7(k), PHMSA proposes to reserve where the omitted chapters and appendices would traditionally be located for future regulatory flexibility. See "Section II.B.6. AAR Specifications for Tank Cars Incorporation by Reference" for additional details.

PHMSA also proposes to incorporate by reference the following AAR documents:

- AAR Manual of Standards and Recommended Practices, Section C—II Specifications for Design, Fabrication and Construction of Freight Cars, Chapter 6 into § 179.400-6;
- AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars) Chapter 2 into § 179.102-3;
- AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars) Chapter 3 into §§ 173.241, 173.242, and 173.247; and
- AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars) Appendix W into § 179.11.

Additional information on the purpose and intent of these IBRs can be found in their respective section-by-section discussions. These standards are available for purchase at the following online location: <https://aarpublications.com/msrp.html>.

Paragraph (l) details IBR documents of the CI. Currently, paragraphs (l)(3) and (l)(4) include the IBR drawings for authorized PRDs for cargo tanks transporting chlorine. As discussed in "Section II.E. P-1712," instead of adding the third drawing found in CI Pamphlet 49 to § 171.7, PHMSA proposes to remove the references to the PRD drawings and incorporate by reference CI Pamphlet 49 in total. Thus, PHMSA proposes to revise paragraph (l)(3) to read "Pamphlet 49, Recommended Practices for Handling Chlorine Bulk Highway Transports, Edition 10, December 2016, into § 173.315" and reserving paragraph (l)(4). This standard is available for purchase at the following online location: <https://www.chlorineinstitute.org/products>.

Paragraph (n) details IBR documents of the CGA. In paragraph (n)(21), PHMSA proposes to update "CGA Technical Bulletin TB-2, Guidelines for Inspection and Repair of MC-330 and

MC-331 Cargo Tanks, 1980” to the 1997 edition, reaffirmed in 2015. The Technical Bulletin is now titled “P-26: Guidelines for Inspection and Repair of MC-330 and MC-331 Anhydrous Ammonia Cargo Tanks (formerly TB-2).” PHMSA proposes to incorporate by reference this newer version because it directs readers to the correct, relevant HMR citations and provides clearer instruction on the guidelines provided in the standard. For example, many of the HMR references in the 1980 edition (*i.e.*, the current IBR) point to part 173; however, the requirements are now found in part 180. PHMSA has reorganized the HMR and, thus, the citations in the 1980 edition are inaccurate, and updating to the 1997 edition will provide correct citations. These standards are available for purchase at the following online location: <https://www.cganet.com/standards/>.

Section 171.8

Section 171.8 defines terms in the HMR. PHMSA proposes to amend the following definitions:

- *Cargo tank*: PHMSA proposes several minor editorial revisions to paragraph (1), which currently defines the materials a cargo tank is intended to hold, the encompassing parts of a cargo tank, and the HMR citations that detail cargo tank specifications. PHMSA proposed revisions include:

- Add “solids” and “semi-solids” to the list of materials transported in cargo tanks, consistent with the § 178.320(a) definition of *cargo tank*;

- Consistent with the proposal to add a definition for *component*, which includes “fittings” as a type of component, replace the term “fittings” with the term “components.” See “Section IV. Section-by-Section Review; Part 178; Section 178.320”;

- Alphabetize the list of parts of a cargo tank encompassed in the definition;

- Revise the phrase “the definition of a tank” to read as “cargo tank specifications” in the parenthetical introductory language as this more accurately describes the section references list in paragraph (1);

- Add a reference to § 178.345-1, as it is currently not included in the citation list, but should be included, as this section details cargo tank specifications for DOT Specification 406, 407, and 412 cargo tanks.

- *Design Certifying Engineer*: PHMSA proposes to make an editorial amendment to the current cargo tank DCE definition and add provisions to account for a tank car DCE. To accommodate the new criteria for a tank

car DCE, PHMSA proposes to reorganize the current cargo tank DCE requirements from paragraphs (1)–(3) to paragraphs (1)(i)–(iii). PHMSA also proposes an editorial amendment in proposed paragraph (1)(i) to clarify that the one year of work experience requirement is a minimum requirement. The definition currently specifies a person must have exactly one year of experience in cargo tank structural or mechanical design with an engineering degree; however, it is not PHMSA’s intent to limit this to only one year of experience. Instead, a person with at least one year of work experience in cargo tank structural or mechanical design, in addition to an engineering degree, meets the definition of a DCE for cargo tanks.

Additionally, and as previously discussed, PHMSA proposes to add criteria for a tank car DCE. As such, PHMSA proposes to revise the introductory paragraph and add paragraphs (2)(i) and (ii). The proposed criteria in paragraphs (2)(i) and (ii) mirror the current cargo tank DCE criteria in paragraphs (1)(i) and (ii). Specifically, as proposed, a *Design Certifying Engineer* for a tank car is “a person registered in accordance with subpart . . . J of part 107 . . . who has the knowledge and ability to perform stress analysis of pressure vessels and otherwise determine whether a . . . tank car design and construction meets the applicable DOT specification.” In addition, a tank car DCE is a person who either: “(i) has an engineering degree and at least one year of work experience in tank car structural or mechanical design or (ii) is currently registered as a professional engineer by an appropriate authority of a State of the United States or a province of Canada.” See “Section II.B.2. Tank Car Design Approval” for additional information on the proposed creation of tank car DCEs and “Section II.B.5. Tank Car Facility and Design Certifying Engineer Registration” for additional details on proposed registration requirements for DCEs.

Section 171.22

Section 171.22 authorizes the use of international dangerous goods transportation standards in place of the HMR, subject to the conditions and restrictions of §§ 171.22 to 171.26, including use of the International Civil Aviation Organization’s (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air (Technical Instructions), the IMDG Code, Transport Canada’s Transportation of Dangerous Goods (TDG) Regulations, and the International Atomic Energy Agency (IAEA)

Regulations. PHMSA proposes to revise paragraph (f)(4) to specify that in addition to retaining a copy of the shipping paper, a person who provides for transportation or receives for transportation a shipping paper must make the shipping paper readily accessible for inspection. PHMSA and its modal partners have determined that the current shipping paper accessibility requirements in § 171.22(f)(4) create unnecessary delays during routine inspections because these forms are often made available several hours or days after the inspections are conducted. Therefore, PHMSA proposes to revise paragraph (f)(4) to indicate more clearly the expectation that shipping paper information must be made readily accessible to inspectors or other authorized individuals during inspections. This change is intended to increase safety by improving the ability of inspectors to conduct their reviews of hazardous materials shipments and increase efficiency by facilitating a quicker return to commerce for hazardous materials delayed by inspection. The intent of this revision is to ensure timely provision of shipping paper information for inspection of shipments in transportation (*e.g.*, container inspections in port areas). Access to historic shipping paper information after transportation has ended is a separate scenario, and may have other standards for reasonable provision of shipping paper information (*e.g.*, close of business the following business day for historic rail shipping paper information). See “Section IV. Section-by-Section Review; Part 174; Section 174.24” for further discussion of historic shipping paper availability in rail transportation.

Section 171.23

Section 171.23 establishes HMR requirements for specific materials and packagings transported under the ICAO Technical Instructions, IMDG Code, Transport Canada’s TDG Regulations, and the IAEA Regulations. PHMSA proposes to revise the introductory text of paragraph (b)(5) and paragraph (b)(5)(iii) to clarify that the letters “RQ” and the name of the hazardous substance must be marked only on non-bulk packages that contain reportable quantities of a hazardous substance. The HMR do not currently require this marking on bulk packages because § 172.324, which requires the “RQ” marking, only applies to non-bulk packages. However, PHMSA and USCG understand that international shippers occasionally misinterpret § 171.23(b) as requiring this marking on bulk packagings. This proposed revision is

intended to decrease burdens on shippers by clarifying which markings are required and to avoid confusion in port areas. Shippers may apply the letters “RQ” and the name of the hazardous substance on a bulk packaging, but PHMSA and USCG discourage this practice as it might be unnecessarily confusing and burdensome.

Part 172

Section 172.101

Section 172.101 lists the HMT and provides explanatory text on the use of the table. Paragraph (j) provides explanatory text about Columns (9A) and (9B) of the HMT, including an indication that Column (9A) of the HMT identifies the maximum quantity of hazardous materials that may be offered in one package when transported by passenger-carrying aircraft or passenger-carrying rail car. However, as defined in § 171.8, a *rail car* means a car designed to carry freight or non-passenger personnel by rail. Therefore, a “passenger-carrying rail car” is inconsistent with the definition of a *rail car*. PHMSA proposes to revise editorially § 172.101(j) to indicate instead that Column (9A) is for the quantity limitation of passenger-carrying aircraft and passenger-carrying rail. This proposal decreases potential regulatory confusion without impacting safety. The proposed language was approved by consensus vote at the May 25, 2017, RSAC meeting and offered to PHMSA and FRA for consideration.

Section 172.102

This section details the meaning and requirements of the special provisions listed in Column (7) of the HMT. Special provision 13 is assigned to “UN1005, Ammonia, anhydrous, 2.2” and “UN3318, Ammonia solution, relative density less than 0.880 at 15 degrees C in water, with more than 50 percent ammonia, 2.2.” PHMSA proposes to clarify that these materials are subject to security plan requirements. In final rule HM–232F,³² PHMSA specified this stance:

While anhydrous ammonia is classed for domestic transportation as a Division 2.2 material, it does pose a significant inhalation hazard and, thus, should be subjected to safety and security requirements that address that hazard. [PHMSA] note[s] further that by requiring security plans for materials that meet the definition for a material poisonous by inhalation, all materials that exhibit PIH characteristics are covered even if they are not specifically identified in column 3 of the

§ 172.101 table as Division 2.3 or 6.1 materials.

However, as currently written, it is not clear that security plan requirements apply to these shipments. Therefore, to ensure safe transportation of these hazardous materials, to facilitate compliance with the HMR, and to provide additional clarity, PHMSA proposes to specify that security plan requirements apply to materials assigned to special provision 13. This does not affect the classification of UN1005 and UN3318, and they may continue to be placarded with the Division 2.2 placard for domestic transportation. Additionally, this proposed change does not mean that persons who transport UN1005 or UN3318 are subject to FMCSA safety permit requirements; rather, the change is an explicit reminder that security plan requirements apply to this material.

PHMSA also proposes to revise special provision B45. This special provision, which is currently assigned to “UN1067, Dinitrogen tetroxide, 2.3 (5.1, 8),” requires that, “each tank must have a reclosing combination pressure relief device equipped with stainless steel or platinum rupture discs approved by the AAR Tank Car Committee.” In conformance with other proposals throughout this NPRM regarding AAR TCC approval requirements, PHMSA proposes to replace the reference to AAR TCC approval with a reference to a tank car DCE approval.

Section 172.303

This section identifies that no person may offer for transportation or transport a package marked as a hazardous material, unless the package contains that hazardous material, its residue, or it is excepted in accordance with paragraph (b) of the section. PHMSA proposes to add paragraph (b)(4) to permit the continued display of the “BIOHAZARD”, “HOT”, or sour crude oil markings when the hazardous material is no longer present. Section 172.502(b)(2) currently authorizes this continued display, as the section specifies that the display of a “BIOHAZARD”, “HOT”, or sour crude oil marking is not a prohibited placard. However, because § 172.303 does not include a matching provision to allow for the continued display of the “BIOHAZARD”, “HOT”, or sour crude oil markings, there may be potential confusion. Therefore, to provide regulatory clarity and to reinforce the current authorization, PHMSA proposes the editorial revision in § 172.303 to mirror the allowance in § 172.502.

Section 172.328

Section 172.328 details cargo tank marking requirements. Paragraph (d) requires that after October 3, 2005, each on-vehicle manually activated remote shutoff device for closure of the internal self-closing stop valve must have “Emergency Shutoff” marked on the cargo tank.

PHMSA proposes to add a paragraph title of “Emergency shutoff marking” to paragraph (d) to clarify that the paragraph relates to emergency shutoff markings. The Office of **Federal Register** Document Drafting Handbook provides instruction that when one section paragraph has a heading, all of the other paragraphs in the section should as well. As the other paragraphs in § 172.328 have headings, this editorial proposal ensures conformity with the Office of **Federal Register** Drafting Document Handbook.

PHMSA proposes to further revise paragraph (d) editorially. First, PHMSA proposes to remove the compliance date of October 3, 2005, from paragraph (d). As this date has passed, there is no need for the compliance date to remain in the paragraph. PHMSA also proposes to add introductory language to this paragraph to specify that the emergency shutoff marking is only required for cargo tank motor vehicles subject to emergency remote shutoff device requirements under the HMR. This is not intended to add any new regulatory requirements; instead, it is added to clarify editorially the applicability of the paragraph.

Lastly, PHMSA proposes to require that the emergency shutoff marking requirement applies to both internal and external self-closing stop valves, instead of just internal self-closing stop valves. This proposal addresses a potential safety gap where an external self-closing stop valve is on the cargo tank, but it is not appropriately marked. Thus, both internal and external self-closing stop valves can be appropriately identified and activated during a hazardous material incident, which leads to an increase in safety.

Section 172.336

Section 172.336 outlines special provisions for the display of UN ID numbers. PHMSA proposes to revise the § 172.336(c) table, which provides scenarios where UN ID numbers are either not required or an exception applies. As discussed in “Section II.D. Cargo Tank Marking for Petroleum Distillate Fuels,” PHMSA proposes to add a sixth row to the table to authorize display of the UN ID number representing the petroleum distillate fuel with the lowest flash point that is

³² 75 FR 10973 (Mar. 9, 2010).

transported in a cargo tank in different trips on the previous or current business day. However, due to different emergency response procedures, PHMSA also proposes that the exception is not applicable when the cargo tank transports gasoline and alcohol fuel blends consisting of more than 10% ethanol. This is consistent with the current requirements in the fifth row of the table. Specifically, PHMSA proposes that in this circumstance, the UN ID numbers “3475” or “1987” must also be displayed, as appropriate, and the cargo tank may only display “3475” or “1987” when the material is in the cargo tank. Therefore, if the liquid petroleum distillate fuel with the lowest flash point transported in the cargo tank in different trips on the previous or current business day is a gasoline and alcohol fuel blend consisting of more than 10% ethanol, and it is not being transported in the cargo tank, “3475” or “1987” may not be displayed on the cargo tank. In this scenario, the cargo tank should display either the UN ID number of the liquid petroleum distillate fuel with the next lowest flash point transported in different trips on the previous or current business day or the liquid petroleum distillate fuel that is being transported.

Lastly, PHMSA proposes to specify that the exception in the fifth row only applies to compartmented cargo tanks and compartmented tank cars. This will distinguish clearly the fifth and sixth row exceptions. The fifth row authorizes the display of the UN ID number of the petroleum distillate fuel with the lowest flash point when the cargo tank or tank car contains more than one petroleum distillate fuel. The fifth-row exception is only possible when the cargo tank or the tank car is compartmented (*i.e.*, it has multiple compartments each with a different petroleum distillate fuel). Therefore, PHMSA proposes to remove the term “cargo tank” to indicate clearly the exception only applies to “compartmented cargo tanks or compartmented tank cars.”

Section 172.504

Section 172.504 prescribes the general requirements for placarding. Paragraph (b) authorizes the use of the “DANGEROUS” placard when transporting two or more categories of hazardous materials that require a different placard specified in table 2 of § 172.504(e). PHMSA proposes to prohibit the use of the “DANGEROUS” placard to describe multiple categories of hazardous materials being transported by vessel. PHMSA and USCG identified vessel operator confusion with the display of the

“DANGEROUS” placard because the “DANGEROUS” placard is not authorized in the IMDG Code. It is advantageous to harmonize the HMR with the IMDG Code to promote efficient vessel transportation by removing the authorization to use this placard. Furthermore, the “DANGEROUS” placard may not provide adequate information on the hazardous materials inside the container for emergency response onboard vessels. PHMSA and USCG experience is that it is also very rare for the “DANGEROUS” placard to be displayed on a freight container for vessel transportation. Therefore, PHMSA proposes to add this limitation in a new paragraph (b)(2), while also moving the existing usage limitation for the “DANGEROUS” placard (over 2,205 lbs. aggregate gross weight or more of one category of material is loaded at one loading facility) to a new paragraph (b)(1). Please note that “DANGEROUS” placards may continue to be appropriately used for highway or rail transportation, when applicable, prior to, or after, the portion of transportation by vessel.

Section 172.516

Section 172.516 details the visibility and display of placards, including paragraph (d), which specifies that the recommended placard holder specifications are set forth in Appendix C. PHMSA proposes to revise the size of the recommended placard holder dimensions in Appendix C to part 172. As detailed in “Section IV. Section-by-Section Review; Part 172; Appendix C to Part 172,” the recommended placard holder that is currently authorized in the HMR may continue to be used, even if the revised placard holder in Appendix C to part 172 is adopted in a final rule. However, to ensure that there is no confusion with this allowance, PHMSA proposes to revise § 172.516(d) to add a reference to the placard holder authorized in Appendix C prior to a final rule effective date as an authorized placard holder.

Section 172.704

Section 172.704 details HMR training requirements. Paragraph (a)(2) includes requirements for function-specific training. PHMSA proposes to add paragraph (a)(2)(iii) to reference § 177.816 for highway transportation function-specific training. This new paragraph will help to provide regulatory clarity and ensure those persons transporting hazardous materials by highway meet the function-specific training in § 177.816, without adding any additional requirements.

Section 172.704(e)(1) excepts a hazmat employee from the paragraph (a)(3) safety training when the hazmat employee repairs, modifies, reconditions, or tests packagings, as qualified for use in the transportation of hazardous materials, and who does not perform any other function in the HMR. PHMSA proposes to revise paragraph (e)(1) to add an exception from the security awareness training requirement in paragraph (a)(4). Final rule HM-126F,³³ added training requirements to the HMR, including the exception from safety awareness training in paragraph (e)(1). Security awareness training was not included in the exception because the requirement for security awareness training was not added to the HMR until RSPA published final rule HM-232.³⁴ In HM-232, RSPA provided the following reasoning for the need of security awareness training:

Because many hazardous materials transported in commerce may potentially be used as weapons of mass destruction or weapons of convenience, it is critical to the assurance of public safety that training for persons who offer and transport hazardous materials in commerce include a security component.

While HM-232 provides a need for security awareness training, RSPA did not comment on whether it intended to exclude security awareness training from the exception in paragraph (e)(1). PHMSA affirms that security awareness training is essential to ensure that hazardous materials are transported in commerce safely. However, upon review, PHMSA acknowledges that the burden of security awareness training imposed on hazmat employees who only manufacture, repair, modify, recondition, or test packagings, and do not perform any other function subject to the HMR, may not present the same security benefit as for those who directly offer or transport hazardous materials. PHMSA expects that the packagings a hazmat employee manufactures, repairs, modifies, reconditions, or tests are empty and free of hazardous materials, and we seek comment on this expectation. As described in HM-232, the creation of security awareness training was related to concerns about hazardous materials transported in commerce being used as weapons of mass destruction or weapons of convenience. A hazmat employee whose sole hazmat function is qualifying a packaging would not interact with a hazardous material that could be used as a weapon; therefore, PHMSA does not expect a reduction in

³³ 20 FR 20944 (May 15, 1992).

³⁴ 68 FR 14510 (Mar. 25, 2003).

security by providing these employees an exception from security awareness training. Therefore, PHMSA proposes to add the security awareness training of paragraph (a)(4) to the paragraph (e)(1) exception for persons performing only repairs, modifications, reconditioning, or testing of packagings and no other functions subject to the HMR.

Additionally, PHMSA proposes to expand the eligibility of hazmat employees excepted from safety and security training to include package “manufacturers.” In review of paragraph (e)(1), it was determined that package manufacturers were unintentionally excluded from this exception and including package manufacturers to this exception ensures the paragraph conforms to guidance previously issued by PHMSA.³⁵ Therefore, PHMSA proposes to include package “manufacturers” among the list of hazmat employees excepted from safety and, as proposed, security awareness training. Although these changes broaden the population of persons excepted from safety and security awareness training, PHMSA expects the safety and security of hazardous materials transportation will be maintained because of this training’s primary focus on persons who offer or transport hazardous materials.

Section 172.820

Section 172.820 outlines additional security plan requirements for certain hazardous materials transported by rail. The requirements for a rail carrier to identify and analyze practicable alternative routes are specified in paragraph (d). As currently written, there is no instruction provided for a situation where no alternative routes exist. Therefore, PHMSA proposes to revise paragraph (d) to provide an exception from the requirement to conduct an alternative route analysis, when no practicable alternative routes exist, including consideration of interchange agreements. The rail carrier must describe, in writing, the remediation or mitigation measures to be implemented, if any, on the primary route in conformance with § 172.820(d)(1)(iii) and certify that an alternative route does not exist for a given primary route. For example, a shortline railroad with only one possible route to move material subject to § 172.820 is not required to analyze alternative routes owned by other railroads. HMIWG discussed the proposed paragraph (d)(3) at its August

16–17, 2016, meeting. The proposed language was approved by consensus vote at the May 25, 2017, RSAC meeting and offered to PHMSA and FRA for consideration. PHMSA expects safety will be maintained as a result of this proposal, because it is not possible to conduct an alternate route analysis where no alternate route(s) exist. In this NPRM, we propose a minor revision to the proposed text of (d)(3) to indicate that the exception applies to the requirements of (d)(1) and (d)(2).

Appendix C to Part 172

Appendix C to part 172 specifies the dimensions for a recommended placard holder. PHMSA proposes to revise the recommended placard holder drawing from a one-side minimum dimension of 273 mm (10 ¾ inch) to 250 mm (9.84 inch). This revised dimension meets the current minimum placard size in § 172.519(c). In final rule HM–218F,³⁶ PHMSA made miscellaneous amendments to update and clarify certain regulatory requirements, including amending the placard dimensions in § 172.519(c) to harmonize with international standards. Specifically, HM–218F revised the dimensions of a placard from at least 273 mm (10.8 inches) on each side to the current dimension of at least 250 mm (9.84 inches) on each side. However, when the revision was made to § 172.519(c), an accompanying revision to the recommended placard holder dimensions in Appendix C to part 172 was not made. This has resulted in placard holders that may not correctly fit placards thereby, creating the potential for certain communication elements of the placard to be obscured. To prevent this potentially unsafe and noncompliant situation, PHMSA proposes to reduce the dimensions of the recommended placard holder with revised dimensions that are consistent with the current minimum placard dimension of 250 mm (9.84 inches) on each side, because hazard communication information may be obscured. Appendix C provides only recommended dimensions. A larger version of a placard holder suitable for larger placards may continue to be used since the side dimensions for the placards and placard holders are a minimum specification.

Part 173

Section 173.31

Section 173.31 prescribes the requirements for use of tank cars. Paragraph (a)(2) specifies that tank cars

and appurtenances may be used for the transportation of any commodity for which they are authorized and as specified on the certificate of construction. PHMSA proposes to revise paragraph (a)(2) in conformance with the proposal to replace AAR TCC approval with tank car DCE approval. Specifically, PHMSA proposes to indicate that tank cars and appurtenances may be used for the transportation of the commodity specified on the DAC, while also providing a one-year transition period during which certificates of construction may still be issued. Existing tank cars approved for use by the AAR TCC may continue in use for the rest of their authorized life pursuant to their existing AAR Form 4–2 certificate of construction, subject to periodic qualification as required by part 180 subpart F. Additionally, PHMSA proposes to replace the reference to the AAR TCC approval with approval by a tank car DCE, consistent with the other proposed changes.

Section 173.31(d) outlines the requirements for examination of a tank car prior to shipping. Review of incident data involving non-accident hazardous materials releases from tank cars indicates that most releases occur because of improperly secured closures on tank cars. Additionally, the majority of those failures occur at the manway cover due to a failure to secure the manway in accordance with the equipment owner and gasket manufacturer closure instructions, including the bolt securement sequences, tools, and torque specifications. Currently, there is no requirement in the HMR that offerors of tank cars containing hazardous materials develop and implement closure procedures that are consistent with the industry standards and Original Equipment Manufacturer (OEM) recommendations. However, the HMR does require manufacturers of other packagings, namely those specified in part 178, to forward closure instructions to each person to which the package is transferred, and that each person who closes those packagings must do so in accordance with the manufacturer’s closure instructions.

Therefore, in the interest of improving safety and consistency with requirements for closures for part 178 packaging types, PHMSA proposes several amendments to § 173.31(d). For clarity, PHMSA proposes to amend the format of paragraph (d) by revising the paragraph title to read “pre-transportation closure, securement, and examination of tank cars” and providing each paragraph a title. PHMSA proposes

³⁵ See Letter of Interpretation Reference No. 05–0064: <https://www.phmsa.dot.gov/regulations/title49/interp/05-0064>.

³⁶ 76 FR 43510 (Jul. 20, 2011).

additional substantive amendments by adding introductory text on the expectations of offerors prior to transportation, and by adding regulatory text to require a closure and securement procedure including a two-year periodic review of the procedure. As proposed, offerors must develop and maintain a written procedure for closing and securing all tank car openings. PHMSA and FRA expect that offerors will use available best practices and guidance from packaging and component manufacturers in development of these procedures. These proposed changes to § 173.31(d) are designed to ensure that minimum standards for closures and their securement on tank cars are implemented to prevent releases of hazardous material. Rail carriers, rail hazmat shippers, equipment owners, and manufacturers all have a vested interest in ensuring tank cars are routinely operated and closed in a reliable and repeatable manner that is consistent with industry standards and OEM recommendations. PHMSA and FRA expect that this regulatory change will result in a net benefit to safety by ensuring proper securement of tank car closures, thus reducing the number of hazardous material releases by rail. Reduction in releases will have a positive impact on the environment, including potential reductions in greenhouse gas emissions.

Section 173.31(g) outlines the requirements for tank car loading and unloading. The proposed changes to § 173.31(g) are intended to clarify the requirements for tank car unloading by adopting language from long-standing PHMSA letters of interpretation.³⁷ These letters of interpretation explain that the intent of paragraph (g) is to ensure the entry to a track where a tank car is being loaded or unloaded is secured. The proposed revisions to § 173.31(g) clarify that the mechanism used to satisfy securement should be under the direct control of the loading or unloading operator and locked in place so that it can only be removed by the employee responsible for the product transfer. The mechanism should also be capable of stopping or diverting incoming rail equipment to prevent contact with the tank car being offloaded (*e.g.*, lined and locked switch or derail). The example of bumper blocks in the current requirements of paragraph (g)(1) are proposed to be

removed because, as discussed at HMIWG meeting, the majority of companies subject to this requirement accomplish compliance with the use of a derail or a switch. Additionally, PHMSA and FRA have concerns that some bumper blocks do not satisfy the requirements of the paragraph. Bumper blocks may continue to be used to meet the requirements of paragraph (g) provided they provide an equivalent level of security to lining and locking switches or using derails, but PHMSA proposes not to specifically call out bumper blocks as an option in paragraph (g). Lastly, in new paragraphs (g)(1)(i)(A)–(D), PHMSA proposes to clarify the performance of track securement operations in association with loading or unloading of tank cars to account for circumstances in which the securement may be temporarily removed for necessary intra-plant repositioning of rail cars. The proposed requirements in (g)(1)(i)(A)–(D) align with current industry practice and are intended to protect railroad personnel and the tank car being loaded or unloaded from interaction with other rail cars undergoing switching in intra-plant operations that would otherwise be delayed or obstructed without the possibility of temporarily removing measures for securement of the track. The final recommended language was approved by consensus vote at the May 25, 2017, RSAC meeting and offered to PHMSA and FRA for consideration.

Section 173.150

Section 173.150 details exceptions for Class 3 (flammable and combustible liquids) hazardous materials. Paragraph (f)(3) provides an exception for combustible liquids transported in bulk packaging or combustible liquids meeting the definition of a hazardous substance, hazardous waste, or a marine pollutant. In § 173.150(f)(3)(viii), PHMSA proposes to add a reference to § 177.837(c). This is a conforming amendment to the proposed requirement in § 177.837(c) to require bonding and grounding for the transfer of lading for combustible liquids or flammable liquids reclassified as combustible liquids in cargo tanks. PHMSA expects that for the safe transportation of combustible liquids in cargo tanks, bonding and grounding requirements should apply when taking the exception in § 173.150(f). See “Section IV. Section-by-Section Review; Part 177; Section 177.837” for additional discussion.

Section 173.159

Section 173.159 details packaging requirements and exceptions for the

transportation of wet batteries (*i.e.*, electric storage batteries, commonly of the rechargeable type, that contain a liquid electrolyte component that is corrosive). Paragraph (e) specifies that the transportation of wet batteries by highway and rail is excepted from the requirements of HMR when transported in accordance with conditions outlined in this paragraph. Over the past 10 years, over 700 incidents involving the transportation of wet batteries have been reported due to improper preparation of batteries for transportation. Not all of the referenced incidents are associated with the transportation of wet batteries in accordance with paragraph (e), but incidents involving the transportation of wet batteries under other provisions are still relevant to the transportation of wet batteries under paragraph (e) because they show what may occur when wet batteries are not properly prepared for transportation.

Many of these incidents involved a release of corrosive battery fluid from wet batteries because of load shifting or falling over while in transportation. Through inspections, PHMSA identified that improper loading, securement, and transportation of wet batteries likely caused a number of these incidents. Therefore, PHMSA proposes to add more specificity in the provisions of § 173.159(e) to clarify the expectations for load securement of the batteries shipped under this provision and ensure the safe transportation of wet batteries. This increased clarification will enhance the safety of transport of wet batteries and reduce the number of incidents resulting from improper load securement and transportation. In addition, PHMSA notes that it is the responsibility of all persons conducting transportation functions, including loading and unloading, to ensure proper compliance with § 173.159(e), and if there is a violation, PHMSA, along with any respective modal administration, will attempt to identify and bring any enforcement proceeding against the person who did not comply with § 173.159(e).

Paragraph (e)(2) currently requires that wet batteries be loaded or braced to prevent damage and short circuits in transit. This provision has been in the HMR since its inception, as originally codified in 1956.³⁸ Although load securement is not specifically mentioned in paragraph (e)(2), securing hazardous materials against shifting under normal transportation conditions is a basic hazardous materials transportation safety requirement. For transportation by highway and rail,

³⁷ See PHMSA Letters of Interpretation Gale to Ross, May 31, 2006 (Reference No. 06–0058: <https://www.phmsa.dot.gov/regulations/title49/interp/06-0058>) and Foster to Rodgers, October 11, 2018 (Reference No. 18–0032: <https://www.phmsa.dot.gov/regulations/title49/interp/18-0032>).

³⁸ 21 FR 4432 (June 23, 1956).

packages containing hazardous materials are required to be secured against shifting while in transportation in accordance with §§ 177.834 and 174.55, respectively. This requirement protects hazardous materials, including wet batteries, from falling over or spilling under normal transportation conditions, preventing damage and short circuits during transportation. After evaluation of the aforementioned incidents involving wet batteries, PHMSA proposes to amend the language of § 173.159(e)(2) to include securement of the batteries to enhance the safe transportation of wet batteries shipped under this exception. Specifically, PHMSA proposes to clarify that loading or bracing of wet batteries includes securing wet batteries against shifting while in transit. In addition, and similar to §§ 177.834 and 174.55, PHMSA proposes to indicate that securement against shifting includes relative motion between packages, under conditions normally incident to transportation. PHMSA expects this language will help prevent damage to batteries while in transportation and possible release of their liquid contents. While “method of securement” is not defined in the HMR, PHMSA has issued Letters of Interpretation regarding securement methods. For example, in Letter of Interpretation Ref. No. 19–0039,³⁹ PHMSA specifies that various methods for securement include tie-downs, using dunnage or other cargo, shoring bars, jack bars, or toe-boards. Furthermore, Letter of Interpretation Ref. No. 11–0198⁴⁰ includes banding in this list. This is not an exclusive list; instead, these demonstrate potential methods for securement to prevent shifting, including relative motion between packages. In addition, the use of one of these methods is only satisfactory when there is securement against shifting, including relative motion, under conditions normally incident to transportation. Lastly, PHMSA notes that for highway transportation, the Federal Motor Carrier Safety Regulations (FMCSR; 49 CFR parts 350–399), specifically part 393 subpart I—Protection Against Shifting and Falling Cargo—details requirements for the prevention of loss and shifting of load.

PHMSA also identified instances where persons offer for transportation or transport wet batteries as unregulated shipments, even though they are still

subject to the provisions of the HMR under § 173.159(e). While these shipments are not subject to many of the HMR provisions, including § 172.704 training requirements, a person who is complying with § 173.159(e) must still know and understand the applicable requirements in order to safely transport wet batteries. This applies to both shippers and carriers, including those persons who load, unload, or transport wet batteries in accordance with § 173.159(e). However, because persons engaged in this operation have been shown not to be aware of the specific provisions, PHMSA proposes to revise paragraph (e) to specify that “the offeror must inform persons loading the batteries and the operator of the vehicle transporting batteries of the requirements of this paragraph.” PHMSA expects that this will enhance the safe transportation of wet batteries under § 173.159(e) and add only minimal burden because, as previously mentioned, being aware of the requirements of § 173.159(e) is necessary for a person to properly apply the exception. This proposed text reinforces that a person must be aware of the requirements to properly perform said requirements. In order to accommodate the proposed language, we propose to redesignate the language currently located in paragraph (e)(5), requiring compliance with incident reporting, to new paragraph (e)(6), and moving the conjunction “and” to connect (e)(5) and (e)(6).

Sections 173.241, 173.242, and 173.247

Sections 173.241, 173.242, and 173.247 are bulk packaging authorization sections for low hazard, medium hazard, and elevated temperature liquid and solid materials, respectively. Each section authorizes AAR specification tank cars for the transportation of hazardous materials. Section 173.241 authorizes AAR Class 203W, 206W, and 211W tank cars, § 173.242 authorizes AAR Class 206W tank cars, and § 173.247 authorizes AAR Class 203W, 206W, and 211W tank cars. However, the specifications for these packages are not found in the HMR; they are found in Chapter 3 of the AAR Specifications for Tank Cars. In order to ensure that no changes are made to the construction specifications of these hazmat packagings without PHMSA and FRA review, PHMSA proposes to incorporate by reference the 2014 edition of Chapter 3 of the AAR Specifications for Tank Cars into each section. AAR Class 203W, 206W and 211W tank cars currently in service may remain in use, provided they continue to meet the specification to which they

were constructed. PHMSA proposes a transition period of one year from the effective date of the final rule for compliance with the 2014 edition of the AAR Specifications for Tank Cars for new-build AAR specification 203W, 206W, and 211W tank cars.

Section 173.241

See “Section IV. Section-by-Section Review; Part 173; Sections 173.241, 173.242, and 173.247” for details on the revisions proposed to this section.

Section 173.242

See “Section IV. Section-by-Section Review; Part 173; Sections 173.241, 173.242, and 173.247” for details on the revisions proposed to this section.

Section 173.247

See “Section IV. Section-by-Section Review; Part 173; Sections 173.241, 173.242, and 173.247” for details on the revisions proposed to this section.

Section 173.314

Section 173.314 specifies packaging for compressed gases transported by a tank car or a multi-unit tank car. Paragraph (b)(4) currently indicates that the term “approved” for purposes of the section means approval by the AAR TCC. PHMSA proposes to remove and reserve paragraph (b)(4). The language in (b)(4) is an outdated holdover from an earlier regulatory structure, since tank car specification requirements are now found in Part 179, rather than Part 173. Therefore, we propose to remove and reserve (b)(4), consistent with other proposed changes.

Section 173.315

Section 173.315 describes the requirements for the transportation of compressed gases in cargo tanks and portable tanks. Paragraph (h) specifies gauging device requirements for cargo tanks and portable tanks. PHMSA proposes a minor editorial amendment in paragraph (h) to reference paragraph (e) for a tank filled by weight. This proposed change helps to ensure consistent application of the requirement and provides additional clarity which will enhance safety.

Paragraph (i) provides cargo tank and portable tank requirements for pressure relief devices, with paragraph (i)(13) detailing the specifications for safety relief valves on chlorine cargo tanks. PHMSA proposes to revise § 173.315(i)(13) to replace the reference to specific PRD drawings with a general reference to CI Pamphlet 49 for authorized safety relief valves. This proposal allows the use of the Midland PRD in addition to the Crosby PRD on

³⁹ See Letter of Interpretation Reference No. 19–0039: <https://www.phmsa.dot.gov/regulations/title49/interp/19-0039>.

⁴⁰ See Letter of Interpretation Reference No. 11–0198: <https://www.phmsa.dot.gov/regulations/title49/interp/11-0198>.

cargo tanks transporting inhalation hazards to provide additional regulatory flexibility without reducing safety. See “Section II.E. P-1712” or “Section IV. Section-by-Section Review; Part 171; Section 171.7” for further discussion on this proposed change.

Paragraph (j) details packaging requirements for consumer storage containers used for liquefied petroleum gas. Paragraph (j)(1) provides requirements for storage containers for liquefied petroleum gas or propane charged to five percent of their capacity or less and intended for permanent installation on consumer premises. PHMSA proposes to remove the reference to propane as an editorial amendment. Propane is a type of liquefied petroleum gas and therefore, a specific reference to propane is unnecessary and redundant. Furthermore, as paragraphs (j)(2) and (3) do not include a reference to propane (only refers to liquefied petroleum gas) a reader could mistakenly assume that propane is not eligible for these storage container requirement sections, which is not the case since propane is a liquefied petroleum gas. Therefore, PHMSA expects this proposed amendment will clarify the regulatory applicability of paragraph (j).

Paragraph (m) details the general requirements for cargo tanks used exclusively in husbandry service that are commonly known as nurse tanks. On behalf of FMCSA, the Iowa State University is conducting a multi-year research project related to the occurrence and potential methods of reducing anhydrous ammonia (NH₃) nurse tank failures.⁴¹ The December 2013, final report of Phase II of the project titled, “Testing and Recommended Practices to Improve Nurse Tank Safety,” recommended that post-weld heat treatment (annealing) should be performed on all new nurse tanks as a part of the manufacturing process to reduce the occurrence of stress corrosion cracking failure.⁴² Consistent with this recommendation and to ensure safe transportation of hazardous materials in nurse tanks, PHMSA proposes to add paragraph (m)(1)(viii) requiring that all nurse tanks manufactured 90 days after the effective date of a final rule be stress relieved through full post-weld heat treatment. In addition, this proposal addresses, in part, NTSB Safety Recommendation H-04-023 that was issued as a result of an incident involving the release of

anhydrous ammonia because of a failed nurse tank.⁴³ FMCSA notes that the two major manufacturers of nurse tanks are already performing full post-weld heat treatment on their cargo tanks, thus this new requirement will primarily provide PHMSA oversight by including it as a condition to allow the use of a non-DOT specification cargo tank for transportation of anhydrous ammonia. This proposed requirement ensures that this additional safety measure will be implemented by both current and new nurse tank manufacturers.

Paragraph (n)(1) details the required emergency discharge control equipment for cargo tank motor vehicles in liquefied compressed gas service. During FMCSA industry workshops, stakeholders have noted that this table is confusing. Therefore, PHMSA proposes to reformat information in the table in paragraph (n)(1) for ease of understanding. This includes separating out current regulatory requirements unique to certain scenarios and adding an additional column to specify requirements when there are obstructed view deliveries under § 177.840(p). PHMSA does not intend to make any substantive changes to existing requirements in this table, however we are adding information from § 177.840(p) into the table to increase usability. PHMSA invites comments on the usability of the reformatted table. We believe reformatting the table will reduce confusion, which will lead to increased compliance and therefore an improved level of safety.

Section 173.320

This section details exceptions for the transportation of cryogenic liquids. Subject to certain requirements, paragraph (a) provides an exception from the requirements of the HMR for atmospheric gases and helium, cryogenic liquid in Dewar flasks, insulated cylinders, insulated portable tanks, insulated cargo tanks, and insulated tank cars, transported by motor vehicle or railcar. Paragraph (b) provides an additional exception for certain atmospheric gases and helium. PHMSA proposes to revise paragraph (a) for ease of understanding, with no substantive impact to the current provisions of the paragraph. In addition to editorial amendments, PHMSA proposes to revise the packaging type of an insulated cargo tank to a “cargo tank motor vehicle,” as this is more appropriate terminology describing the completed transportation package. This amendment will increase the clarity of

the regulations, leading to greater compliance and increasing safety.

Specifically, PHMSA proposes to remove the phrase “atmospheric gases and helium” in paragraphs (a) and (b). Furthermore, PHMSA proposes to consistently reference “cryogenic liquids authorized to use this section by Column 8(A) of the § 172.101 Hazardous Materials Table of this subchapter” in both paragraphs (a) and (b). This proposed change also makes the section more consistent with the HMR, removing any ambiguity between whether a material is an atmospheric gas and if it is afforded an exception in this section. PHMSA intends that this proposed change be editorial and not make any substantive revisions to the current regulatory requirements. This increased clarity will lead to less confusion and thus, enhance safety. The cryogenic liquids assigned “320” in Column 8(A) of the § 172.101 Hazardous Materials Table are the same as the materials defined as “atmospheric gases” in § 171.8, except that “320” is also assigned to two “not otherwise specified” (“n.o.s.”) entries, UN3158 and UN3311. PHMSA seeks comment on this change, and whether there are materials classified as “UN3158 Gas, refrigerated liquid, n.o.s. 2.2” or “UN3311 Gas, refrigerated liquid, oxidizing, n.o.s. 2.2 (5.1)” that are composed of a gas or gas mixture other than air, nitrogen, oxygen, argon, krypton, neon, xenon, or helium.

Part 174

Section 174.9

Section 174.9 identifies inspection requirements for rail cars at locations where a hazardous material is accepted for transportation or placed in a train. Paragraph (a) includes specifics on carrier inspection requirements. PHMSA proposes an editorial amendment in paragraph (a) to indicate more clearly that the inspections performed in § 174.9 are in conjunction with those required in 49 CFR parts 215 and 232 for identification of defective freight car components and brake systems, respectively. Currently, the text refers readers to parts 215 and 232 “of this title.” PHMSA believes it will be clearer to the reader if we replace “this title” with “49 CFR” parts 215 and 232.

Furthermore, the current language in § 174.9 does not specifically address situations where a train is seen departing a location with readily apparent improper hazard communication, unapplied closures, or leaking hazardous materials. In order to address this situation, PHMSA proposes to add paragraph (e) to specify that in

⁴¹ <https://www.fmcsa.dot.gov/regulations/hazardous-materials/cargo-tank-safety>.

⁴² The report is available at: <https://rosap.nhtbts.gov/view/dot/163>.

⁴³ <https://data.ntsb.gov/carol-main-public/basic-search>.

the event of the observation of a train with readily apparent improper hazard communication, unapplied closures, or leaking hazardous materials, it will be presumed that the rail car was not inspected properly by the carrier. During the June 8–9, 2016, HMIWG RSAC meeting, PHMSA noted that hazard communication includes communication such as placards, markings, and stenciling. The final recommended language was approved by consensus vote at the May 25, 2017, RSAC meeting and offered to PHMSA and FRA for consideration. PHMSA expects the addition of paragraph (e) will increase compliance with the HMR's existing closure securement and hazard communication requirements, and therefore increase safety.

Section 174.14

Section 174.14 requires that hazardous material shipments be expedited to within 48 hours upon acceptance at the originating location, commonly known as the “48-hour rule.” The purpose of this requirement is to ensure that rail cars carrying hazardous materials are not held for long periods of time, hazardous material transportation is moving forward continuously, and rail cars that are being delayed are not being used for storage purposes. Currently, § 174.14 does not allow any exceptions to the 48-hour rule when the receiving facility is not capable of receiving the shipment. During the August 27–28, 2013, FRA public meeting and the June 8–9, 2016, HMIWG meeting, it was noted that FRA uses enforcement discretion with regard to the 48-hour rule in certain cases, such as delays due to inadequate space in a consignee facility or situations where the shipment contains only the residue of a hazardous material, to avoid unnecessary shuttling of hazmat cars to and from local railyards to comply with the regulation.

In order to align the HMR with FRA's enforcement discretion practices, PHMSA proposes new paragraphs (a)(1) through (3) to add exceptions for specific scenarios when circumstances preclude delivery to the consignee destination or when the shipment contains only the residue of a hazardous material. In addition, PHMSA proposes to revise paragraph (a) to add a recordkeeping requirement for the rail carrier to document the reason for the delay. This record can be in a paper or electronic form. PHMSA and FRA note that it is not the intention to require a rail carrier to create a new recordkeeping system if one meeting the proposed requirements is already in place. PHMSA and FRA also propose an

editorial revision to remove “transfer stations” from paragraph (a), as this is an obsolete reference. The final recommended language was approved by consensus vote at the May 25, 2017, RSAC meeting and offered to PHMSA and FRA for consideration. PHMSA expects the formalization of existing FRA enforcement discretion related to the 48-hour rule will maintain the current level of safety of rail transportation while affording rail carriers greater flexibility within the scope of the expedited movement.

Note that in the revised language of § 174.14 offered by the RSAC to PHMSA and FRA for consideration, a fourth exception was included that would have created an exception to the 48-hour rule for shipments delivered to the final destination on a shipping paper. In accordance with § 171.1(c)(4)(i)(B), rail cars delivered to the final destination marked on the shipping paper, but on track that is not a “private track or siding,” are still in transportation. The RSAC language offered to PHMSA and FRA for consideration in paragraph (a)(4) would then except shipments delivered to non-private track from expedited movement, and they could remain on the track, “in transportation,” indefinitely. It was not FRA or PHMSA's intent to authorize such activity in the HMR. Therefore, the RSAC-approved fourth option (*i.e.*, a paragraph (a)(4)) is not being proposed. Shipments of hazardous material that have been delivered to their final destination on a private track or siding are not “in transportation,” (*see* § 171.1) and therefore are not subject to the 48-hour rule.

Section 174.16

Section 174.16 specifies requirements for delivery of certain hazardous materials at agency stations. In current operations, rail cars carrying hazardous materials covered under § 174.16 no longer deliver these types of materials to agency stations, which no longer exist. As was noted by AAR at the August 27–28, 2013, FRA public meeting, hazardous materials currently covered under § 174.16 are unloaded at the rail car facility where they are delivered. If the hazardous material is not picked up by the consignee or the shipment is rejected, the delivering carrier obtains disposition instructions from the offeror of the shipment. To address the change in rail carrier operations and in an effort to remove language that is no longer applicable to current operations, PHMSA proposes to remove and reserve this section. PHMSA notes that any additional transportation of these materials must comply with all

applicable regulations. The decision to remove and reserve this section was approved by consensus vote at the May 25, 2017 RSAC meeting and offered to PHMSA and FRA for consideration. PHMSA expects that removing this obsolete provision will increase the clarity of the HMR for carriers dealing with shipments rejected or not picked up.

Section 174.20

Section 174.20 outlines the allowance for a rail carrier to impose local or carrier restrictions for hazardous materials when acceptance, transportation, or delivery is unusually hazardous. At the August 27–28, 2013 FRA public meeting, AAR proposed that paragraph (a) be deleted as it was redundant and covered in the language from paragraph (b). However, following further review, AAR proposed at the June 8–9, 2016 RSAC meeting that the entire section be deleted as the requirements should be left up to individual carriers, and that reporting to the AAR's Bureau of Explosives is not necessary. PHMSA agrees and proposes to remove and reserve the section in its entirety. The decision to remove and reserve this section was approved by consensus vote at the May 25, 2017, RSAC meeting and offered to PHMSA and FRA for consideration. PHMSA expects removing this section will not adversely impact safety because rail carriers will still be able to make a determination that local conditions make the acceptance, transportation, or delivery of hazardous materials unusually hazardous.

Section 174.24

This section details requirements for the acceptance of shipping papers by a carrier and shipping paper retention requirements. Paragraph (b) specifies that a shipping paper must be made available to an authorized official of a Federal, State, or local government agency at a reasonable time and location. However, there is no further specificity on what is meant by a “reasonable time.” In an effort to clarify the requirements, PHMSA proposes to revise paragraph (b) and indicate that the shipping paper must be provided at reasonable times and locations, “but no later than the close of business the following business day from the time of the request in non-emergency circumstances.” The proposed language still mandates that the documentation be made available to inspectors at a “reasonable time and location,” so when the information is readily available at the time that an inspector requests it, PHMSA and FRA expect that

it shall be provided at that time, as it has been historically. For non-emergency document requests that are for past shipments (*e.g.*, shipments made weeks/months ago), or for all shipments made by a particular shipper or in a particular car, the RSAC reached consensus that a reasonable deadline would be close of business the following business day.

During the May 5 and June 8–9, 2016, HMIWG meetings, there was in-depth discussion to determine the most appropriate timeframe that a carrier would be able to provide the shipping paper information in non-emergency situations. One business day was proposed as an alternate to a much shorter time, such as 30 minutes. One business day also addresses the needs of railroads that only operate Monday through Friday. As discussed, if a request for a shipping paper is made on Friday afternoon, the carrier has until the close of business on Monday to provide the shipping paper. PHMSA considers close of business to be 5:00 p.m. local time for the office of the authorized official of a Federal, State or local government agency requesting the shipping paper. PHMSA seeks public comment if this is a reasonable meaning of “close of business.” During HMIWG meetings, it was noted that this allowance is the longest acceptable amount of time to provide a shipping paper in a non-emergency situation, and the information might be available much sooner. Furthermore, it was discussed that this allowance is for non-emergency situations, where an emergency is defined as an event when an emergency response telephone number, as specified in § 172.604, is contacted. The final recommended language was approved by consensus vote at the May 25, 2017, RSAC meeting and offered to PHMSA and FRA for consideration.

Additionally, in the first sentence of paragraph (b), as approved by RSAC and offered to PHMSA and FRA for consideration, it was proposed to replace “person” with “carrier.” PHMSA and FRA expect that such a revision could create unnecessary confusion in situations where a third party has been contracted to take on carrier functions (*e.g.*, maintaining shipping papers). Therefore, for clarity and to maintain alignment with other modal shipping paper retention sections, PHMSA will maintain the HMR’s current applicability of the paragraph (b) retention requirements to each “person” who receives a shipping paper required by this section. PHMSA expects the proposed revision to § 174.24 will improve safety oversight by allowing authorized governmental

representatives to access historical shipping paper information in a timelier manner during inspections and investigations.

Please note that this standard for reasonable time and place—close of business the following business day—is applicable specifically to review of historic shipping paper information in non-emergency rail transportation scenarios after transportation has ended. In particular, provision of shipping papers during transportation (*e.g.*, container inspections in port areas) is one example of a scenario where the following business day is generally too long a time period to meet the needs of inspectors and prevent unnecessary delays. See “Section IV. Section-by-Section Review; Part 171; Section 171.22” for further discussion of shipping paper accessibility in port areas.

Section 174.50

Section 174.50 prescribes requirements for nonconforming or leaking packages. This section specifies that non-bulk packages may not be forwarded unless they are repaired, reconditioned, or overpacked in appropriate salvage packaging. For bulk packages, an OTMA is required to authorize movement for a non-conforming or leaking package, unless movement is necessary to reduce or eliminate an immediate safety risk. PHMSA proposes to revise § 174.50 in order to identify more clearly the applicability and the exceptions regarding obtaining an OTMA from FRA.

To evaluate the proposed revisions to § 174.50 and consider harmonization and reciprocity with Transport Canada, HMIWG established an OTMA Task Force that included FRA, PHMSA, RSI, AAR, CI, TFI, and the American Petroleum Institute (API). In addition to evaluating § 174.50, the OTMA Task Force worked to develop the Hazardous Material Guidance (HMG) Document HMG–127 (Revision 5). Following multiple meetings, the OTMA Task Force voted to accept HMG–127 and the proposed language in § 174.50. The proposed text of HMG–127 (Revision 5) is included in the docket for review along with this NPRM.⁴⁴ The proposed regulatory text addresses administrative topics, while HMG–127 specifies further guidance on obtaining an OTMA. HMG–127 discusses how to apply for an OTMA, categories and conditions for choosing the correct category of an OTMA, when a root cause analysis is

required as a condition of an OTMA, and what information should be included in a root cause analysis. Note, however, that HMIWG did not reach consensus on proposed text in § 174.50(d)(2)(v) when it was put forward to a vote. Recommended language for this section was approved by consensus vote at the May 25, 2017, RSAC meeting and offered to PHMSA and FRA for consideration. PHMSA proposes the following revisions to § 174.50:

- Discuss in paragraph (a) the general requirements for non-conforming and leaking packages, including non-bulk packages;
- List scenarios in paragraph (b) where an OTMA issued by the Associate Administrator for Safety, FRA is not required to move a non-conforming or leaking bulk package;
- Discuss in paragraph (c) the approval process for an OTMA;
- List in paragraph (d) the marking, notification, recordkeeping, routing, and root cause analysis requirements for OTMA grantees; and
- Clarify in paragraph (e) the responsibility for compliance with OTMA requirements and consequences for non-compliance.

The exceptions proposed in paragraph (b)(2) and (3) codify long-standing FRA policy. Non-compliant rail cars that are clean and contain no hazardous materials residue, addressed in paragraph (b)(2), do not pose a risk of hazardous materials release. The intent of the proposed exception in paragraph (b)(2) is to expedite the movement of these cars to a facility at which repairs can be conducted. These are typically DOT–111 tank cars that are not carrying hazmat and have been cleaned. Currently, FRA receives approximately 730 OTMAs per year for clean cars. The exception proposed in paragraph (b)(3) for rail cars discovered to be overloaded by a minor amount is intended to address known weigh-in-motion and static scale error tolerances, and additionally align with Transport Canada standards. The exceptions proposed in paragraphs (b)(1), for movement necessary to reduce or eliminate an immediate threat of harm to human health or the environment, and (b)(4), for rail cars moving in accordance with a Transport Canada temporary certificate, exist in the currently effective 174.50, and we propose to move them to paragraphs (b)(1) and (b)(4), respectively, for clarity.

Additionally, throughout § 174.50, PHMSA proposes to replace the acronym “OTMA” with “One-Time Movement Approval” to increase clarity for readers of the HMR who are not

⁴⁴ See HMG–127: <https://www.regulations.gov/document/PHMSA-2018-0080-0001>.

familiar with the OTMA process. In § 174.50(d)(1), PHMSA proposes editorial edits to the language approved by RSAC and offered to PHMSA and FRA for consideration to increase the clarity of the marking requirement for non-conforming rail cars. Specifically, based on consultation with FRA, PHMSA proposes to add the following marking into the HMR; this marking is currently a requirement in each OTMA issued by FRA (except those overloaded by weight).

<p>HOME SHOP FOR REPAIRS DO NOT LOAD or MOVING FOR DISMANTLING DO NOT LOAD</p>

In § 174.50(d)(2)(ii), PHMSA proposes editorial edits to the language approved by RSAC and offered to PHMSA and FRA for consideration. This proposed language shortens the sentences and clarifies the notification requirements, specifically that the approval grantee must ensure the consignee or final destination facility has been notified and will accept the non-conforming tank car. This ensures that the tank car is only consigned to a location capable of accepting the car, and unloading the product, if necessary. If the maintenance activities are to be conducted by a mobile unit, they must occur at the maintenance destination indicated in the application.

In § 174.50(d)(4), PHMSA proposes editorial revisions to the language approved by RSAC and offered to PHMSA and FRA for consideration. These proposed edits include clarifying instructions on routing rail cars moving under OTMAs, specifically that the OTMA grantee and railroad(s) involved in the movement must select the most appropriate route to the nearest cleaning and/or repair facility capable of performing the required cleaning and/or repairs. This aligns with an existing requirement in OTMAs issued by FRA.

Lastly, final rule HM-215O⁴⁵ harmonized the HMR with international standards and codified recognition of Temporary Certificates issued by Transport Canada for cross-border movements of non-conforming tank cars to or from Canada. To ensure this allowance remains, PHMSA proposes to specify the authorization for the use of Temporary Certificates in lieu of OTMAs for cross-border movements to or from Canada in § 174.50(b)(4).

PHMSA expects the revisions proposed to § 174.50 to formalize and

clarify the OTMA process will increase efficiency for rail car owners and railroads, as well as FRA staff processing OTMA requests. PHMSA also expects that over time, lessons learned from the root cause analysis that FRA is authorized to require in OTMAs will reduce the number of non-accidental releases, creating safety and environmental benefits.

Section 174.58

PHMSA proposes to add § 174.58 to detail what “extent practicable” means for rail transportation with respect to the § 171.8 definition of *residue*. This language was originally proposed as a change to the definition of *residue* in § 171.8, as part of the recommend language developed by RSAC Task 13-02, approved by consensus vote at the May 25, 2017, RSAC meeting, and offered to PHMSA and FRA for consideration. However, PHMSA proposes to relocate the RSAC-approved language from the definition of *residue* in § 171.8 to § 174.58. If RSAC’s proposed revision is made in § 171.8, the changes made to the definition of *residue* would have broader implications than the intent of clarifying its meaning for purposes of rail transportation of hazardous material. The intent of the proposed change remains the same as the RSAC proposal; to clarify that “extent practicable” means the material that remains in a bulk package after it has been unloaded using properly functioning service equipment and plant process equipment. Because part 174 is related to rail transportation operations, PHMSA proposes that this regulatory language more appropriately fits in new section § 174.58, instead of as part of the definition of *residue* in § 171.8 which has broader applicability. Note that in accordance with the § 171.8 definition of *residue*, a tank car must be unloaded to the maximum “extent practicable” in order to be transported with the residue description. PHMSA welcomes comment on the proposed implementation of this language. PHMSA expects this proposed revision will provide further clarity on what is considered residue for rail shipment of hazardous material and increase safety by ensuring bulk packages that actually qualify for “residue” status are shipped with that description.

Section 174.59

Section 174.59 details the requirements for marking and placarding rail cars carrying hazardous materials. PHMSA proposes to revise the requirements for replacing lost placards and to provide context to the

“next inspection point.” Specifically, PHMSA proposes the “next inspection point” be revised to the “nearest inspection point” and clarify that this point is “in the direction of travel” and “where mechanical personnel responsible for inspections related to 49 CFR parts 215 and 232 are on duty.” As discussed during the May 5 and June 8–9, 2016, HMIWG meetings, the intention of this provision is that lost placards are replaced as best and as soon as they can at a location where personnel are present and capable of performing inspections. During HMIWG meetings, it was also suggested that § 174.59 reflect similar language from 49 CFR parts 215 and 232, specifically that placards are to be “replaced at the next inspection point, interchange, or rail yard in the same direction as the train movement.”

The proposed revision to § 174.59 aligns with 49 CFR parts 215 and 232, by clarifying the “nearest inspection point,” where the placards can be replaced is in the direction of train movement. The final recommended language was approved by consensus vote at the May 25, 2017, RSAC meeting and offered to PHMSA and FRA for consideration. PHMSA expects this proposed revision will improve safety by clarifying the intent of the provision and ensuring the missing hazard communication placards are replaced as soon as possible.

Additionally, the recommended RSAC language for § 174.59 removes reference to “car certificates.” PHMSA and FRA seek comment on the removal of the reference to “car certificates” in § 174.59.

Section 174.63

This section outlines handling and loading requirements for portable tanks, intermodal (IM) portable tanks, intermediate bulk containers (IBCs), large packagings, cargo tanks, and multi-unit tank car tanks transported by rail. PHMSA proposes to make editorial revisions to the title of § 174.63 to specify the section applies to rail transport in COFC or TOFC service.

Additionally, paragraph (b) specifies requirements applicable to transport of a bulk packaging inside a fully closed transport vehicle or fully closed freight container. PHMSA proposes to clarify the current reference to IM 101 and IM 102 as types of portable tanks. This proposed change is editorial in nature and does not impose any new requirements.

Paragraph (c) provides instruction, specifically, six conditions, for an alternate method of transportation to paragraph (b) for bulk packaging using COFC or TOFC service. PHMSA

⁴⁵ 85 FR 27810 (Mar. 11, 2020).

proposes to revise the condition in paragraph (c)(1), which outlines authorized packaging sections, by adding packagings authorized in § 173.247 for elevated temperature materials to the list of packaging sections, as well as Division 2.2 materials not specifically listed in the § 173.315(a)(2) table that are packaged as authorized in the table and § 173.315 conditions. This proposed amendment will authorize these packagings to be transported without requiring approval from FRA. PHMSA expects that adding existing safe, authorized packagings for elevated temperature materials and non-flammable gases to the COFC or TOFC authorization will not compromise safety and will increase flexibility for shippers of these materials.

PHMSA also proposes to amend paragraph (c)(2) to indicate that a rail car transporting a bulk package in COFC or TOFC service must comply with applicable regulatory requirements for the type of rail car being used. The current requirement instructs the shipper that the “tank” and flatcar used must comply with applicable requirements of the HMR concerning its specification, but use of the term “tank” obscures the intended general reference to bulk packagings in § 174.63, and the HMR contains no specifications for flatcars. The proposed amendments will instead refer generally to bulk packagings that must adhere to applicable specifications and to flatcars that must comply with applicable rail car regulatory requirements. This amendment will provide greater clarity, which will enhance the safety of transporting these bulk packagings by rail. The final recommended language was approved by consensus vote at the May 25, 2017, RSAC meeting and offered to PHMSA and FRA for consideration.

Section 174.67

Section 174.67 outlines the requirements for transloading of tank cars. HMIWG reviewed this section to update, clarify, and remove regulations where appropriate. The recommended language was approved by consensus vote during the May 25, 2017, RSAC meeting and submitted to PHMSA and FRA for consideration. However, since the 2017 submission of the recommended language and following an in-depth review by PHMSA and FRA, in this NPRM we propose additional changes to the recommended language. These changes are not intended to revise the intent of HMIWG, but to ensure that the section is easier to read and consistent with the rest of the HMR—such as removing and

reserving certain paragraphs instead of redesignating them—and to promote clear understanding of the requirements for safe transloading.

PHMSA proposes to modify the title of the section from “unloading” to “transloading”—as approved by HMIWG—because this more accurately reflects the operations covered by this section. Transloading is a subset of loading or unloading that includes both loading tank cars from, and unloading tank cars into, another packaging for continued movement in transportation.

As approved by HMIWG, PHMSA proposes to remove the introductory sentence of this section because it is unnecessary and inconsistent with other sections in the HMR. The sentence merely states, “for transloading operations, the following rules must be observed.” With the proposed retitling of the section, it is now unnecessary.

Paragraph (a)(1) specifies requirements for hazmat employees performing unloading operations. PHMSA proposes minor revisions to paragraph (a)(1) to clarify that this section applies specifically to transloading, as opposed to all unloading operations, as approved by HMIWG. PHMSA notes here that tank car loading and unloading is covered in § 173.31 (Use of Tank Cars) and, as such, proposes to add reference to § 173.31(d) (examination before shipping) and (g) (tank car loading and unloading) to increase awareness of relevant requirements for tank car loading and unloading.

Paragraph (a)(2) specifies requirements for securing a tank car against motion. PHMSA proposes to revise paragraph (a)(2) by removing the current language and replacing it with a reference to § 173.31(g), as the language currently in paragraph (a)(2) is unnecessarily duplicative of the requirements in § 173.31(g).

Paragraphs (a)(3) and (4) specify securement of access to the track and required warning signage, respectively. As recommended by HMIWG, PHMSA proposes to remove and reserve paragraphs (a)(3) and (4) because the track securement language would now become unnecessarily duplicative of the proposed track securement language in § 173.31(g) (*see* discussion of proposed amendments to § 173.31(g)).

Paragraph (a)(5) specifies the written safety procedures that must be maintained and available for transloading operations, including measures to account for the physical and chemical properties of the lading being transloaded. In paragraph (a)(5), PHMSA proposes to include a statement that the procedures must include

measures to address the safe handling and operation of the tank car and tank car service equipment, as well as account for physical and chemical properties of the lading being transloaded. HMIWG determined that many of the prescriptive elements of this section may be outdated or inconsistent with current industry best practices for certain materials, operations, and modern tank car designs. Thus, many of the prescriptive elements of § 174.67 in the currently effective paragraphs (b)–(g), (n), and (o) were removed and it was the intent of HMIWG that these prescriptive elements would be substituted with new performance-based language proposed in paragraph (a)(5). However, upon further review of the language approved by the RSAC, PHMSA proposes a modification to the recommended language of (a)(5) to clarify our expectations on what the transloading procedures must cover. PHMSA and FRA reviewed the prescriptive instructions proposed for removal from paragraphs (b)–(g), (n) and (o), and used the subjects addressed by the instructions to generate a list of procedures the proposed paragraph (a)(5) instructions must address. PHMSA expects that the transloading procedures required by paragraph (a)(5) must address, at a minimum, the following:

- Temperature monitoring and pressure relief;
- Safe operation of the tank car for product loading or unloading;
- Proper disposal of used seals and other debris;
- Measures to avoid spillage of contents outside the tank;
- Operation of tank car service equipment;
- Proper removal of product plugs that prevent adequate operation of the service equipment; and
- Proper tool maintenance measures including the types of tools to use, calibration, cleanliness, and instructions on tool use.

To clarify our intent, PHMSA proposes to add this list of minimum elements to the transloading procedure requirement in paragraph (a)(5). Additionally, PHMSA notes that the current language of paragraph (a)(5) does not include a specific instruction that transloading facilities must follow their written procedures. The removal of the prescriptive instructions in this section increases the importance of the written procedures for safe transloading operations; therefore, we propose to add the phrase “and adhere to” to the requirement to maintain written transloading procedures in order to

ensure that these procedures are actually implemented.

As agreed to by HMIWG, PHMSA proposes to remove and reserve paragraph (a)(6), which currently specifies requirements to relieve pressure in the tank car before removing a manhole cover or outlet valve cap from the tank car. As noted by HMIWG, the current requirement is too prescriptive, outdated, and not necessarily consistent with current industry best practices. Furthermore, procedures to monitor the temperature and to relieve pressure should be part of the overall safety procedures and measures referenced in the proposed performance-based requirement of new paragraph (a)(5); therefore, we are removing the duplicative measures in current paragraph (a)(6) and reserving the paragraph.

The RSAC-approved regulatory text for § 174.67 proposed to remove the existing requirements in currently effective paragraphs (b) through (g), to re-designate the requirements in paragraphs (h) through (l) into these newly removed paragraphs, and also to update the requirements in (h) through (l) to address changes in tank car design and operation. However, since the 2017 submission of the recommended actions and following an in-depth review by PHMSA and FRA, we have determined that redesignating the existing requirements would result in confusion; therefore, in this NPRM we propose to remove and reserve paragraphs (b) through (g), and to make the RSAC-approved revisions to the section while maintaining the existing paragraph structure. For example, rather than proposing to revise the requirements for securing unloading connections that are currently found in paragraph (h) and moving the requirements to paragraph (b), we propose to revise the requirements in paragraph (h) and leave it in its current location in the section. Otherwise, a current reference citation to paragraph (h) in another section of the HMR or existing guidance documents would no longer make sense. Below we discuss the revisions to each of the remaining paragraphs of § 174.67.

PHMSA proposes to remove and reserve paragraph (b), which includes prescriptive language on the operation of various types of manway designs. The current language has become outdated and does not encompass modern-day manway cover designs or industry best practices. Procedures for safely operating various types of manway designs must be included in the safety procedures required by proposed paragraph (a)(5) of this section, and should be consistent with the design,

OEM recommendations, and industry best practices. Structurally, HMIWG voted to replace this paragraph with the requirements currently proposed in paragraph (h) instead of removing and reserving paragraph (b). For ease of understanding and to ensure no other regulatory citations or guidance documents need to be updated, PHMSA instead proposes to remove and reserve paragraph (b).

Paragraph (c) contains prescriptive procedures for operation of manhole covers during unloading through the bottom outlet valve. The current language has become outdated and does not encompass modern day manway cover designs or industry best practices. The transloading operator's procedure for safely operating the tank car for product unloading must be adequately addressed by the safety procedures required by proposed paragraph (a)(5) of this section. Structurally, HMIWG voted to remove this paragraph and replace it with the requirements currently proposed in paragraph (j) rather than removing and reserving paragraph (c). However, for readability and so no other regulatory citations or guidance documents need to be updated, PHMSA proposes to remove and reserve this paragraph instead.

Paragraph (d) contains prescriptive safety procedures for unloading of product from a tank car. Paragraph (d) may not be applicable to certain types of transloading operations and may no longer be consistent with current industry best practices. As such, PHMSA proposes to remove and reserve the requirements. These procedures should be adequately covered by the safety procedures developed and updated by the transloading operator to comply with proposed paragraph (a)(5) of this section. Structurally, HMIWG proposed to remove this paragraph and replace it with the requirements currently proposed in paragraph (k) instead of removing and reserving paragraph (d). However, for readability and so no other regulatory citations or guidance documents need to be updated, PHMSA proposes to remove and reserve this paragraph instead.

Paragraph (e) currently states that seals or other substances shall not be thrown into the tank, and the contents of the tank may not be spilled over the car or tank. HMIWG determined the requirement in this paragraph was unnecessarily prescriptive, as the procedures for properly removing and disposing of seals and other substances must be included in the safety procedures required by proposed (a)(5) of this section. Furthermore, the HMR already prohibits residual hazardous

material on the outside of the packaging. Structurally, HMIWG proposed to remove this paragraph and replace it with the requirements currently proposed in paragraph (l) instead of removing and reserving paragraph (e). However, to ensure ease of understanding and so no other regulatory citations or guidance documents need to be updated, PHMSA proposes to remove and reserve this paragraph instead.

Paragraph (f) currently contains prescriptive safety procedures for operating a top-operated bottom outlet valve. HMIWG determined that these prescriptive safety procedures for valve operation are outdated and do not reflect current bottom outlet designs. The requirements for bottom outlet valve operation must be part of the safety procedures as required by proposed paragraph (a)(5) of this section. Structurally, HMIWG agreed to remove this paragraph and replace it with the requirements currently proposed in paragraph (m) instead of removing and reserving paragraph (f). However, to ensure ease of understanding and so no other regulatory citations or guidance documents need to be updated, PHMSA proposes to remove and reserve this paragraph instead.

Paragraph (g) currently contains prescriptive procedural requirements for operation of equipment to remove product plugs that prevent adequate operation of the valves and equipment. In 2017, HMIWG agreed to remove and reserve this paragraph. For some operations, the current procedures of paragraph (g) may be outdated or inconsistent with current industry best practices. Instead, PHMSA and FRA have determined such prescriptive procedures must be included and updated in the safety procedures required by proposed paragraph (a)(5) of this section. As such, PHMSA proposes to remove and reserve this paragraph (g).

Paragraph (h) currently details securement requirements for connections used for the transfer of hazmat into—or out of—a tank car. PHMSA proposes to amend paragraph (h) by removing the word “unloading” from it, as agreed to by HMIWG. However, as previously mentioned, instead of moving this paragraph to replace paragraph (b)—as agreed to by HMIWG—PHMSA proposes to make this change without moving the paragraph. Finally, the language is further modified for clarity by removing the reference to “pipes on the dome” since connections could include more

than just pipes (e.g., valves, hoses, or reducers).

Currently, paragraph (i) provides requirements for the facility operator during unloading, paragraph (j) includes certain exceptions for attendance, and paragraph (k) specifies requirements when an unloader is absent. In this NPRM, PHMSA proposes minor revisions to paragraphs (i)(2)(i), (j)(2), (k) introductory text, (k)(4), and (k)(5). These minor edits align these paragraphs with the rest of the proposed amendments in § 174.67 and were agreed to by HMIWG.

Paragraph (l) currently prescribes the actions that must be taken as soon as a tank car is completely unloaded. As agreed to by the HMIWG, PHMSA proposes to remove the closure securement language and replace it with a reference to pre-transportation closure securement regulations in § 173.31. This is being proposed because we believe this securement of closures and removal of unloading connections language is unnecessary and redundant of existing requirements in § 173.31(d) associated with pre-trip examination of the tank car.

Paragraph (n) currently contains prescriptive environmental remediation procedures when oil or gas has been spilled. As agreed to by HMIWG, PHMSA proposes to remove and reserve paragraph (n) because specific instruction on the environmental remediation or cleanup of a hazmat spill is outside the scope of the HMR. However, such procedures may be included as part of the facility's safety procedures in order to meet other applicable federal, state, or local requirements.

Paragraph (o) currently includes language requiring tools to be kept clean. As recommended by HMIWG, PHMSA proposes to remove and reserve paragraph (o). Tool maintenance measures including the types of tools to use, calibration, cleanliness, and instructions on use must be included in the safety procedures required by proposed paragraph (a)(5) of this section. Therefore, we are removing the redundant language covered by this paragraph and reserving it.

Overall, PHMSA expects that the proposed revisions to § 174.67 will maintain safety by allowing transloading to be conducted in accordance with written safety procedures and industry best practices developed specifically for the tank car designs involved and materials being transferred, instead of prescriptive standards.

Section 174.81

Section 174.81 specifies segregation requirements for the transportation of hazardous materials by rail. Paragraph (g) specifies the instructions for the Class 1 (explosive) segregation table in paragraph (f). In review of these requirements, PHMSA notes that paragraph (g)(3)(iv) has outdated terminology. Currently, the paragraph specifies requirements and limitations for detonators and detonating primers. However, the term "detonating primers" is no longer used in the HMR. Final rule HM-189M⁴⁶ corrected editorial errors, made minor regulatory changes, and improved the clarity of certain provisions to the HMR. One of these revisions was updating the wording "detonating primers" to the more accurate terminology of "detonating assemblies and boosters with detonators." However, PHMSA identified this editorial correction was not made in § 174.81(g)(3)(iv). Therefore, PHMSA proposes to revise the terminology of "detonating primers" to "detonating assemblies and boosters with detonators." In review of § 174.81(g)(3)(iv), PHMSA also determined the phrase "Division 1.4S explosives" created unnecessary confusion in the applicability of Note 4. Detonators, detonating assemblies, and boosters with detonators, whether Division 1.1, 1.2, or 1.4, may not be transported in the same rail car with Division 1.1 and 1.2 material (except other detonators, detonating assemblies, and boosters with detonators). These requirements align with current standards for highway and vessel explosive segregation. PHMSA expects these editorial clarifications will improve clarity of the HMR while not creating any additional burdens for rail transportation of explosives.

Part 176

Section 176.2

Section 176.2 defines terms for the purposes of part 176. In conjunction with the USCG, PHMSA proposes an editorial revision to the definition of *Commandant (CG-522)*, USCG to reflect organizational updates within the USCG. The proposed revisions include replacing the acronym "CG-522" with the current acronym "CG-ENG," which stands for United States Coast Guard Office of Design and Engineering Standards; replacing the "Office of Operating and Environmental Standards" with the current name "Office of Design and Engineering Standards"; and replacing the outdated

postal code "20593-0001" with the current postal code of "20593-7509."

Section 176.84

Section 176.84 describes the requirements to store, handle, and segregate hazardous materials for cargo and passenger vessels, with paragraph (a) specifying the meaning of the Column 10B of the § 172.101 HMT stowage codes (e.g., "stow away from hydrazine"). Limited quantities are not subject to the stowage code provisions found in Column 10B of the HMT (see § 172.101(k)), however § 176.84(a) does not restate that limited quantities are not subject to the stowage code provisions assigned by Column 10B of the HMT.

The International Vessel Operators Dangerous Goods Association (IVODGA) submitted a comment⁴⁷ to the 2017 Regulatory Reform Notice, stating that placing the limited quantity stowage code exception only in § 172.101(k) created confusion for shippers and vessel operators. IVODGA requested that PHMSA revise § 176.84 editorially to reiterate that limited quantities are not subject to the stowage codes assigned by Column 10B of the § 172.101 HMT. PHMSA and the USCG agree that § 176.84 should be revised editorially to reiterate the limited quantity exception to reduce confusion. Therefore, PHMSA proposes to revise § 176.84(a) editorially by duplicating the limited quantity exception language from § 172.101(k). PHMSA expects this revision will increase safety and efficiency by reducing confusion for shippers and carriers of limited quantity materials.

Section 176.340

Section 176.340 describes requirements for the vessel transportation of combustible liquids in portable tanks. Paragraph (c) specifies portable tanks approved by the Commandant (CG-MSO), USCG are authorized for the transportation of combustible liquids by vessel. PHMSA proposes an editorial revision, to replace the acronym "CG-MSO" with that office's current acronym "CG-ENG." This revision will provide clarity and reduce confusion by aligning the HMR with USCG's current office structure.

Section 176.905

Section 176.905 describes the requirements for transporting vehicles powered by an internal combustion

⁴⁶ 61 FR 51334 (Oct. 1, 1996).

⁴⁷ See IVODGA OST Regulatory Reform comment: <https://www.regulations.gov/document?D=DOT-OST-2017-0069-2399>.

engine, fuel cell, batteries, or a combination of these fuel sources by vessel. Paragraph (i) specifies when a vehicle complies with the requirements of the paragraph, it is not subject to the HMR. PHMSA proposes to add paragraph (i)(7) to provide an exception from the requirements of the HMR for vehicles stored incidental to movement on shore prior to or after vessel transportation. This exception is intended to mirror the HMR's broad exception for vehicles transported by highway or rail in accordance with § 173.220(h)(1). PHMSA expects this will have no impact on the safe transportation of vehicles while providing regulatory relief for vessel transporters.

Part 177

Section 177.801

Section 177.801 specifies that a forbidden material, or hazardous material not prepared in accordance with the HMR, is not authorized for transportation by motor vehicle. PHMSA proposes to expand the section to include additional scenarios that are unacceptable for transportation. These are proposed for ease of regulatory understanding and clarity and are not new restrictions. To accomplish this, the first half of the introductory paragraph is proposed as a new paragraph (a). Additionally, the second half of the introductory paragraph is moved to a new paragraph (b) and revised to specify that a hazardous material not classified, packaged, marked, labeled, or placarded in accordance with the requirements of the HMR or by special permit may not be accepted for transportation or transported. These additional examples will provide greater clarity of what materials are not acceptable for transportation under the HMR and will increase safety.

Section 177.804

This section requires motor vehicle carriers of hazardous materials comply with the FMCSR and paragraph (a) specifies motor carriers and other persons subject to part 177 must also comply with specific provisions of the FMCSR. PHMSA has been made aware there is potential confusion in a scenario where a vehicle is subject to the HMR, but the vehicle is not of sufficient size to be subject to the FMCSR. Therefore, to provide regulatory clarity without reducing safety, PHMSA proposes to amend paragraph (a) to specify compliance with the FMCSR is only applicable to vehicles that are subject to the FMCSR.

Section 177.816

Section 177.816 specifies the requirements for highway transportation driver training. Currently, paragraph (c) specifies that §§ 177.816(a) and (b) training requirements may be satisfied with a tank vehicle or hazardous materials endorsement. In collaboration with FMCSA, PHMSA has become aware that cargo tank motor carriers are relying solely on the tank endorsement or hazardous materials endorsement provision in paragraph (c) to meet the training requirements related to cargo tank driving functions. FMCSA advises that most states have a six- or seven-year expiration on Commercial Driver's Licenses (CDLs), far beyond the three-year refresher training required by §§ 172.704 and 177.816(d). While paragraph (c) allows for the tank endorsement or hazardous materials endorsement to meet training requirements, the HMR does not allow the period of renewal of a tank vehicle or hazardous materials endorsement to supersede the three-year HMR requirement. Therefore, to assist in understanding of the current regulatory requirements and increase compliance, PHMSA proposes to add qualifying language to paragraph (c) to specify that the tank vehicle or hazardous materials endorsement may be used in place of the training requirements if it appropriately covers the requirements in paragraph (a) and (b). Furthermore, PHMSA proposes to add language to paragraph (d) stating that the training frequency must meet the requirements of § 172.704(c), which is required at minimum every three years. This clarification will enhance safety by ensuring everyone understands and abides by the current requirement that periods between training cannot exceed three years and will help ensure all operators are aware of the most current issues and response plans.

Section 177.835

Section 177.835 specifies additional requirements for the transportation of Class 1 hazardous materials by motor vehicle. Paragraph (d) provides conditions and requirements for Class 1 materials to be transported in multipurpose bulk trucks (MBTs). PHMSA proposes to revise paragraph (d) to specify an MBT may not be transported with a cargo tank that is required to be marked or placarded. Final rule HM-233D⁴⁸ established standards for the safe transportation of certain bulk explosives. In HM-233D, PHMSA added paragraph (d) to allow

Class 1 (explosive) materials to be transported with Division 5.1 (oxidizing), Class 8 (corrosive), and/or combustible liquids in MBTs under conditions set forth in IME Standard 23 and § 177.835(g). This regulatory allowance was based on the adoption of DOT-SP 11579. Following publication of this final rule, FMCSA noted that certain private motor carriers are transporting explosive materials for mining and quarrying in MBTs along with a secondary cargo tank motor vehicle transporting Division 1.5 hazardous materials (sometimes referred to as a "pup" cargo tank motor vehicle). However, it was not PHMSA's intention to authorize this configuration in HM-233D, as it was not authorized in DOT-SP 11579. As this is not indicated clearly in § 177.835(d), PHMSA proposes to specify an MBT may not be transported with any cargo tank that is required to be marked or placarded under § 177.823. PHMSA expects this proposed language to increase safety and eliminate the inconsistency between DOT-SP 11579 and the current regulatory requirements. In addition, this proposal is consistent with the existing prohibition in § 177.835(c)(3) that specifies Division 1.1 or 1.2 (explosive) materials may not be loaded or carried on a combination of vehicles when any vehicle in the combination is a cargo tank that is required to be marked or placarded under § 177.823.

Section 177.837

Section 177.837 specifies the requirements for the transportation of Class 3 (flammable liquids) hazardous materials by motor vehicle. Paragraph (c) specifies bonding and grounding requirements before and during transfer of lading to or from a cargo tank. This requirement only applies to flammable liquids; the HMR do not currently require cargo tanks that are transferring combustible liquids to be bonded and grounded in accordance with the requirements of this section. However, combustible liquids and flammable liquids that have been reclassified as combustible liquids exhibit characteristics similar to materials classed as flammable liquids, particularly regarding vapors. Both combustible liquids and flammable liquids that have been reclassified as combustible liquids also have the potential for initiation by the static charge produced by product flow through a piping system on a cargo tank motor vehicle that is not bonded and grounded.

PHMSA identified four recent incidents involving combustible liquids that may have been minimized by the

⁴⁸ 80 FR 79423 (Dec. 21, 2015).

proposed bonding and grounding requirement prior to loading or unloading. Below are summaries of these incidents, which highlight the potential severity of incidents, resulting total damages, and release of hazardous materials:

- August 5, 2015: A cargo tank was loading diesel fuel at a fuel station when a fire ignited under the hood of the vehicle, resulting in \$349,130 in total damages. 4,500 gallons of diesel fuel was released.

- August 4, 2016: An explosion occurred at a shipper's loading facility while diesel fuel was being loaded into a cargo tank motor vehicle. Total damage costs amounted to almost \$2 million and a release of 2,500 gallons.

- January 31, 2018: While a cargo tank motor vehicle was being loaded, Fuel Oil (No. 1, 2, 4, 5, or 6) was released, followed by an explosion and fire. The total damages were \$1.3 million and 2,534 gallons were released.

- June 3, 2019: An explosion occurred while aviation fuel was being loaded into a cargo tank motor vehicle, resulting in a release of 3,104 gallons of hazardous material and approximately \$7.3 million in total damages. In addition, this incident resulted in one major injury and three minor injuries.

Based on these incidents and to ensure the safe transportation of these materials, PHMSA proposes to revise paragraph (c) to specify that a flammable liquid, a combustible liquid, or a flammable liquid reclassified as combustible liquid is subject to the bonding and grounding requirements of § 177.837.

Section 177.840

This section details additional requirements for Class 2 (gases) hazardous materials transported by highway. Paragraph (n) states that in the event of an unintentional release of liquefied compressed gas to the environment, the internal self-closing stop valve or other primary means of closure must be shut. Paragraph (r)(2) requires the qualified person monitoring the unloading of a cargo tank motor vehicle containing liquefied compressed gas using a facility-provided hose be within arm's reach of the mechanical means of closure for the internal self-closing stop valve. Lastly, paragraph (t) requires the qualified person monitoring the unloading of a cargo tank motor vehicle containing liquefied compressed gas and being unloaded without emergency discharge equipment be within arm's reach of the mechanical means of closure for the internal self-closing stop valve. All three of these paragraphs only reference internal self-

closing stop valves and do not include a reference to external self-closing stop valves. However, there are cargo tank motor vehicles that transport liquefied compressed gas that have external self-closing stop valves. In total, FMCSA estimates that there are approximately 122,014 cargo tank motor vehicles that transport Division 2.2 (non-poisonous nonflammable gas) hazardous materials, which includes liquefied compressed gases, that have internal and/or external self-closing stop valves. Given the high number of cargo tank motor vehicles that may utilize external self-closing stop valves, primarily in cryogenic service, it is important to ensure that requirements for access to the means of closure for internal self-closing stop valves also apply to external self-closing stop valves. Therefore, PHMSA is adding clarifying language that these access requirements apply to both internal and external means of closure. PHMSA expects these additional provisions will continue to ensure the safe transportation of cargo tank motor vehicles and proposes to revise these paragraphs to require external self-closing stop valves to comply with the same requirements as internal self-closing stop valves. In review of historical rulemaking language, PHMSA does not expect it was the explicit intent to exclude external self-closing stop valves from these requirements.

Lastly, in paragraph (t), PHMSA proposes to remove the reference to December 31, 1999, as it is obsolete, and all chlorine cargo tank motor vehicles are now subject to the additional unloading requirements specified in this paragraph. This editorial revision increases regulatory clarity without diminishing safety.

Section 177.841

This section provides additional requirements when transporting Division 6.1 and Division 2.3 hazardous materials via motor vehicle. Paragraph (e)(1) specifies when a package bears a POISON or POISON INHALATION HAZARD label or placard, it may not be transported in the same motor vehicle with foodstuffs, feed, or edible material intended for consumption by humans or animals unless the poisonous material is packaged in a specific way. In the interest of safety, PHMSA proposes to revise paragraph (e)(1) to also include packages bearing or required to bear a POISON GAS label or placard in the list of restricted hazardous materials with foodstuffs, feed, or edible material.

Paragraph (e)(2) specifies a package bearing or required to bear a POISON, POISON GAS, or POISON INHALATION HAZARD label is not

authorized for transportation in the driver's compartment of a motor vehicle. Due to new motor vehicle designs, PHMSA proposes to revise this paragraph to specify that this also includes "enclosed van trucks with no permanent barrier separating the driver from the cargo component." As the intent of this paragraph is to ensure a driver is not exposed to a poisonous material while in transportation, this revision ensures the continued safety of drivers in transportation.

Part 178

Section 178.320

Section 178.320 specifies general requirements for DOT specification cargo tank motor vehicles and paragraph (a) includes definitions that apply to DOT specification cargo tank motor vehicles.

PHMSA proposes to amend the following definitions:

- *Cargo tank*: During review of § 178.320, PHMSA noted that *cargo tank* was also defined in § 171.8, with minor editorial differences. PHMSA proposes to revise the § 171.8 definition of *cargo tank* to align with the current definition in § 178.320. See "Section IV. Section-by-Section Review; Part 171; Section 171.8" for details on the proposed changes to the § 171.8 definition of *cargo tank*. Subsequently, instead of also proposing to revise the definition in this section to match, PHMSA proposes to replace the definition of *cargo tank* with a reference to the definition in § 171.8. This avoids unnecessary duplication and ensures if a future revision is necessary, it will only have to be revised in a single location. Furthermore, this still ensures that a reader who looks to § 178.320 for the definition of *cargo tank* is able to locate the definition in § 171.8 easily.

- *Cargo tank motor vehicle*: The definition of *cargo tank motor vehicle* is currently defined in both §§ 171.8 and 178.320, with no differences between the two. Similar to the proposal to the definition of *cargo tank* in this section, PHMSA proposes to replace the § 178.320 definition of *cargo tank motor vehicle* with a reference to the definition in § 171.8. This avoids any potential future discrepancy between the same definition in two sections of the HMR.

- *Minimum thickness*: PHMSA proposes to add the word "in" to the last sentence of this definition, as an editorial amendment for correct grammar.

PHMSA proposes to add the following definitions:

- *Cargo tank motor vehicle certification date*: Based on stakeholder

feedback, PHMSA and FMCSA understand there is some confusion on the difference between the cargo tank motor vehicle certification date and the original test date. It is important to understand the difference, as the HMR require the cargo tank motor vehicle certification date to be marked on the specification plate, with the original test date marked on the name plate. To reduce any confusion, PHMSA proposes to add a definition for *cargo tank motor vehicle certification date* and *original test date*. PHMSA proposes to define *cargo tank motor vehicle certification date* as the date the cargo tank motor vehicle manufacturer certifies the completed cargo tank motor vehicle complies in all respects with the DOT specification and the ASME Code, if applicable. See below for a discussion on the proposed definition of *original test date*.

- **Component:** Section 178.320 currently defines an *appurtenance* as “any attachment to a cargo tank that has no lading retention or containment function and provides no structural support to the cargo tank.” Because a component may have some form of lading retention function, either during loading, unloading, in-transit, or a combination thereof, it does not meet the definition of an *appurtenance*. Having no definition in § 178.320 can cause confusion. Therefore, PHMSA proposes to add a definition for *component* to mean “any attachment to the cargo tank or cargo tank motor vehicle, including valves, piping, fittings, ladders, clips, protection devices, and hoses that contain lading during loading, unloading or transportation, or are required to be pressure or leak-tested in accordance with the requirements of part 180 of this subchapter.”

- **Flexible connector:** In § 180.407(d)(2)(ii) of this NPRM, PHMSA proposes to specify that a flexible connector is a part of the piping system, but it is not currently defined in the HMR. Therefore, PHMSA proposes to add a definition for the term *flexible connector*. The proposed definition is similar to the definition in NFPA Standard No. 58, and PHMSA proposes a *flexible connector* to mean “a short component of a piping system, not exceeding 36 in. (.91 m) overall length, fabricated of flexible material and equipped with suitable connections on both ends.” Furthermore, PHMSA proposes this definition specifies that “liquefied petroleum gas resistant rubber and fabric or metal, or a combination thereof, or all metal may be used.”

- **Lading retention system:** PHMSA proposes to add a definition of *lading retention system* as it is referenced several places in the HMR but is not currently defined. Having no definition in the HMR can cause regulatory confusion, so adding a definition will decrease confusion and enhance safety. PHMSA proposes that a *lading retention system* means “the cargo tank wall and any associated components or equipment that, if damaged, could result in the release of the contents of the package.” This proposed definition aligns with Letter of Interpretation Ref. No. 03–0057.⁴⁹ As specified in the letter, PHMSA considers piping and valves to be a part of the associated components or equipment in the lading retention system.

- **Lining:** There are a variety of linings used in the cargo tank industry, such as internal and external linings and coatings, and while the term is used throughout the HMR, it is not defined. By adding a definition of *lining* to § 178.320, PHMSA expects this will ensure effective communication within the regulated community and will prevent any future confusion, thus enhancing safety. PHMSA proposes *lining* to mean “an internal layer of different material covering the inside surface of the cargo tank.”

- **Name plate:** The terms “ASME plate,” “name plate,” and “specification plate” are not used throughout the HMR consistently. This has created a considerable amount of confusion among the regulated community. This uncertainty is amplified when considering the challenges associated with mounting a used ASME Code cargo tank to a new chassis. To address the issue and alleviate industry frustration, PHMSA proposes to establish a definition for *name plate* (as well as a definition for *specification plate*). PHMSA proposes *name plate* to mean “a data plate permanently attached to the cargo tank by the cargo tank manufacturer for the purpose of displaying the minimum information required by the ASME Code, as prescribed in §§ 178.337–17(b), 178.338–18(b), or 178.345–14(b) of this part, as appropriate.” PHMSA and FMCSA expect this definition aligns with current industry practice and stakeholder understanding. See below for a discussion on the proposed definition of *specification plate*.

- **Original test date:** As previously discussed, there is confusion on what constitutes the original test date marked

on the name plate and the cargo tank motor vehicle certification date stamped on the specification plate. Some in the regulated community have indicated the original test date is the date the cargo tank was actually completed, while others believe it is the cargo tank motor vehicle certification date. However, if the original test date is the date the cargo tank motor vehicle is certified, this does not take into account certain circumstances during the manufacturing process. For example, sometimes a cargo tank motor vehicle is constructed in two phases where the cargo tank is manufactured but it is assembled and mounted on a chassis at a later date (thus becoming a cargo tank motor vehicle). Alternatively, there are other circumstances where a cargo tank is assembled and mounted on a different chassis, and it is necessary to know when the original cargo tank was manufactured. Therefore, as previously discussed, to ensure consistent understanding of the HMR, PHMSA proposes to add definitions for *cargo tank motor vehicle certification date* and *original test date*. PHMSA proposes that *original test date* mean “the date the cargo tank manufacturer performed the original pressure test in accordance with part 178, to verify the structural integrity of the cargo tank in accordance with the requirements for new construction prescribed in this part.”

- **Sacrificial device:** PHMSA noted that *sacrificial device* is currently defined in § 178.345–1 (the section for DOT Specification 406, 407, and 412 cargo tank motor vehicles definitions); however, the definition also applies to DOT Specification MC 331 cargo tank motor vehicles. Therefore, PHMSA proposes to move the definition for *sacrificial device* from § 178.345–1(c) to § 178.320.

- **Shear section:** PHMSA noted that *shear section* is currently defined in § 178.345–1 (the section for DOT Specification 406, 407, and 412 cargo tank motor vehicles definitions); however, the definition also applies to DOT Specification MC 331 and 338 cargo tank motor vehicles. Therefore, PHMSA proposes to move the definition for *shear section* from § 178.345–1(c) to § 178.320.

- **Specification plate:** As previously mentioned, PHMSA proposes to add a definition for *specification plate* to help distinguish it from a *name plate* and provide greater clarity. PHMSA and FMCSA expect that this proposed definition aligns with current industry practice and stakeholder understanding. PHMSA proposes that a *specification plate* means “a data plate containing the applicable markings provided in

⁴⁹ See Letter of Interpretation Reference No. 03–0057: <https://www.phmsa.dot.gov/regulations/title49/inter/03-0057>.

§§ 178.337–17(c), 178.338–18(c), or 178.345–14(c), as appropriate, and permanently attached to the cargo tank or cargo tank motor vehicle chassis by the manufacturer. The markings on this plate are certification by the manufacturer that the cargo tank or the cargo tank motor vehicle conforms in all respects with the specification requirements of this subchapter.”

PHMSA requests comment on these proposed definitions and how they affect different functions. Specifically, are all the possible alternatives included in the proposed regulatory language? Does any of the proposed regulatory language obstruct current activities or functions?

Section 178.337–1

This section sets forth the general requirements for DOT Specification MC 331 cargo tank motor vehicles. Paragraph (d) addresses the requirement for reflective design of the cargo tank. PHMSA proposes to remove the requirement that specifies that the cargo tank must be painted. This is consistent with previously issued Letters of Interpretation Reference Nos. 11–0067, 14–0180, 15–0242, and 19–0107. This provides for additional regulatory flexibility while still maintaining safe transportation of hazardous materials. Specifically, PHMSA proposes to remove the requirement for the cargo tank to be painted, which allows for the use of a wrap, cover, or paint on uninsulated cargo tanks to meet the reflexivity performance standard.

Paragraph (g) provides definitions specific to MC 331 cargo tank motor vehicles. In review of this section, and the cargo tank motor vehicle definitions in § 178.320, PHMSA noted duplicative definitions for *internal self-closing stop valves* in §§ 178.320 and 178.337–1. PHMSA proposes to remove the definition of *internal self-closing stop valves* in § 178.337–1 to avoid unnecessary duplication and ensure that if the definition needs to be revised in the future, it only has to be revised in one regulatory section.

Section 178.337–2

This section details materials authorized for DOT Specification MC 331 cargo tanks. Paragraph (b)(2)(i) specifies the materials of construction for chlorine cargo tanks manufactured after January 1, 1975, must conform to ASTM A 612 Grade B or A 516/A 516M, Grade 65 or 70 (IBR, see § 171.7 of this subchapter). However, PHMSA and FMCSA noted that steel is no longer defined as grade A or B. Therefore, PHMSA proposes to remove the

reference to Grade B steel appropriately to remove any potential confusion.

Sections 178.337–3, 178.338–3, and 178.345–3

Sections 178.337–3, 178.338–3, and 178.345–3 detail structural integrity requirements for DOT Specification MC 331; MC 338; and DOT Specification 406, 407, and 412 cargo tank motor vehicles, respectively. Paragraph (g) in §§ 178.337–3 and 178.338–3 and paragraph (f) in § 178.345–3 specify the design, construction, and installation of an attachment, appurtenance, structural support member, or accident protection device.

In paragraph (g)(3) of §§ 178.337–3 and 178.338–3 and paragraph (f)(3) of § 178.345–3, PHMSA proposes to specify the welding of any appurtenance to the cargo tank wall applies to both “internal or external” appurtenances. Consistent with long-standing letters of interpretation previously issued by PHMSA, this revision provides regulatory clarity and ensures continued safe manufacture of cargo tank motor vehicles.⁵⁰ In these long-standing letters of interpretation, PHMSA notes that internal appurtenances may not be attached to the cargo tank wall without mounting pads. An example of internal appurtenances are baffles, which require mounting pads to be attached to the cargo tank wall.

PHMSA also proposes minor editorial revisions to §§ 178.338–3(g)(3) as well as § 178.345–3(f) and (f)(3) to ensure consistency throughout the HMR, as these paragraphs outline the same requirements for different types of cargo tank motor vehicles. In § 178.338–3(g)(3), PHMSA proposes to add the preposition “to” in the first sentence for grammatical accuracy. In addition, when comparing these paragraphs, PHMSA identified that “accident damage protection” was not specified in the applicability of § 178.345–3(f) for DOT 400 series cargo tanks, but it was identified in § 178.337–3(g) for MC 331 cargo tanks and § 178.338–3(g) for MC 338 cargo tanks. As these paragraphs have the same regulatory intent, PHMSA proposes to add accident damage protection to § 178.345–3(f). PHMSA expects this proposal will eliminate any potential confusion from regulatory inconsistency, which will increase safety. PHMSA also proposes to revise the first reference of “shell or

head” in § 178.345–3(f)(3) to read as “shell wall or head wall,” similar to §§ 178.337–3(g)(3) and 178.338–3(g)(3).

Furthermore, §§ 178.337–3(g)(3)(iii), 178.338–3(g)(3)(iii), and 178.345–3(f)(3)(iii) require that when welding any appurtenance to the cargo tank wall with a mounting pad, the pad must extend at least two inches in each direction from any point of an appurtenance or structural support member. The second sentences of these sections also specify “[t]his dimension may be measured from the center of the attached structural member.” PHMSA proposes to remove this sentence, because it can lead to confusion while only providing an option on how that measurement can be made. The circumstance for this option mostly applies to only small attachments where, because of either location or function, it is easy to measure from the center of the structural member. PHMSA expects that because this provision is only applicable in some, but not all, circumstances, it creates confusion in situations where the center of the attached structural member cannot be identified or the measurement from the center does not make sense. Therefore, to eliminate any potential confusion, PHMSA proposes to remove this sentence. Although PHMSA proposes to remove the regulatory instruction, the dimension may still be measured from the center of the attached structural member, if applicable.

Finally, PHMSA is proposing an editorial revision to these three sections to remove the phrase “or structural support members.” Structural support members are not required to be attached to the tank shell with mounting pads (see final rule HM–213)⁵¹ therefore PHMSA proposes to remove the phrase to eliminate confusion over requirements for use of mounting pads with structural support members.

Section 178.337–3

See “Section IV. Section-by-Section Review; Part 178; Sections 178.337–3, 178.338–3, and 178.345–3” for details on the revisions proposed to this section.

Sections 178.337–8, 178.338–11, and 178.345–11

Section 178.337–8 details requirements for the openings, inlets, and outlets of DOT Specification MC 331 cargo tank motor vehicles; § 178.338–11 details discharge control devices for DOT Specification MC 338 cargo tank motor vehicles; and

⁵⁰ See Letters of Interpretation Reference Nos. 07–0169 and 14–0235. Letter of Interpretation Reference No. 07–0169 is available at: <https://www.phmsa.dot.gov/regulations/title49/interp/07-0169>. Letter of Interpretation Reference No. 14–0235 is available at: <https://www.phmsa.dot.gov/regulations/title49/interp/14-0235>.

⁵¹ 68 FR 19257 (April 18, 2003).

§ 178.345–11 details tank outlet requirements for DOT Specification 406, 407, and 412 cargo tank motor vehicles. PHMSA proposes to add paragraph (a)(4)(vii) in § 178.337–8, paragraph (c)(2)(iii) in § 178.338–11, and paragraph (b)(1)(iv) in § 178.345–11 to require if the cargo tank is equipped with a mechanical means of remote closure for manual operation, it must not be obstructed by equipment or appurtenances in a manner that prevents access to or operation of the remote means in an emergency. FMCSA has encountered cargo tank motor vehicles where the manual emergency remote shut off device has been obstructed by various equipment or appurtenances that were added after the date of manufacture. This is a safety concern because obstructions to the manual emergency remote shut off device make the device harder to activate in an emergency, which may cause an incident to occur or worsen an incident in progress. Therefore, to address this safety concern, PHMSA proposes to provide an indication in new paragraphs §§ 178.337–8(a)(4)(vii), 178.338–11(c)(2)(iii), and 178.345–11(b)(1)(iv) that if equipped with a mechanical means of remote closure, it must not be obstructed to prevent operation or access in an emergency.

Section 178.337–8

See “Section IV. Section-by-Section Review; Part 178; Sections 178.337–8, 178.338–11, and 178.345–11” for details on the revision proposed to this section.

Section 178.337–9

This section prescribes requirements for PRDs, piping, valves, hoses, and fittings for DOT Specification MC 331 cargo tanks. Paragraph (a)(3) requires each valve used on a DOT Specification MC 331 cargo tank motor vehicle be designed, constructed, and marked for a rated pressure not less than the design pressure of the cargo tank. PHMSA proposes to replace the term “valve” with “pressure relief device” as this matches the title of paragraph (a) more appropriately.

Paragraph (b) specifies piping, valves, hoses, and fittings requirements for DOT Specification MC 331 cargo tanks. PHMSA proposes to revise the paragraph (b) title from “Piping, valves, hose, and fittings” to “Components and other pressure parts.” This proposed title aligns with the proposed § 178.320 definition of *components* and more appropriately illustrates the requirements of the paragraph. PHMSA expects this proposed change will help to reduce any regulatory confusion.

PHMSA also found the HMR does not assign responsibility to who must ensure that all components meet paragraph (b) requirements, causing potential regulatory confusion. To address this uncertainty, PHMSA proposes to specify that the cargo tank motor vehicle manufacturer is responsible for ensuring that all components comply with the paragraphs that follow. This aligns with other HMR requirements that require the cargo tank motor vehicle manufacturer to issue the certificate of construction as well as the specification plate and name plate. Therefore, PHMSA expects this proposed amendment to paragraph (b) will reduce regulatory uncertainty and thus, increases safety.

Paragraph (b)(1) specifies the burst pressure requirements for all piping, pipe fittings, hose, and other pressure parts, except for pump seals and PRDs. In order to be consistent with the ASME Code, PHMSA proposes to replace the phrase “design pressure” with the phrase “MAWP,” the acronym for maximum allowable working pressure used in the ASME Code. This proposed change eliminates an inconsistency between the ASME Code and the HMR and thus, increases safety. In addition, PHMSA proposes to revise the reference for chlorine service from paragraph (b)(7) to paragraph (b)(8), as an editorial amendment.

Paragraph (b)(6) requires cargo tank manufacturers and fabricators to demonstrate that all piping, valves, and fittings installed on a cargo tank are free from leaks by testing them at not less than 80 percent of the design pressure marked on the cargo tank. PHMSA proposes to replace the term “cargo tank manufacturers and fabricators” with “cargo tank motor vehicle manufacturers” as this better aligns with the responsibilities of manufacturers of cargo tank motor vehicles. Additionally, and similar to the proposed change in paragraph (a)(3), PHMSA proposes to revise the terminology to test at not less than 80 percent of “design pressure” to “MAWP,” as this better aligns with ASME requirements. Lastly, PHMSA proposes to specify the test should be conducted based off the “name plate after the piping is installed on the cargo tank motor vehicle” as opposed to “cargo tank” to provide further clarity on this requirement. These proposed changes provide regulatory clarity without impacting safety.

Paragraph (b)(7) specifies requirements for a hose assembler of DOT Specification MC 331 cargo tanks. PHMSA proposes to move the requirements in paragraph (b)(7) to its

own new paragraph (e) to provide enhanced visibility, improve regulatory compliance, and thus, improve safety. Subsequently, PHMSA proposes to reserve paragraph (b)(7). Furthermore, in new paragraph (e), PHMSA proposes to add a title of “hose assembler requirements” to align with the rest of § 178.337–9 and the Office of Federal Register Document Drafting Handbook, which requires that when one section paragraph has a heading, all of the other paragraphs in the section should as well. Lastly, as a clarifying statement, PHMSA proposes to reference the § 180.416(f) written report requirement for the hose assembler tests. PHMSA expects that adding this reference will improve compliance and therefore, increase safe transportation of hazardous materials.

Sections 178.337–10 and 178.338–10

These sections detail accident damage protection requirements of DOT Specification MC 331 and MC 338 cargo tank motor vehicles. Paragraph (c)(1) of both sections specify rear-end tank protection device requirements. PHMSA proposes to replace the words “valves, piping, and fittings” with “components,” as this is consistent with the new definition proposed in § 178.320.

Paragraph (c)(1) also specifies the rear bumper dimensions must meet the requirements of § 393.86. However, FMCSA notes there is stakeholder confusion on whether the referenced dimensional requirements or the wheels back vehicle exception in § 393.86 applies. The historical applicability and intent of this paragraph is that the referenced dimensional requirements in § 393.86 apply to accident damage protection. Therefore, to remove any potential confusion, and therefore, increase safety, PHMSA proposes to add a sentence specifying that the wheels back exception provided in 49 CFR 393.86 does not apply.

Section 178.337–10

See “Section IV. Section-by-Section Review; Part 178; Sections 178.337–10 and 178.338–10” for details on the revisions proposed to this section.

Sections 178.337–17 and 178.338–18

Sections 178.337–17 and 178.338–18 detail marking requirements for DOT Specification MC 331 and MC 338 cargo tank motor vehicles, respectively. Paragraph (a) details general requirements for both the name plate and the specification plate. In addition to editorial revisions, PHMSA proposes to specify that the responsibility of applying the name plate and

specification plate fall on the manufacturer, as a clarifying statement. While not explicitly stated, this codifies current practice to remove any ambiguity and ensure continued safe hazardous materials transportation. PHMSA notes this requirement means that the requirements for the name plate, when applicable, and specification plate fall on the person responsible for building the cargo tank, cargo tank motor vehicle, or both. PHMSA also proposes to remove the compliance date of October 1, 2004, as this date has passed, and all DOT Specification MC 331 and MC 338 cargo tank motor vehicles are subject to these requirements.

Paragraph (a)(4) in both sections indicates the specification plate may be attached to the cargo tank motor vehicle chassis rail and details methods on how to do so. PHMSA proposes to revise paragraph (a)(4) to specify the specification plate must be attached to the cargo tank or its integral supporting structure, instead of the cargo tank motor vehicle chassis rail. A DOT Specification MC 331 or MC 338 cargo tank potentially has a longer useable lifespan than the life of the motor vehicle chassis to which it is originally attached. As such, it is possible for the original specification plate to be separated from the cargo tank if the cargo tank is remounted to a different chassis, which poses a safety risk to knowing the specification of the cargo tank. Therefore, to remove this possible scenario, PHMSA proposes to require the specification plate be mounted to the cargo tank itself or an integral supporting structure. Additionally, PHMSA proposes minor editorial amendments for sentence structure clarity. These changes increase regulatory consistency by aligning the specification plate attachment language with that of the DOT 400 series cargo tank motor vehicle specification.

Section 178.337–17

See “Section IV. Section-by-Section Review; Part 178; Sections 178.337–17 and 178.338–18” for details on the revisions proposed to this section.

Section 178.337–18

This section requires appropriate documentation certifying that a completed cargo tank motor vehicle conforms to DOT Specification MC 331 cargo tank requirements and the ASME Code. PHMSA proposes revisions that better align this section with the certification requirements (and proposed changes) in §§ 178.338–19 and 178.345–15 to increase regulatory

consistency and thus, compliance and safety.

Paragraph (a) details requirements for the cargo tank data report and a certificate of construction. In the introductory text to paragraph (a), PHMSA proposes to specify the data report is the “cargo tank’s ASME Form U–1A data report as required by Section VIII of the ASME Code” to align with §§ 178.338–19(a)(1) and 178.345–15(b)(2). Additionally, as an editorial amendment, PHMSA proposes to clarify the “certificate” is the “Certificate of Compliance.” PHMSA proposes to make similar editorial changes in paragraphs (a)(1) and (3).

Moreover, PHMSA proposes to add language to paragraph (a)(3) to specify that when a cargo tank motor vehicle is manufactured in two or more stages and after the cargo tank motor vehicle is brought into full compliance with the applicable specification and ASME Code, the final manufacturer must mark the specification plate with the cargo tank motor vehicle certificate date and attach the specification plate to the completed cargo tank in accordance with § 178.338–18(a). PHMSA expects this proposed language better aligns this section with §§ 178.338–19 and 178.345–15 and current ASME Code requirements.

Lastly, PHMSA proposes to make a minor editorial amendment to paragraph (a)(4) by removing the indication that the cargo tank motor vehicle must have the Registered Inspector stamp, the specification plate, and issue a Certificate of Compliance, and instead specifying that the Registered Inspector shall complete these actions. This aligns the paragraph better with §§ 178.338–19 and 178.345–15.

Section 178.338–3

See “Section IV. Section-by-Section Review; Part 178; Sections 178.337–3, 178.338–3, and 178.345–3” for details on the revisions proposed to this section.

Section 178.338–10

See “Section IV. Section-by-Section Review; Part 178; Sections 178.337–10 and 178.338–10” for details on the revisions proposed to this section.

Section 178.338–11

See “Section IV. Section-by-Section Review; Part 178; Sections 178.337–8, 178.338–11, and 178.345–11” for details on the revision proposed to this section.

Section 178.338–18

See “Section IV. Section-by-Section Review; Part 178; Sections 178.337–17

and 178.338–18” for details on the revisions proposed to this section.

Section 178.338–19

This section details the requirements for the certification of DOT Specification MC 338 insulated cargo tank motor vehicles. PHMSA proposes revisions that better align this section with the certification requirements (and proposed changes) in §§ 178.337–18 and 178.345–15 to increase regulatory clarity.

Paragraph (a) specifies documents that must be furnished to the owner of a cargo tank motor vehicle. PHMSA proposes to move the current language in paragraph (a)(1) to paragraph (a) introductory text, with minor editorial amendments. Subsequently, PHMSA proposes to revise paragraph (a)(1) to specify that the Certificate of Compliance must be signed by an official of the manufacturer responsible for compliance and a DCE. As mentioned, these changes better align this section with §§ 178.337–18 and 178.345–15 to increase regulatory consistency and clarity. There are no proposed revisions to paragraph (a)(2), but it appears in the regulatory text of this NPRM for the **Federal Register**.

Paragraph (b) specifies requirements when a cargo tank is manufactured in two or more stages. PHMSA proposes to redesignate paragraph (b) as paragraph (a)(3) in addition to editorial amendments to mirror § 178.337–18. Additionally, PHMSA proposes to specify that when the cargo tank motor vehicle is brought into full compliance with the applicable specification and ASME Code, the final manufacturer must mark the specification plate with the cargo tank motor vehicle certificate date and attach the specification plate to the completed cargo tank in accordance with § 178.338–18(a). PHMSA also proposes to remove the language in this paragraph related to what the certification must include.

Paragraph (c) details requirements in the event of a change in ownership. Because PHMSA proposes to redesignate paragraph (b) as paragraph (a)(3), PHMSA proposes to redesignate paragraph (c) as paragraph (b). Because of this proposed redesignation, PHMSA proposes to reserve paragraph (c). Lastly, PHMSA proposes editorial amendments in new paragraph (b) to align with other cargo tank specification certification sections.

Section 178.345–1

This section details the general requirements for DOT Specification 406, 407, and 412 cargo tank motor vehicles. Paragraph (c) includes definitions for

these types of cargo tank motor vehicles. However, there are several definitions in § 178.345–1 that are also found in § 178.320, some of which have different wording. As this could cause confusion, PHMSA proposes to remove all the definitions which are already found in § 178.320. Reducing confusion in the regulations helps to increase compliance and thus, safety. Additionally, and as discussed in “Section IV. Section-by-Section Review; Part 178; Section 178.320,” PHMSA proposes to move the definitions for *sacrificial device* and *shear section* to § 178.320 as they apply to other types of cargo tank motor vehicles in addition to DOT Specification 406, 407, and 412 cargo tank motor vehicles.

Section 178.345–3

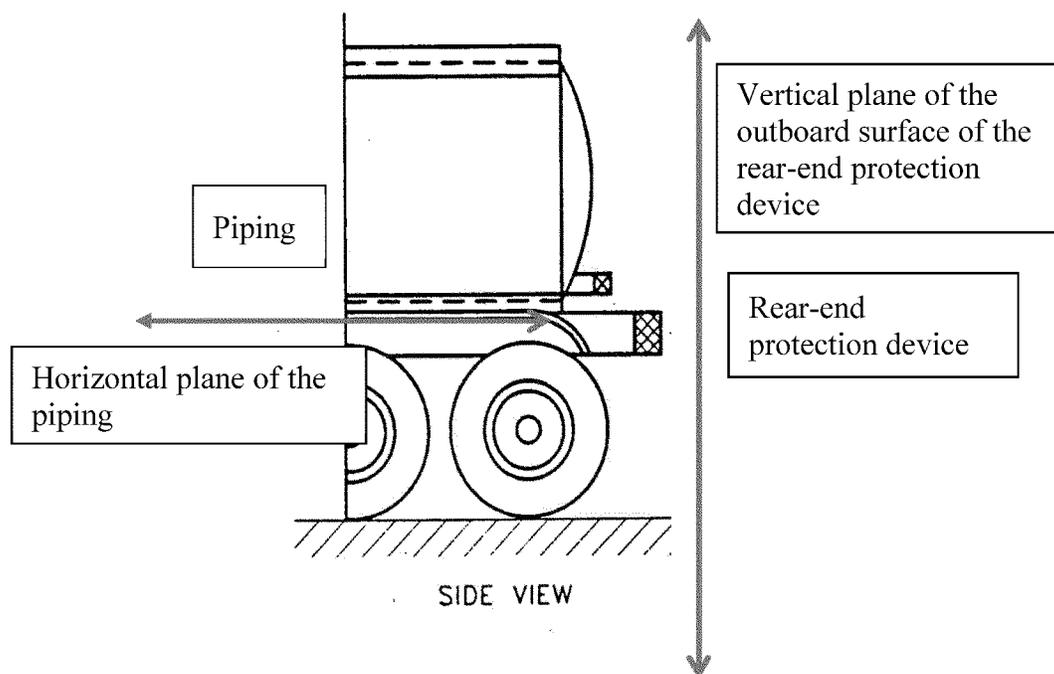
See “Section IV. Section-by-Section Review; Part 178; Sections 178.337–3, 178.338–3, and 178.345–3” for details on the revisions proposed to this section.

Section 178.345–8

This section details accident damage protection for DOT Specification 406, 407, and 412 cargo tank motor vehicles. Paragraph (d) specifies rear-end tank protection, with paragraph (d)(1) describing design requirements for the rear-end cargo tank protection device. PHMSA proposes to split paragraph (d)(1) into two paragraphs—paragraphs (d)(1)(i) and (ii)—to better clarify

deflection design requirements and increase readability, which ultimately increases safety. PHMSA proposes that paragraph (d)(1)(i) contains the rear-end cargo tank protection device design requirements for cargo tanks where the rear-end protection device is on the same horizontal plane as the component. PHMSA proposes that paragraph (d)(1)(ii) contains design requirements for a rear-end cargo tank protection device when the component is not on the same horizontal plane. This proposed language is for clarification. Figure 1 details the difference between the vertical plane and horizontal plane.

Figure 1: Section 178.345-8 Difference between Vertical Plane and Horizontal Plane



Paragraph (d)(2) indicates the dimension requirements for the rear-end cargo tank protection device. Paragraph (d)(3) specifies additional design requirements for the rear-end protection device and its attachments on DOT Specification 406, 407, and 412 cargo tank motor vehicles. In paragraphs (d)(2)(i)–(iii) and (3), PHMSA proposes to spell out the dimensions instead of using a numerical value, for grammatical correctness.

During review of cargo tank motor vehicle manufacturers and other facilities that design and install rear-end protection devices, FMCSA inspectors identified that manufacturers who

calculate and construct rear-end devices were not properly calculating the 2 “g” impact, which is a result of potentially confusing regulations in paragraph (d)(3). As this results in non-compliant rear-end protection devices that fail under impact, PHMSA proposes to revise paragraph (d)(3) to clarify this requirement and ensure the continued safe transportation of hazardous materials. To achieve this clarity, PHMSA proposes to revise the term “rated payload” to “gross vehicle weight rating” and add a sentence to specify “the structures supporting the rear-end protection device, including the frame and the attachments to the

frame must be capable of withstanding the 2 ‘g’ load.”

Section 178.345–11

This section details requirements for the openings, inlets, and outlets of DOT Specification 406, 407, and 412 cargo tank motor vehicles. Paragraph (b) requires each cargo tank loading/unloading outlet to be equipped with an internal or external self-closing stop valve. PHMSA proposes to revise paragraph (b)(1)(ii) to specify that if the actuating system fails, each loading/unloading outlet must remain securely closed and capable of retaining the cargo tank’s lading. This provides

additional clarification that failure is another circumstance where the loading/unloading outlet must remain securely closed if the actuating system fails. This increases safety because if the actuating system fails, the outlet should still be closed and capable of retaining liquid to ensure continued safe transportation of hazardous materials.

See “Section IV. Section-by-Section Review; Part 178; Sections 178.337–8, 178.338–11, and 178.345–11” for details on the proposal to add paragraph (b)(1)(iv) to this section.

Section 178.345–13

This section specifies the pressure and leakage test requirements for DOT Specification 406, 407, and 412 cargo tank motor vehicles, with paragraph (a) detailing that the pressure and leakage tests must be in accordance with this section and §§ 178.346–5, 178.347–5, or 178.348–5. PHMSA proposes to revise the language in paragraph (a) to specify that the pressure and leakage tests must be performed by the cargo tank motor vehicle manufacturer. This aligns with current industry practice and provides a clear distinction on the person with responsibility to perform these tests, which increases regulatory compliance and safety.

PHMSA also proposes to add a sentence to specify the leakage test shall be performed after the piping is installed on the cargo tank motor vehicle. PHMSA and FMCSA expect that this aligns with current industry practice, while ensuring the continued safe transport of the cargo tank motor vehicle and reducing the likelihood of a release of hazardous materials.

Section 178.345–14

This section specifies the marking requirements for DOT Specification 406, 407, and 412 cargo tank motor vehicles. Paragraph (a) provides general certification requirements. PHMSA proposes to add a clarifying statement to paragraph (a) that if information is required to be displayed on the name plate, it does not need to be repeated on the specification plate. This is consistent with other DOT specification requirements.

PHMSA also proposes certain editorial amendments in this section. Paragraph (b)(3) indicates that the tank MAWP in psig must be marked on the tank nameplate. In this paragraph, PHMSA proposes to specify that by “tank,” the requirement applies to a “cargo tank.” Paragraph (c) provides requirements for marking of the specification plate, with paragraphs (c)(6) and (7) requiring the marking of the maximum loading and unloading

rates, respectively. PHMSA proposes to revise paragraph (c)(6) to allow for “NONE” and paragraph (c)(7) to allow for “OPEN MH” or “NONE” as an indication of no limit on the loading and unloading rate, respectively.

Lastly, paragraph (d) includes the requirements for a multi-cargo tank motor vehicle. PHMSA proposes to revise this paragraph to refer to the definition of *design type* in § 178.320(b) instead of the “same materials, manufactured thickness, minimum thickness, and to same specification.” This revision is intended to clarify the intent of the exception from the requirement to display multiple name plates for compartmented cargo tanks separated by voids. “Design type” is a more efficient and simpler phrase to communicate the intent of this exception.

Section 178.345–15

This section details certification requirements for DOT Specification 406, 407, and 412 cargo tank motor vehicles. PHMSA proposes revisions that better align this section with the certification requirements (and proposed changes) in §§ 178.337–18 and 178.338–19.

Paragraph (a) includes requirements for certification documents. In paragraph (a), PHMSA proposes to expand the requirements. This includes requiring that the cargo tank motor vehicle manufacturer must supply, and the owner must obtain, a cargo tank’s ASME Form U–1A data report as required by Section VIII of the ASME Code and a Certificate of Compliance stating that the completed cargo tank motor vehicle conforms in all respects to the DOT specification and the ASME Code. As mentioned, this better aligns paragraph (a) with other cargo tank certification requirements in §§ 178.337–18 and 178.338–19.

Paragraph (b)(1) details the signatory requirements of the certificate. Similar to proposed changes in paragraph (a), PHMSA proposes to revise paragraph (b)(1) to specify the certificate must be a Certificate of Compliance signed by an official of the cargo tank motor vehicle manufacturer responsible for compliance, and a DCE.

Lastly, paragraph (e) includes requirements for specification shortages. PHMSA proposes to revise paragraph (e) editorially to better align this paragraph with other cargo tank specification certification requirements. The substantive requirements for cargo tanks manufactured in two or more stages are not changed in this proposal.

Section 178.348–1

This section specifies the general requirements for DOT Specification 412 cargo tank motor vehicles. Paragraph (d) requires a cargo tank with a MAWP greater than fifteen psig must be of circular cross-section. Paragraph (e) specifies ASME construction requirements depending on the MAWP of the cargo tank. Cargo tank manufacturers have expressed confusion over the current regulatory requirements in this section, particularly when a DOT 412 specification cargo tank must be certified to the ASME Code. Therefore, to alleviate this confusion and increase regulatory compliance, PHMSA proposes to revise paragraph (d) to specify when a cargo tank motor vehicle has a MAWP greater than fifteen psig, it must be constructed and certified in accordance with Section VIII of the ASME Code. Subsequently, PHMSA proposes to revise paragraph (e) to specify when a cargo tank motor vehicle has a MAWP of fifteen psig or less, it must be constructed in accordance with Section VIII. PHMSA also proposes to redesignate paragraphs (e)(2)(i)–(viii) as paragraphs (e)(1)–(8) without making any revisions, other than an editorial revision in current paragraph (e)(2)(iii) to spell out the numerical value of 15 psig. These proposed revisions are not intended to amend the intent of the section, but instead increase regulatory clarity.

Part 179

Section 179.2

Section 179.2 is the definition section for tank car specifications in part 179. PHMSA proposes to add introductory text to specify that terms defined in §§ 171.8 and 180.503 for tank car maintenance and qualification also apply to part 179. This will help to address any confusion with defined terms in these related regulatory sections.

In addition, PHMSA proposes to amend the following definitions:

- *Approved*: In paragraph (a)(2), PHMSA proposes to remove the reference to the AAR Tank Car Committee and replace it with a reference to DCE approval. See “Section II.B.2. Tank Car Design Approval” for additional details.

- *Tank car facility*: PHMSA proposes to amend this definition to express the original intent that only facilities that qualify tank cars for transportation meet the definition. See “Section II.B.4. Tank Car Facility Definition” for additional details.

PHMSA proposes to add the following definitions:

- *Component*: PHMSA proposes to add this definition in paragraph (a)(4) to mean “service equipment, safety systems, linings or coatings, other elements specifically required by this part and any elements used to achieve a performance standard in this part.” This new definition is intended to align with commonly understood industry usage and will increase clarity in the HMR.

- *Tank car*: This new definition is proposed for the purposes of construction, maintenance, and qualification in parts 179 and 180. As proposed, *tank car* means “a tank car tank and all of its components.” This definition aligns with commonly understood industry usage and will increase clarity in the HMR. To ensure paragraph (a) remains alphabetical, this new definition is proposed to replace the currently reserved paragraph (a)(9).

Section 179.3

Section 179.3 currently prescribes requirements to submit tank car designs to AAR for approval. PHMSA proposes to rename and extensively revise this section to remove the requirement for AAR approval and replace it with a requirement for design approval by a registered tank car DCE. See “Section II.B.2. Tank Car Design Approval” for additional details. PHMSA proposes that one Design Approval Certificate issued for the tank car or service equipment will cover all tank cars or service equipment built to an approved design, material and construction, or modification, provided the tank cars or service equipment are identical. When ownership of a tank car is transferred, the new owner must obtain the Design Approval Certificate from the previous owner or Design Certifying Engineer for the tank car to remain in service. Builders and shippers may apply for special permits for unapproved tanks and equipment, in accordance with the special permit procedural requirements in §§ 107.101–107.127.

Section 179.4

Section 179.4 currently prescribes requirements for proposing a new tank car specification to AAR. PHMSA proposes to revise this section. The role of the AAR TCC in the review of new tank car specifications is proposed to be replaced with review by a registered tank car DCE. Proposals for new tank car specifications must first be submitted for review by a DCE. If the DCE determines the new specification design is suitable, then the designer of the new specification design must then apply to

PHMSA for a DOT–SP to construct and use the tank cars or submit a petition for rulemaking to add the new specification to the HMR. See “Section II.B.2. Tank Car Design Approval” for additional details.

Section 179.5

Section 179.5 currently prescribes requirements for the tank car Certificate of Construction. PHMSA proposes to change the name of the section from “Certificate of construction” to “Design Approval Certificate” and extensively revise this section to reflect the new DAC requirements. PHMSA proposes that the new DAC requirements generally mirror the information and drawings currently required to be submitted to AAR on AAR Forms 4–2 or 4–5, for tank car tanks and service equipment, respectively. PHMSA proposes that the DCE must ensure all required information is present on the DAC, review the materials, certify compliance with the HMR by signing the certification statement, and submit the DAC to the tank car owner.

While generally mirroring the information required on the AAR Form 4–2 or 4–5, PHMSA proposes that instead of requiring the initial commodity (as currently required on AAR Form 4–2 or 4–5), the DAC must list all of the materials intended for transportation in the tank car and service equipment. This commodity information is critical to determining appropriate materials of construction and fitting arrangements for the tank car design, among other design considerations. If a tank car user decides to use the tank car or service equipment to transport a commodity not listed on the DAC, PHMSA proposes that the DCE must modify the DAC to approve the transportation of the new material before the tank car or service equipment may be used for the new commodity. As proposed, the DCE must evaluate the design of the tank car and service equipment, including but not limited to material compatibility, design pressure, operating temperature, and service life when determining whether the tank car or service equipment is appropriate for the new commodity.

See “Section II.B.2. Tank Car Design Approval” for additional details on these proposed changes.

Section 179.6

Section 179.6 prescribes requirements for tank car repairs and alterations. PHMSA proposes a minor revision to this section. PHMSA proposes to no longer require compliance with those sections of AAR Specifications for Tank Cars Appendix R that require AAR

approval for tank car repairs. Rather, PHMSA proposes that for all tank car repairs not specifically described in Appendix R, DCE approval is required.

Section 179.7

Section 179.7 prescribes requirements for a tank car facility QAP. PHMSA proposes to no longer require tank car facilities to seek AAR approval for QAPs. PHMSA proposes that each tank car facility must register with PHMSA under proposed part 107 subpart J and certify that it maintains QAP that meets the requirements of parts 107 and 179.

PHMSA proposes several additional revisions to the QAP requirements:

- Remove reference to “repair” in paragraphs (a)(2), (b)(3), (b)(5), and (f) because “repair” is already encompassed in the § 180.503 definition of *maintenance*.

- Remove “program” in paragraph (a)(2), to clarify that the QAP must identify non-conformities in the tank car during manufacture, inspection, testing, qualification, and maintenance of the tank car.

- Add the phrase “qualification and maintenance” in paragraph (b)(3) to align the scope of the QAP with qualification.

- Revise paragraph (b)(4) to require that the tank car facility’s QAP covers all materials and components that are installed to create the tank car. The tank car facility that qualifies the car is responsible for all activities prior to qualification.

- Add the word “applicable” to paragraph (b)(8) to indicate there are requirements in the AAR Specifications for Tank Cars that are no longer applicable to tank car facilities (*e.g.*, approval requirements).

- Remove “AAR” from paragraph (d) because PHMSA proposes to no longer require AAR approval. See “Section II.B.2. Tank Car Design Approval” for additional details.

- Revise paragraph (f) to add a requirement that a tank car facility must maintain a valid tank car facility registration in accordance with part 107, subpart J.

See “Section II.B.3. Tank Car Facility Quality Assurance Program” for further details on the proposed changes to QAP requirements.

Section 179.10

Section 179.10 discusses requirements for tank mounting. PHMSA proposes to require that tank mounting arrangements meet the requirements of AAR Specifications for Tank Cars Chapter 6 in currently reserved paragraph (b). This will address NTSB Recommendation R–12–

007, which recommends that PHMSA address deficiencies in tank car center sill or draft attachment designs by adopting AAR's revised attachment requirements. The 2014 edition of AAR Specifications for Tanks Cars proposed for incorporation contains the recommended revised center sill and draft attachment requirements, which addresses separate NTSB Recommendation R-12-009 issued to AAR.

Section 179.11

Section 179.11 prescribes the requirements for tank car welding procedures. Paragraph (a) currently requires that welding procedures, welders, and fabricators be approved by AAR. PHMSA proposes to revise paragraph (a) to require that welding procedures, welders, and fabricators must meet the requirements in AAR Specifications for Tank Cars Appendix W, except for compliance with paragraph 1.2. Appendix W, which is already incorporated by reference into the welding-specific sections in part 179 (e.g., § 179.100-9). If this proposal were adopted in a final rule, compliance with paragraph 1.2 of Appendix W, which requires AAR certification for the facility at which the welding occurs, would no longer be required. Facilities that conduct fusion welding on tank cars that meet the definition of "tank car facility," as proposed in this NPRM, must register with PHMSA. See "Section II.B.4. Tank Car Facility Definition" and "Section II.B.5. Tank Car Facility and Design Certifying Engineer Registration" for further details.

Section 179.24

This section discusses requirements for permanent identification plates mounted on the inboard surfaces of the body bolsters of a tank car. PHMSA proposes to revise paragraph (a)(2), to remove reference to the AAR form. Additionally, PHMSA proposes to remove and reserve paragraph (a)(3)(i), which, requires stamping the AAR Number on the identification plates. PHMSA proposes these edits to conform to the proposal to replace AAR TCC approval with approval by a tank car DCE. Specifically, PHMSA proposes to remove reference to AAR Form 4-2 in paragraphs (a)(2), (a)(2)(i), (a)(2)(iv), (a)(2)(v), (a)(2)(viii), and (a)(3)(i), as PHMSA proposes to replace the AAR Form 4-2 requirement with a DAC. Additionally, PHMSA proposes to remove and reserve paragraph (a)(2)(iii) to remove the requirement to stamp the AAR approval number as this has no equivalent in the DAC.

Sections 179.100-9, 179.100-10, 179.100-18, 179.200-10, 179.200-11, 179.200-22, 179.220-10, 179.220-11, 179.300-9, 179.300-10, 179.400-11, 179.400-12, 179.400-15, and 179.400-18

These sections deal with welding requirements for tank cars and incorporate by reference the AAR Specifications for Tank Cars (M-1002) Appendix W. In each section, PHMSA proposes to add language indicating compliance with paragraph 1.2 of Appendix W is not required, because that paragraph of Appendix W requires AAR certification for the facility at which welding occurs. Facilities that conduct fusion welding on tank cars that meet the definition of "tank car facility," as proposed in this NPRM, must register with PHMSA. Tank car facilities that qualify tank cars that have undergone welding at another location are responsible for ensuring that the welding operations are conducted in accordance with Appendix W. See "Section II.B.4. Tank Car Facility Definition" and "Section II.B.5. Tank Car Facility and Design Certifying Engineer Registration" for further details. Additionally, in §§ 179.100-9, 179.200-10, and 179.220-10, PHMSA proposes to remove the sentence requiring that welding procedures, welders, and fabricators be approved. Welding procedures, as well as welder and fabricator qualification must be addressed in a tank car facility's quality assurance program. See "Section II.B.3. Tank Car Facility Quality Assurance Program" for additional details.

Section 179.100-9

See "Section IV. Section-by-Section Review; Part 179; Sections 179.100-9, 178.100-10, 179.100-18, 179.200-10, 179.200-11, 179.200-22, 179.220-10, 179.220-11, 179.300-9, 179.300-10, 179.400-11, 179.400-12, 179.400-15, and 179.400-18" for details on the revisions proposed to this section.

Section 179.100-10

See "Section IV. Section-by-Section Review; Part 179; Sections 179.100-9, 178.100-10, 179.100-18, 179.200-10, 179.200-11, 179.200-22, 179.220-10, 179.220-11, 179.300-9, 179.300-10, 179.400-11, 179.400-12, 179.400-15, and 179.400-18" for details on the revisions proposed to this section.

Section 179.100-12

Section 179.100-12 outlines the use of manway nozzles, covers, and protective housing on rail cars. Paragraph (c) details requirements for bolting the protecting housing to the manway cover. PHMSA proposes to

revise § 179.100-12(c) to permit the use of an alternative means of connecting the manway protection housing to the tank car. See "Section II.F. P-1724" for further discussion on this proposed change. PHMSA also proposes a minor grammatical amendment to paragraph (c) to spell out "seventy percent" instead of a numerical value.

Section 179.100-18

See "Section IV. Section-by-Section Review; Part 179; Sections 179.100-9, 178.100-10, 179.100-18, 179.200-10, 179.200-11, 179.200-22, 179.220-10, 179.220-11, 179.300-9, 179.300-10, 179.400-11, 179.400-12, 179.400-15, and 179.400-18" for details on the revisions proposed to this section.

Section 179.102-3

Section 179.102-3 prescribes additional requirements for pressure tank cars containing poisonous-by-inhalation material. PHMSA proposes to IBR the requirements of section 2.2.1.2 of Chapter 2 of the AAR Specifications for Tank Cars, M-1002. Specifically, PHMSA proposes to require tank cars manufactured after the effective date of an eventual final rule that transport poisonous-by-inhalation hazardous material have tank car heads and shells that are Charpy impact tested in accordance with the requirements of section 2.2.1.2.

Please note that the exception in AAR Specifications for Tank Cars Chapter 2 section 2.2.1.2 exempts shell and head material intended for low temperature service that is subject to longitudinal Charpy impact testing at -50 °F from the transverse Charpy impact test. Therefore, steel used for the head and shell of hydrogen chloride tank cars is not subject to the transverse Charpy impact test proposed here but remains subject to the longitudinal Charpy impact testing at -50 °F in accordance with § 179.102-17.

This proposed change responds to NTSB recommendation R-19-001,⁵² which recommended that PHMSA implement enhanced fracture toughness requirements for tank heads and shells for tank cars transporting poisonous-by-inhalation material. Although not incorporated by reference in the HMR, tank car manufacturers have been subject to this test requirement since 2005 through AAR interchange standards. Therefore, PHMSA expects that this proposed amendment will not place any additional burden on tank car manufacturers while improving safety

⁵² See NTSB Safety Recommendation R-19-001: <https://www.nts.gov/safety/safety-recs/reclatters/R-19-001-005.pdf>.

by increasing clarity on steel toughness requirements for PIH tank cars.

Section 179.103–5

Section 179.103–5 prescribes requirements for bottom outlets for DOT–114A tank cars. In accordance with the proposal to remove all reference to approval by the AAR, PHMSA proposes to remove the phrase “approved by the AAR Committee on Tank Cars” in paragraph (b)(1) for permanent attachment of supplementary exterior fittings. As proposed, a DCE will fill the approval role previously delegated to AAR. See “Section II.B.2. Tank Car Design Authority” for additional details.

Section 179.200–7

This section specifies authorized materials of construction for non-pressure tank car tanks (Classes DOT–111AW, 115AW, and 117AW). Paragraph (b) specifies allowable steels for the carbon steel plate. Currently, ASTM A 537 steel is not authorized in paragraph (b).⁵³ However, ASTM A 537 steel has similar properties to ASTM A 516 steel, which is currently authorized in paragraph (b). Furthermore, ASTM A 537 steel is currently authorized in § 179.100–7 for pressure tank cars. PHMSA has also received a petition requesting authorization to use ASTM A 537 steel in construction of non-pressure tank cars (P–1760; Baier Rail).⁵⁴ Lastly, PHMSA has issued DOT–SP 20908 to allow for the use of ASTM A 537 steel for non-pressure tank car tanks.⁵⁵ Therefore, PHMSA proposes to add ASTM A 537 steel to the table in paragraph (b). Please note, DOT–SP 20908 requires radiographic examination for 1 out of every 50 nozzle groove weld joints produced in accordance with the special permit. This condition is a requirement associated with the 7.5-inch nozzle extension authorized in the special permit; therefore, we do not propose to adopt this condition into the HMR for tank cars and appurtenances constructed solely from ASTM A 537 steel. PHMSA seeks comment on this proposal.

Section 179.200–10

See “Section IV. Section-by-Section Review; Part 179; Sections 179.100–9,

178.100–10, 179.100–18, 179.200–10, 179.200–11, 179.200–22, 179.220–10, 179.220–11, 179.300–9, 179.300–10, 179.400–11, 179.400–12, 179.400–15, and 179.400–18” for details on the revisions proposed to this section.

Section 179.200–11

See “Section IV. Section-by-Section Review; Part 179; Sections 179.100–9, 178.100–10, 179.100–18, 179.200–10, 179.200–11, 179.200–22, 179.220–10, 179.220–11, 179.300–9, 179.300–10, 179.400–11, 179.400–12, 179.400–15, and 179.400–18” for details on the revisions proposed to this section.

Section 179.200–17

Section 179.200–17 prescribes requirements for bottom outlets for DOT–111 and DOT–117 non-pressure tank cars. In accordance with the intent to remove all references to approval by the AAR TCC, PHMSA proposes to remove the phrase “by the AAR Committee on Tank Cars.” A DCE will fill the approval role previously delegated to AAR. See “Section II.B.2. Tank Car Design Authority” for additional details.

Section 179.200–22

See “Section IV. Section-by-Section Review; Part 179; Sections 179.100–9, 178.100–10, 179.100–18, 179.200–10, 179.200–11, 179.200–22, 179.220–10, 179.220–11, 179.300–9, 179.300–10, 179.400–11, 179.400–12, 179.400–15, and 179.400–18” for details on the revisions proposed to this section.

Section 179.220–10

See “Section IV. Section-by-Section Review; Part 179; Sections 179.100–9, 178.100–10, 179.100–18, 179.200–10, 179.200–11, 179.200–22, 179.220–10, 179.220–11, 179.300–9, 179.300–10, 179.400–11, 179.400–12, 179.400–15, and 179.400–18” for details on the revisions proposed to this section.

Section 179.220–11

See “Section IV. Section-by-Section Review; Part 179; Sections 179.100–9, 178.100–10, 179.100–18, 179.200–10, 179.200–11, 179.200–22, 179.220–10, 179.220–11, 179.300–9, 179.300–10, 179.400–11, 179.400–12, 179.400–15, and 179.400–18” for details on the revisions proposed to this section.

Section 179.220–15

Section 179.220–15 details requirements for support systems for DOT–115 tank cars. PHMSA proposes to remove the phrase “of approved design” from paragraph (b) for cushioning devices. It is PHMSA and FRA’s understanding that AAR approvals are

not currently issued for cushioning devices. Therefore, PHMSA proposes that a tank car manufacturer may certify the cushioning device tested to meet the performance standards of paragraph (b) without requiring approval from the DCE. Safety will be maintained by continuing to require that all systems used to meet the requirements of this section must be tested by the manufacturer to demonstrate their ability to limit body forces to 400,000 pounds maximum at a ten miles per hour impact. PHMSA also proposes a minor editorial change to spell out “ten miles per hour” instead of the numerical value “10.”

Section 179.220–18

Section 179.220–18 prescribes requirements for bottom outlets for DOT–115 tank cars. In accordance with the proposed removal of all reference to approval by the AAR TCC, PHMSA proposes to remove the phrase “by the AAR Committee on Tank Cars.” A DCE will fill the approval role previously delegated to AAR. See “Section II.B.2. Tank Car Design Authority” for additional details.

Section 179.300–9

See “Section IV. Section-by-Section Review; Part 179; Sections 179.100–9, 178.100–10, 179.100–18, 179.200–10, 179.200–11, 179.200–22, 179.220–10, 179.220–11, 179.300–9, 179.300–10, 179.400–11, 179.400–12, 179.400–15, and 179.400–18” for details on the revisions proposed to this section.

Section 179.300–10

See “Section IV. Section-by-Section Review; Part 179; Sections 179.100–9, 178.100–10, 179.100–18, 179.200–10, 179.200–11, 179.200–22, 179.220–10, 179.220–11, 179.300–9, 179.300–10, 179.400–11, 179.400–12, 179.400–15, and 179.400–18” for details on the revisions proposed to this section.

Section 179.400–5

Section 179.400–5 prescribes requirements for weld-impact test results. PHMSA proposes an editorial correction to this section to insert the required language to make the IBR of Appendix W valid. It appears the omission of IBR language was an oversight, and PHMSA proposes to correct it. Additionally, PHMSA proposes to add language indicating that compliance with paragraph 1.2 of Appendix W is not required, because that section requires AAR approval. See “Section II.B.6. AAR Specifications for Tank Cars Incorporation by Reference” for additional details.

⁵³ See Letter of Interpretation Reference No. 19–0076: <https://www.phmsa.dot.gov/regulations/title49/interp/19-0076>.

⁵⁴ See <https://www.regulations.gov/document/PHMSA-2021-0101-0001>.

⁵⁵ See DOT–SP 20908: <https://www.phmsa.dot.gov/approvals-and-permits/hazmat/file-serve/offer/SP20908.pdf/offerserver/SP20908>.

Section 179.400–6

Section 179.400–6 prescribes bursting and buckling pressure requirements for the outer jacket of a cryogenic liquid tank car. PHMSA proposes to fix an editorial error and IBR Chapter Six of AAR Manual of Standards and Recommended Practices, Section C–II Specifications for Design, Fabrication and Construction of Freight Cars, rather than Chapter Six of AAR Manual of Standards and Recommended Practices, Section C–III, Specifications for Tank Cars, Specification M–1002. Section 6.2 does not exist in C–III, while section 6.2 is the relevant section in C–II; PHMSA has identified that this error dates back to the creation of § 179.400–6 in final rule HM–115.⁵⁶ PHMSA expects that this editorial change will increase clarity without creating any additional burden on DOT–113 manufacturers.

Section 179.400–11

See “Section IV. Section-by-Section Review; Part 179; Sections 179.100–9, 178.100–10, 179.100–18, 179.200–10, 179.200–11, 179.200–22, 179.220–10, 179.220–11, 179.300–9, 179.300–10, 179.400–11, 179.400–12, 179.400–15, and 179.400–18” for details on the revisions proposed to this section.

Section 179.400–12

See “Section IV. Section-by-Section Review; Part 179; Sections 179.100–9, 178.100–10, 179.100–18, 179.200–10, 179.200–11, 179.200–22, 179.220–10, 179.220–11, 179.300–9, 179.300–10, 179.400–11, 179.400–12, 179.400–15, and 179.400–18” for details on the revisions proposed to this section.

Section 179.400–13

Section 179.400–13 details requirements for support systems for cryogenic liquid tank cars. PHMSA proposes to remove the phrase “of approved design” from paragraph (b) for cushioning devices. It is PHMSA and FRA’s understanding that approvals are not currently issued for cushioning devices. Therefore, PHMSA proposes a tank car manufacturer may certify the cushioning device tested to meet the performance standards of paragraph (b) without requiring approval from the DCE. Safety will be maintained by continuing to require that all systems used to meet the requirements of this section must be tested by the manufacturer to demonstrate their ability to limit body forces to 400,000 pounds maximum at a ten miles per hour impact. In addition, PHMSA proposes a minor editorial amendment

to spell out “ten miles per hour” as opposed to the numerical value.

Section 179.400–15

See “Section IV. Section-by-Section Review; Part 179; Sections 179.100–9, 178.100–10, 179.100–18, 179.200–10, 179.200–11, 179.200–22, 179.220–10, 179.220–11, 179.300–9, 179.300–10, 179.400–11, 179.400–12, 179.400–15, and 179.400–18” for details on the revisions proposed to this section.

Section 179.400–18

See “Section IV. Section-by-Section Review; Part 179; Sections 179.100–9, 178.100–10, 179.100–18, 179.200–10, 179.200–11, 179.200–22, 179.220–10, 179.220–11, 179.300–9, 179.300–10, 179.400–11, 179.400–12, 179.400–15, and 179.400–18” for details on the revisions proposed to this section.

Section 179.400–19

Section 179.400–19 prescribes requirements for valves of cryogenic liquid tank cars. PHMSA proposes to remove the separate approval requirement for valve packing in paragraph (a)(2). The DCE will evaluate valve packing material in the valve approval process.

Section 179.500–17

Section 179.500–17 prescribes marking requirements for DOT 107A seamless steel tank cars. PHMSA proposes to remove the reference to the AAR Bureau of Explosives as it is obsolete because they no longer perform this function.

Section 179.500–18

Section 179.500–18 discusses recordkeeping for DOT 107A seamless steel tank cars. PHMSA proposes several revisions to remove obsolete references to approvals issued by AAR’s Bureau of Explosives from paragraphs (a) and (b)(6) and update the section to reference the DCE in paragraph (c). The reference to AAR Bureau of Explosives is obsolete because they no longer perform this function, and PHMSA proposes to require DCE approval of tank car designs, rather than approval by AAR TCC.

Appendix B to Part 179

Appendix B to part 179 specifies procedures for conducting simulated pool and torch-fire testing of thermal protection systems, as required by § 179.18(c). Review of test results submitted to the Department show there are some inconsistencies in the application of the test due to the lack of certain parameters for clarity in the procedures in Appendix B. PHMSA

proposes the following revisions to ensure consistent and repeatable application of the tests, which will ultimately enhance safety. These proposed revisions received a consensus vote during the May 25, 2017, RSAC meeting and were offered to PHMSA and FRA for consideration.

Paragraph 1: PHMSA proposes to add additional text to clarify that the sample of thermal resistance material used shall be identical (within measurement error) for each test performed under Appendix B in terms of thickness, and thermodynamic and physical properties.

Paragraph 2(a)(1): PHMSA proposes to revise this paragraph to specify the location and frequency of measurements of flame temperature throughout the duration of the test, and that calibration tests must be performed with the steel plate in position.

Paragraph 2(a)(2): PHMSA proposes an editorial change to add metric units to the plate dimensions, which is consistent with dimensions in this paragraph.

Paragraph 2(b)(6): PHMSA proposes to revise this paragraph to add language indicating the consecutive tests must be conducted separately and at different times.

Paragraph 3(a)(1): PHMSA proposes to revise this paragraph to indicate the location and frequency of measurements of flame temperature throughout the duration of the test, and that calibration tests must be performed with the steel plate in position. PHMSA proposes that the temperature and torch velocity must be measured at a distance of not more than 15 cm (6 in) from the test sample surface, along the axis of the fire.

Paragraph 3(a)(2): PHMSA proposes an editorial change to add metric units to the plate dimensions, consistent with dimensions in this paragraph.

Paragraph 3(b)(6): PHMSA proposes to revise this paragraph to add language indicating that the consecutive tests must be conducted separately and at different times.

Part 180

Section 180.3

Section 180.3 details general requirements for the continuing qualification of packagings. Paragraph (b)(3) specifies that test dates displayed in association with certain markings may not be marked unless they are appropriate. PHMSA proposes to add DOT–SP markings to the list of markings in paragraph (b)(3). This proposal provides clarity, as these markings are currently authorized but not listed in this paragraph.

PHMSA also proposes to add paragraphs (c) and (d) to specify

⁵⁶ 48 FR 27674 (Jun. 16, 1983).

additional provisions that are not authorized under this section. Paragraph (c) indicates that a person may not mark that a package has passed a test or inspection if it has not actually passed that test or inspection. Paragraph (d) specifies that no person shall falsify a document or marking indicating that a packaging has passed a test or inspection. Both of these paragraphs provide additional clarity and ensure increased safety; they do not add any new restrictions, as these actions were not and are not authorized prior to publication of this rulemaking.

Section 180.403

This section provides definitions for the qualification and maintenance of cargo tanks. PHMSA proposes to revise the following § 180.403 definitions:

- *Repair*: PHMSA proposes to utilize the existing definition of *rebarrelling* to better define the term *repair*. As defined in § 180.403, *rebarrelling* means “replacing more than 50 percent of the combined shell and head material of a cargo tank.” Alternatively, in the event that less than 50 percent of the combined shell and head material is replaced, the process is considered a repair. Therefore, to remove any ambiguity, PHMSA proposes to revise *repair* to include that it means the replacement of 50 percent or less of the combined shell and head material of a cargo tank. Finally, PHMSA proposes a minor editorial revision to move the word “and” to connect the second and third exclusion clauses. This proposed edit corrects a minor drafting error.

The following definitions are proposed to be added to § 180.403:

- *Certification Plate*: As previously discussed, there has been considerable confusion regarding the use of “name plate” or “specification plate.” This uncertainty is amplified when considering the challenges associated with mounting a used ASME Code cargo tank to a new chassis. PHMSA is proposing the addition of definitions for “Name Plate” and “Specification Plate” into § 178.320; however, these terms do not apply to a data plate attached to a cargo tank that is still in use but is no longer authorized for construction (as identified by § 180.405(c)). The correct term for a data plate attached to this type of tank is “certification plate.” Therefore, PHMSA proposes to define “certification plate” to mean a data plate containing the applicable markings provided in the original specifications for cargo tanks no longer authorized for construction (as identified in § 180.405(c)), and permanently attached to the cargo tank or integral supporting structure by the

manufacturer. The markings on this plate are certification by the manufacturer that the cargo tank or the cargo tank motor vehicle has been designed, constructed, and tested in accordance with the applicable specification.

- *Maintenance*: PHMSA proposes to add this definition for ease of understanding and reading as the term “maintenance” is used throughout part 180, subpart E but it is not currently defined and PHMSA expects this proposed definition will increase clarity without reducing safety. PHMSA proposes that *Maintenance* means “the replacement of components that do not involve welding on a cargo tank wall, on specification cargo tanks or cargo tank motor vehicles.” This aligns with the current definition of *repair* and *rebarrelling* as both of these functions involve welding, while as proposed, *maintenance* means replacement of components that does not involve welding.

- *Objectively reasonable and articulable belief*: PHMSA proposes to add a definition for the phrase “Objectively reasonable and articulable belief.” This means “a belief based on particularized and identifiable facts that provide an objective basis to believe or suspect that a cargo tank or series of cargo tanks may be in an unsafe operating condition.” This phrase will be added as a standard in § 180.407(b)(5), as a condition that requires test and inspection of a cargo tank, replacing “probable cause.” This phrase and definition align with existing language for tank cars in part 180 subpart F. The intent of this revision is to clarify the standard by which a FMCSA investigator or other representative of the Department may require a cargo tank to be inspected and tested prior to further transportation.

- *Set pressure*: PHMSA and FMCSA identified potential confusion because the terms “set pressure” and “set to discharge pressure” are used in various places in the HMR without a corresponding definition in § 180.403. In order to increase regulatory clarity and avoid this confusion, PHMSA proposes to define *set pressure* to mean the pressure of the PRD or pressure relief system at which it starts to open, allowing discharge. This aligns with the definition of *set pressure* in § 178.345–10(d) of the HMR.

Section 180.405

This section details requirements for the qualification of cargo tanks. Paragraph (b) outlines authorized cargo tank specifications and provides requirements for how to recertify cargo

tanks that are no longer authorized to be manufactured (e.g., MC 306, MC 307 or MC 312 specification cargo tanks). However, the HMR does not specify how to replace a specification plate when it is missing. PHMSA has received comments from industry and enforcement communities who have struggled in addressing this situation because of its absence from the HMR. Therefore, PHMSA proposes to provide standards for the replacement of DOT specification certification plates with requirements for different scenarios in new paragraph (b)(3), along with a documentation requirement to provide traceability. These proposed scenarios reduce regulatory uncertainty while ensuring that cargo tanks can safely transport hazardous materials.

Paragraph (c)(2) details requirements for modification of PRDs and outlets. PHMSA proposes an editorial amendment to paragraph (c)(2) by specifying that the paragraph applies to “cargo tank motor vehicles,” as opposed to just “cargo tanks” for regulatory consistency. Additionally, PHMSA proposes to remove paragraphs (c)(2)(i)–(vii) and instead in paragraph (c)(2), reference §§ 173.33(d) and 180.405(h), as these regulations are duplicative. By removing duplicative regulations, PHMSA eliminates any potential inconsistency between the same requirements. These proposed revisions are not intended to change the current regulatory requirements.

PHMSA also proposes to add paragraph (c)(3) to specify that “a cargo tank motor vehicle manufactured and certified prior to the dates listed in table 1 and table 2 of [§ 180.405] may be mounted on a different truck chassis provided the mounting and certification is done in accordance with this subchapter.” This new proposed paragraph provides regulatory clarity and allows for flexibility in mounting a cargo tank that is no longer authorized to be manufactured onto a new chassis, enhancing the safe transportation of hazardous materials in cargo tanks.

Paragraph (h)(3) specifies requirements for modifying reclosing PRDs to more current cargo tank specifications. PHMSA proposes to amend this paragraph editorially by adding a reference to § 173.33(d) and indicating that this requirement applies to a “cargo tank motor vehicle,” instead of just a “cargo tank.”

Paragraph (j) indicates requirements for withdrawal of a specification cargo tank certification. PHMSA proposes to revise this paragraph to indicate when the specification plate is removed, obliterated, or securely covered, it must withstand conditions normally incident

to transportation. FMCSA has encountered cargo tank motor vehicles where adhesive tape or other non-durable method has been used to cover the specification plate but the covering has worn off or been removed; thus, the cargo tank may indicate that it meets a specification when it is no longer in compliance. This proposal is intended for clarification purposes and thus, will enhance safety, as the specification plate should not currently be displayed if the cargo tank does not meet the appropriate specification referenced. PHMSA also proposes minimal editorial amendments to this paragraph to align with the rest of the HMR. Specifically, PHMSA proposes to replace “cargo tank” with “cargo tank motor vehicle,” “certificate” with “Certificate of Compliance,” and re-order the references to §§ 180.407 and 180.413 so that § 180.407 appears first.

Lastly, PHMSA proposes to add paragraph (p) to specify that at the next external visual inspection after the effective date of this final rule, Registered Inspectors must inspect the mechanical means of remote closure to ensure that access or means of manual operation is unobstructed from operation. This proposal mirrors the language proposed in §§ 178.337–8, 178.338–11, and 178.345–11. FMCSA has encountered cargo tank motor vehicles where the mechanical means of remote shut off device has been obstructed by various appurtenances and equipment that were added after the date of manufacture. As obstructions to the manual remote emergency shut off device may result in an incident, PHMSA proposes to add this paragraph in order to address this safety concern.

Section 180.407

This section contains requirements for properly conducting tests and inspections on cargo tank motor vehicles. Since 2003 (when PHMSA last published a cargo tank-specific rulemaking) PHMSA has issued more than 50 letters of interpretation related to § 180.407. In addition, FMCSA issued over 550 violations related to this section in 2019 alone. In listening sessions, enforcement actions, and questions raised during FMCSA/NTTC Cargo Tank Workshops, the cargo tank regulated community has expressed concerns regarding the implementation of this section. PHMSA and FMCSA acknowledge that the requirements of § 180.407, as currently written, generate confusion and create compliance issues in the cargo tank regulated community. To address this confusion and increase understanding of, and compliance with, cargo tank testing and inspection

requirements, PHMSA proposes to amend certain paragraphs, as described below. Ultimately, PHMSA expects that by reducing confusion and providing increased clarity, these proposed amendments will increase safety. Please note that paragraphs not discussed below but contained in the proposed regulatory text, do not contain proposed changes, but rather are included in the proposed regulatory text for the convenience of the **Federal Register**.

Paragraph (a)(1)

This paragraph currently specifies a cargo tank constructed in accordance with a DOT specification, for which a test or inspection has become due, may not be filled and offered for transportation or transported until the test or inspection has been successfully completed. PHMSA proposes several revisions to provide more regulatory clarity, which ensures further compliance with the HMR.

PHMSA proposes to specify this paragraph applies to a “cargo tank motor vehicle” instead of a “cargo tank” as this is more technically correct and aligns with other proposals.

PHMSA also proposes to indicate this paragraph also applies to cargo tank motor vehicles that may not be a DOT specification but may be otherwise subject to this section. This increases safety by ensuring that a cargo tank transporting hazardous materials is not filled and offered if the part 180 subpart E test or inspection date has passed, regardless if it is a specification cargo tank. For example, § 180.407(h) details requirements for certain non-specification cargo tank leakage test requirements. This proposal ensures these non-specification cargo tank motor vehicles may not be filled and offered for transportation if the leakage test date has passed and the cargo tank motor vehicle has not been retested.

Lastly, PHMSA proposes to indicate more clearly that a cargo tank motor vehicle filled prior to the test or inspection due date may still be offered for transportation or transported after the test or inspection due date has passed, as also indicated in § 173.33(a)(3). This is currently authorized in the HMR and this proposal reinforces that allowance. Furthermore, while § 173.33(a)(3) refers to § 180.407(a)(1), there is no reciprocal reference to § 177.33(a)(3) in § 180.407(a)(1). Therefore, PHMSA proposes to reinforce the allowance for a cargo tank to be offered for transportation after the inspection or test date has passed, as long as the cargo tank was filled prior to the inspection or test expiration, and add a reference to

§ 173.33(a)(3) to complete the cross-reference. As this is currently authorized, this proposed revision provides clarity without reducing safety.

Paragraph (a)(2)

This paragraph specifies that, except during a pressure test, a cargo tank may not be subjected to a pressure greater than its design pressure or MAWP. PHMSA proposes an editorial amendment to specify that the MAWP referenced in this requirement is the one marked on the name plate or specification plate. These editorial revisions will enhance clarity, and PHMSA does not expect they will reduce safety.

Paragraph (a)(5)

This paragraph requires a cargo tank to be marked in accordance with § 180.415 when it has passed a test or inspection. PHMSA proposes an editorial amendment to change “cargo tank” to the more appropriate “cargo tank motor vehicle.”

Paragraph (a)(6)

This paragraph contains requirements for a cargo tank that has failed a prescribed test or inspection. PHMSA proposes to specify that the paragraph applies to a “cargo tank motor vehicle” instead of a “cargo tank” as an editorial amendment.

While paragraph (a)(6) only applies to a cargo tank that has failed a prescribed test or inspection, there is a potential regulatory gap for a cargo tank that was improperly tested. It is possible that an improperly tested cargo tank motor vehicle may have failed the prescribed test or inspection if it had been properly conducted. To address this safety gap, PHMSA proposes to require that paragraph (a)(6) also applies to a cargo tank motor vehicle that “has not been properly inspected.” Therefore, if it has been improperly inspected, the cargo tank motor vehicle can be retested or taken out of hazardous materials service.

Paragraph (a)(6)(ii)

This paragraph specifies when meeting the criteria in paragraph (a)(6) (e.g., a cargo tank has failed a prescribed test or inspection), a cargo tank must be removed from hazardous materials service and the specification plate must be removed or covered in a secure manner. PHMSA proposes to revise this paragraph to specify when the specification plate is covered, it must be covered in a manner that can, at a minimum, withstand conditions normally incident to transportation. As noted in “Section IV. Section-by-Section

Review; Part 180; Section 180.405,” FMCSA has encountered cargo tank motor vehicles where adhesive tape or another non-durable method was used to cover the specification plate, but the covering had worn off or been removed. Therefore, the specification plate indicates the cargo tank motor vehicle meets a specification when it is actually no longer in compliance. This proposal aims to reduce the likelihood of this occurring and increase safety. Note that this is a clarifying amendment and even though not in the regulations, it is currently good practice to cover the specification plate in such a way that ensures any covering can withstand conditions normally incident to transportation.

Paragraph (a)(7)

PHMSA proposes to add this paragraph to specify all equipment and instruments used in part 180 subpart E tests and inspections must be calibrated and maintained according to the manufacturer’s instructions. FMCSA has found numerous instances of poorly maintained or uncalibrated equipment being used to qualify cargo tank motor vehicles. This change aims to eliminate any errors in testing caused by poorly maintained equipment and ultimately, increase safety. Additionally, to ensure compliance with this requirement, PHMSA proposes to require the facility to maintain records of the calibration and to retain a copy of the two most recent calibrations, which must be made available to a representative of the Department upon request.

Paragraph (a)(8)

PHMSA proposes to add paragraph (a)(8) to allow for the use of video cameras or fiber optic equipment during any test or inspection, provided that all of the required areas and elements that need to be tested or inspected can be viewed and evaluated in accordance with part 180 subpart E. This provides flexibility in performance of tests and of inspections, while maintaining an equivalent level of safety. Records of the test and inspections must be recorded, as currently required in § 180.417, but there is no requirement to maintain the video camera recordings.

Paragraph (a)(9)

PHMSA proposes to add this paragraph to require the use of the hydrostatic test method for the pressure test whenever the test pressure exceeds 50 psig, except for DOT Specification MC 338 cargo tank motor vehicles in cryogenic service. Essentially, this new paragraph restricts the use of pneumatic testing whenever the test pressure

exceeds 50 psig. There is a significant reduction in the potential for serious injury or death when comparing the pneumatic test to the hydrostatic test at high pressures, due to the incompressible properties of water. Therefore, this proposal ensures that a hydrostatic test is used to test cargo tanks at high pressures to address the high potential safety concern from use of pneumatic testing. In addition, this new paragraph mirrors the limitation for testing of small gas cylinders pneumatically.

PHMSA also proposes to specify that “in all pressure and leakage tests, suitable safeguards must be provided to protect personnel should a system failure occur.” This proposed requirement aims to minimize the risks and reduce the impact of incidents, including the sudden release of compressed air or liquid, and flying debris, associated with performance of pressure tests.

Paragraph (a)(10)

PHMSA proposes to add this paragraph to require that the Registered Inspector must consult with the owner or motor carrier, as appropriate, to determine if materials corrosive or reactive to the cargo tank or components were transported in the cargo tank motor vehicle prior to or since the last test or inspection was performed. The Registered Inspector shall indicate this information on the § 180.415 report and use the information to determine the proper tests and inspections to be conducted on the cargo tank motor vehicle. Cargo tank motor vehicles that have transported material corrosive to the tank are subject to a thickness test, and more frequent internal visual inspections to ensure the lading has not reduced the thickness of the tank below the minimum required thickness. Registered Inspectors often comment to FMCSA that they have no way of determining what the cargo tank motor vehicle has transported since the last inspection, and therefore, this proposed requirement aims to remedy the concerns raised by Registered Inspectors. This also ensures the proper tests and inspections are conducted on the cargo tank motor vehicle based on the hazardous materials that were transported in the cargo tank, which increases the future safe transportation of the cargo tank motor vehicle.

Paragraph (a)(11)

This new proposed paragraph requires all sources of spark, flame, or glowing heat within the area of enclosure where the tests and inspections are conducted (including

any heating system drawing air therefrom) are extinguished, made inoperable, or rendered explosion-proof by a suitable method prior to any tests or inspections subject to this subpart. PHMSA and FMCSA expect that this proposal will reduce the potential for any incidents involving spark, flame, or glowing heat. PHMSA and FMCSA expect that this new paragraph reduces the potential for any incidents involving sparks, flames, or glowing heat while conducting cargo tank tests and inspections and therefore, increases safety.

Paragraph (b)(1)

This paragraph details certain tank defects that require a cargo tank to be tested and inspected without regard to any other test or inspection requirements. PHMSA proposes to revise this paragraph by adding “bulges” to the list of tank defects. If the cargo tank shows evidence of bulges, it demonstrates a potential failure in the structural integrity of the cargo tank. Therefore, to ensure continued safe transportation of hazardous materials in cargo tanks, PHMSA proposes to add this additional tank defect to the list that requires test and inspection. In addition, PHMSA proposes editorial amendments to this paragraph including adding a reference to the definition of minimum thickness in § 178.320, and other grammatical edits for increased readability.

Paragraph (b)(3)

This paragraph specifies a cargo tank that has been out of hazardous materials transportation service for a period of one year or more must be pressure tested in accordance with § 180.407(g), prior to returning to service. PHMSA proposes minor editorial edits to this paragraph, including specifying that this paragraph applies to a “cargo tank motor vehicle” instead of “cargo tank”, specify “one year” as a numerical value for grammatical purposes, and that the pressure test is required prior to further use “in hazardous materials transportation.” These editorial amendments help to increase regulatory consistency and clarity, thus ensuring safe transportation.

Paragraph (b)(5)

This paragraph currently states that a specification cargo tank must be tested and inspected if the Department so requires based on the existence of probable cause that the cargo tank is in an unsafe operating condition. The term “probable cause” normally refers to criminal matters and not necessarily an appropriate standard to apply to

scenarios requiring test and inspection of cargo tanks. Therefore, PHMSA proposes to replace “probable cause” with “objectively reasonable and articulable belief.” This standard is currently in use in part 180 subpart F for tank cars, and PHMSA believes it is also the proper standard for cargo tanks in part 180 subpart E.

PHMSA takes the position that if an investigator inspects a cargo tank motor vehicle and determines it is in need of inspection or re-inspection because evidence has been discovered that the original tests were not performed in accordance with the regulations—or because of defects in the cargo tank motor vehicle itself—that these facts are sufficiently considered an “objectively reasonable and articulable belief.” Therefore, PHMSA proposes to revise this paragraph to replace “probable cause” with “objectively reasonable and articulable belief.” This amendment will provide clarity on when an investigator can require testing and inspection (or reinspection), thus ensuring cargo tanks are safe for transport.

Paragraph (c)

This paragraph specifies each specification cargo tank must be tested and inspected in accordance with the table listed under paragraph (c). PHMSA proposes the following editorial amendments for clarity:

- Specify the most recent inspection is one “completed in accordance with the requirements in part 180;”
- Spell out “cargo tank motor vehicle” instead of the abbreviation “CTMV;”
- Clarify that the inspector in question must be a Registered Inspector; and
- Clarify that this paragraph should apply to a “cargo tank motor vehicle subject to this subpart” instead of a “specification cargo tank.”

These proposed amendments ensure regulatory consistency, thus enhancing safety.

Paragraph (d)(1)

This paragraph applies to the external visual inspection of cargo tank motor vehicles, and states that where insulation precludes a complete external visual inspection as required by §§ 180.407(d)(2) through (d)(6), the cargo tank must also be given an internal visual inspection in accordance with § 180.407(e). PHMSA proposes to add “coverings such as wrappings and coatings” as materials that can preclude a complete external visual inspection to paragraph (d)(1). This is consistent with Letters of Interpretation Reference Nos.

14–0110, 15–0221, 15–0226, 16–0049, 20–0013, and 20–0038 and this proposal will provide regulatory clarity without reducing safety.

Paragraph (d)(2)(i)

This paragraph specifies the tank shell and heads must be inspected during the external visual inspection. PHMSA proposes to require that “during the inspection of the cargo tank shell and heads, all pad attachments on either the cargo tank shell or head shall be inspected for method of attachment or other conditions that may render the appurtenance as unsafe.” This proposed requirement ensures that the pad attachments are properly functioning, which increases the safe transportation of hazardous materials in cargo tanks.

Additionally, PHMSA proposes to specify that the tank shell and heads must be “evaluated in accordance with § 180.411.” This proposed editorial amendment provides additional regulatory clarity to cross-reference the current evaluation requirements and therefore, increase compliance.

Paragraph (d)(2)(ii)

Paragraph (d)(2)(ii) specifies external visual inspection requirements for piping, valves, and gaskets. PHMSA proposes to specify that this paragraph applies to the piping system, which includes flexible connectors in addition to the currently identified piping, valves and gaskets. This proposal provides regulatory clarity as it expands the specificity of what constitutes the piping system and therefore, increases regulatory compliance and thus, safety.

Paragraph (d)(2)(iv)

This paragraph specifies inspection requirements for emergency devices and valves during the external visual inspection. PHMSA proposes to indicate editorially that remote closure devices include “all emergency discharge control systems and delivery hoses required by § 173.315(n).” This proposal is intended to provide clarity compared to the existing regulatory language and is not intended to subject new devices and valves to this requirement. Therefore, this proposal provides additional regulatory clarity to ultimately increase regulatory compliance and safety.

PHMSA also proposes instead of specifying all emergency devices and valves must be “free from” corrosion, distortion, erosion, and any external damage that will prevent safe operation, that they have to be “inspected for” this type of damage. This editorial proposal reinforces that in order to ensure the emergency discharge devices and valves

do not have any corrosion, distortion, erosion, and/or any external damage that will prevent operation. The emergency discharge devices and valves must be inspected as part of the external visual inspection at the interval prescribed in § 180.407(c). While not currently specified in paragraph (d)(2)(iv), inspection of emergency discharge devices and valves is referenced in § 180.417. Therefore, to remove any potential confusion or regulatory inconsistency, PHMSA proposes to add inspection to paragraph (d)(2)(iv). Ultimately, PHMSA expects this clarity will increase safety of cargo tank motor vehicle hazardous materials transportation.

PHMSA further proposes two editorial amendments to the currently effective requirement that “remote closure devices and self-closing stop valves be functioned to demonstrate proper operation.” Specifically, PHMSA proposes to revise the requirement from “remote closure devices” to “all emergency closure devices” consistent with proper terminology throughout the rest of the paragraph. In addition, for grammatical correctness, PHMSA proposes to rewrite the requirement to indicate the equipment must be “operated to demonstrate proper functioning” instead of “functioned to demonstrate proper operations.” Therefore, this sentence is proposed to read, “All emergency closure devices and self-closing stop valves must be operated to demonstrate proper functioning.”

Lastly, this paragraph does not indicate a required distance for testing remote shutoff devices. PHMSA proposes to specify “the distance for testing non-mechanical remote shutoff devices must be in accordance with the original device manufacturer’s specification.” This ensures the non-mechanical remote shutoff device operates safely, as it was originally manufactured to function, and follows optimum testing parameters, which increases safety of cargo tank motor vehicles.

Paragraph (d)(2)(viii)

This paragraph requires all major appurtenances and structural attachments and those elements of the upper coupler assembly that can be inspected without dismantling the upper coupler, must be inspected for any corrosion or damage that may prevent safe operation during the external visual inspection. Section 178.320 defines an *appurtenance* as any attachment to a cargo tank that has no lading retention or containment function and provides no structural

support to the cargo tank. However, the HMR does not define “major appurtenances” and therefore, the “major” qualifier is ambiguous. Therefore, to eliminate the ambiguity and for consistency with the definition of an *appurtenance*, PHMSA proposes to remove the term “major.” PHMSA expects this regulatory clarity will improve compliance and ultimately, safety.

In addition, the issue of whether the king pin should be checked as part of the external visual inspection, and, if so, what criteria should be used, was raised at one of the previously referenced cargo tank technical information sessions. Participants at the session recommended that language be added to state clearly that the king pin is part of the upper coupler assembly. Therefore, as PHMSA expects this increases regulatory compliance and safety, PHMSA proposes to add a clarifier that the upper coupler includes the king pin, while subsequently removing the term “fifth wheel.”

Paragraphs (d)(2)(ix) and (g)(1)(iii)

These paragraphs provide inspection requirements of areas covered by the upper coupler assembly. Paragraph (d)(2)(ix) requires this inspection occurs during the external visual inspection for cargo tanks carrying lading corrosive to the cargo tank and paragraph (g)(1)(iii) requires that this inspection occurs during the pressure test for cargo tanks that do not transport lading corrosive to the cargo tank. PHMSA proposes similar amendments in both paragraphs.

First, PHMSA proposes editorial amendments by specifying these paragraphs apply to “cargo tank motor vehicles” as opposed to “cargo tanks,” consistent with other proposals. In addition, and consistent with proposed amendments in paragraph (d)(2)(viii), PHMSA proposes to remove the references to “fifth wheel,” as it is no longer necessary. See “Section IV. Section-by-Section Review; Part 180; Section 180.407; Paragraphs (d)(2)(viii)” for further discussion on this proposal. Additionally, in paragraph (d)(2)(ix), PHMSA proposes to revise “two-year period” as a numerical value for grammatical consistency.

Furthermore, PHMSA proposes to specify the upper coupler assembly can be removed from the cargo tank for inspection under certain conditions. On some cargo tank motor vehicles, there is sufficient area above the upper coupler and below the bottom of the cargo tank to inspect the bottom of the cargo tank without removing the upper coupler. PHMSA proposes to allow for the inspection of the tank above the upper

coupler where there is sufficient area above the upper coupler and below the bottom of the cargo tank to inspect the tank surface when conducting the inspection by directly viewing the cargo tank. The ability for direct viewing means the area can be inspected without the use of an aid, such as mirrors, cameras, or fiber optics. This proposal is consistent with letters of interpretation issued by PHMSA.⁵⁷ Furthermore, this allowance means that the upper coupler can remain attached, which reduces the potential for improper reattachment, while maintaining the safety standard for inspection (complete visual inspection of the cargo tank shell).

Finally, to reinforce current FMCSR requirements, PHMSA proposes to specify that when the upper coupler assembly is removed from the cargo tank motor vehicle, it must be reattached in accordance with the manufacturer’s instructions and 49 CFR 393.70, the Federal Motor Carrier Safety Regulation section that covers couplers. This proposal reinforces current requirements to ensure the upper coupler assembly is replaced safely and correctly.

Paragraph (d)(2)(ix)

See “Section IV. Section-by-Section Review; Part 180; Section 180.407; Paragraphs (d)(2)(ix) and (g)(1)(iii)” for a discussion on the proposed changes in this paragraph.

Paragraphs (d)(3), (d)(3)(i), and (d)(3)(ii)

Paragraph (d)(3) specifies the inspection requirements for reclosing pressure relief valves. PHMSA proposes to split the current requirements into two new paragraphs to distinguish the requirements more clearly and increase compliance. Subsequently, PHMSA proposes to add introductory language to paragraph (d)(3) to specify the requirements of paragraph (d)(3)(i) and (ii) apply to reclosing pressure relief devices. Additionally, PHMSA proposes to amend all references in new paragraphs (d)(3)(i) and (ii) to “pressure relief valves” as “pressure relief devices” for consistency with the rest of the HMR.

PHMSA proposes that paragraph (d)(3)(i) contains the first sentence of current paragraph (d)(3). Currently, this requires that all reclosing pressure relief valves be externally inspected for corrosion and damage, which might

prevent safe operation. PHMSA proposes no other revisions than the editorial amendment described above.

PHMSA proposes that new paragraph (d)(3)(ii) contains the last two sentences of current paragraph (d)(3). Currently, these last two sentences require that all reclosing pressure relief valves that carry lading corrosive to the cargo tank be removed for inspection and testing. Furthermore, the requirement to remove and test reclosing pressure relief valves must be done in accordance with § 180.407(j). In addition to the editorial amendment described above, PHMSA proposes to consolidate these two sentences into one sentence as the introductory language in the second sentence is duplicative. This consolidation aims at reducing any ambiguity and streamlining the requirement to increase compliance. PHMSA proposes to specify the paragraph applies to “cargo tank motor vehicles” instead of just “cargo tanks,” consistent with other proposed amendments. Lastly, PHMSA proposes to qualify editorially that by “testing” the requirement is for “bench testing” to reduce any potential confusion.

Paragraphs (d)(3)

See “Section IV. Section-by-Section Review; Part 180; Section 180.407; Paragraphs (d)(3), (d)(3)(i) and (d)(3)(ii)” for a discussion on the proposed changes in this paragraph.

Paragraphs (d)(3)(i)

See “Section IV. Section-by-Section Review; Part 180; Section 180.407; Paragraphs (d)(3), (d)(3)(i) and (d)(3)(ii)” for a discussion on the proposed changes in this paragraph.

Paragraphs (d)(3)(ii)

See “Section IV. Section-by-Section Review; Part 180; Section 180.407; Paragraphs (d)(3), (d)(3)(i) and (d)(3)(ii)” for a discussion on the proposed changes in this paragraph.

Paragraph (d)(4)

This paragraph requires ring stiffeners or other appurtenances must be thickness tested at least once every two years. PHMSA proposes editorial revisions, including removing the term “other” in reference to appurtenances, specifying the paragraph applies to “cargo tank motor vehicles” instead of “cargo tanks,” and minor grammatical revisions to align this paragraph with other proposals.

Paragraph (d)(7)

Paragraph (d)(7) requires that an inspector must record the results of an external visual examination. PHMSA

⁵⁷ See Letters of Interpretation Reference Nos. 02-0290 and 11-0059. See Letter of Interpretation Reference No. 02-0290: <https://www.phmsa.dot.gov/regulations/title49/interp/02-0290>. See Letter of Interpretation Reference No. 11-0059: <https://www.phmsa.dot.gov/regulations/title49/interp/11-0059>.

proposes to move the current requirements of paragraph (d)(7) to a new paragraph (d)(9). In its place, PHMSA proposes that paragraph (d)(7) requires external ring stiffeners to be inspected for corrosion, pitting, abraded areas, or damage, and repaired as appropriate during external visual inspection. Ring stiffeners are installed on cargo tank motor vehicles to provide structural support, however, the HMR do not currently require that they are inspected and repaired as appropriate. If the external ring stiffeners fail because they were not inspected and repaired appropriately, the cargo tank motor vehicles would be left vulnerable to an incident, therefore, PHMSA proposes this new requirement to eliminate a potential safety gap.

Paragraph (d)(8)

PHMSA proposes this new paragraph to require Registered Inspectors to inspect weld repairs for leakage and weld defects. Furthermore, PHMSA proposes that the Registered Inspector verify the weld repair was done in accordance with § 180.413. FMCSA determined an incident resulting in death and injuries occurred because the welded repairs were not conducted in accordance with the HMR and the repair facility did not hold the appropriate certificates. To avoid this type of incident in the future and ensure the continued safe transportation of hazardous materials in specification cargo tank motor vehicles, PHMSA proposes to add this verification requirement to reduce improper welding operations.

Paragraph (d)(9)

Based on proposed amendments in paragraphs (d)(7) and (8), PHMSA proposes to move the current requirements of paragraph (d)(7) to new paragraph (d)(9). As previously discussed, current paragraph (d)(7) requires that the inspector must record the results of the external visual examination as specified in § 180.417(b). PHMSA does not propose any additional amendments to this paragraph.

Paragraph (f)

This paragraph provides requirements for lining inspections. The introductory sentence to this paragraph specifies the integrity of the lining on all lined cargo tanks must be verified at least once each year as outlined in paragraph (f). PHMSA identified that this paragraph may be interpreted as contradicting the periodic test and inspection table found under § 180.407(c), which specifies that all lined cargo tanks transporting lading

corrosive to the tank, must undergo a lining inspection every year. To reduce this confusion, PHMSA proposes to revise this paragraph to specify only cargo tank motor vehicles that are required to be lined are required to undergo an annual lining inspection as specified in the rest of paragraph (f).

Paragraph (f)(2)

This paragraph states that linings not made of rubber must be tested using equipment and procedures prescribed by the lining manufacturer or lining installer. PHMSA proposes to revise paragraph (f)(2) to specify “[f]or linings made of materials other than rubber (elastomeric material), the owner of the cargo tank motor vehicle must obtain documentation from the lining manufacturer or installer that specifies the proper procedures for lining and inspection. This documentation must be provided to the Registered Inspector before inspection.” PHMSA expects this requirement will ensure the lining is being properly inspected. Currently, a cargo tank motor vehicle owner is responsible for information regarding the cargo tank motor vehicle, including information on the lining. Additionally, the cargo tank motor vehicle owner should have this information, because, in some cases, the cargo tank motor vehicle is lined upon purchasing, and thus, the information is provided during the course of ownership. However, because it is currently not specified in the HMR, manufacturers may not have this information readily available for Registered Inspectors during inspections. Therefore, this proposed requirement ensures the availability of this documentation to Registered Inspectors to make certain the lining is properly inspected, which increases safety.

Paragraph (f)(3)

Paragraph (f)(3) details requirements for degraded or defective areas of the cargo tank liner. As an editorial amendment, PHMSA proposes to revise “liner” as “lining” as this is more appropriate terminology, consistent with the rest of § 180.407.

Additionally, PHMSA proposes to add a sentence at the end of the paragraph to require that if “degraded or defective areas of the cargo tank lining are repaired or if the lining is replaced, it must comply with the lining manufacturer’s or installer’s procedures, subject to the lining requirements of the HMR.” This aligns with the proposed requirement in paragraph (f)(2) to require that the cargo tank motor vehicle owner provide a Registered Inspector with documentation from the lining

owner for inspection and testing. See “Section IV. Section-by-Section Review; Part 180; Section 180.407; Paragraph (f)(2).” If the lining is repaired or replaced without being in compliance with the lining manufacturer or installer’s procedures, it may affect the structural integrity of the cargo tank. Therefore, this proposed requirement is in the interest of safety and aligns with general industry practice.

Paragraph (g)(1)(ii)

This paragraph details pressure test procedures for self-closing pressure relief valves. PHMSA proposes editorial amendments to this paragraph. These amendments include updating terminology to align more appropriately with other references in the HMR, revising “pressure relief valves” to “pressure relief devices,” and specifying the self-closing PRDs must be removed from the cargo tank motor vehicle (instead of cargo tank).

Paragraph (g)(1)(iii)

See “Section IV. Section-by-Section Review; Part 180; Section 180.407; Paragraph (d)(2)(ix) and (g)(1)(iii)” for a discussion on the proposed changes in this paragraph.

Paragraph (g)(1)(viii)

This paragraph details requirements for pressure testing of cargo tanks by the hydrostatic test method. PHMSA proposes editorial corrections to this paragraph. PHMSA believes that the terms “including its domes” and “to not less than the pressure” do not contribute to the clarity of the paragraph. Therefore, PHMSA proposes to remove the language from the paragraph to ensure increased clarity, compliance, and ultimately increase safety. Additionally, PHMSA proposes to spell out numerically “10 minutes” for grammatical accuracy consistent with other proposals.

Paragraph (g)(3)

This paragraph details requirements for the internal inspection by wet fluorescent magnetic particle method for MC 330 and MC 331 cargo tanks. PHMSA proposes to update the IBR of CGA Technical Bulletin TB-2 to CGA Technical Bulletin P-26 (formerly TB-2) in § 171.7. See “Section IV. Section-by-Section Review; Part 171; Section 171.7” for a discussion on the proposed change to this IBR. As this IBR is referenced in paragraph (g)(3), PHMSA proposes to update the reference to specify the new name of the CGA Technical Bulletin.

Paragraph (g)(6)

Paragraph (g)(6) specifies the acceptance criteria that must be met before a cargo tank can be returned to service. PHMSA proposes to remove the terms “pneumatic inspection pressure” and “excessive permanent expansion.” The “pneumatic inspection pressure” term is outdated and “excessive permanent expansion” is duplicative because it is covered by the acceptance criteria of “shows distortion” in the paragraph. Lastly, PHMSA proposes to specify this paragraph applies to “cargo tank motor vehicles” as opposed to just “cargo tanks.” These proposals increase regulatory clarity and therefore, increase the safe transportation of hazardous materials.

Paragraph (h)(1)

Paragraph (h)(1) specifies leakage test requirements. In paragraph (h)(1), PHMSA proposes to make several editorial amendments. PHMSA proposes to replace the requirement that the leakage test must include “testing product piping” to instead require that the leakage test include “all components of the cargo tank wall, and the piping system.” Furthermore, PHMSA proposes to revise “accessories” and “venting devices” to read as “pressure relief devices.” Lastly, PHMSA proposes to spell out “percent” instead of using the percent sign (%). These changes are intended to align with more current terminology and not revise the intent of these requirements. Therefore, PHMSA expects this proposed change makes the regulations clearer, which ultimately increases safety.

Paragraph (h)(1)(i)

This paragraph provides an alternate leakage test pressure for a cargo tank with an MAWP of 690 kPa (100 psig) or more. PHMSA proposes a minor editorial revision specifying this paragraph applies to a “cargo tank motor vehicle” instead of a “cargo tank,” which aligns with other proposed changes.

Paragraph (h)(1)(ii)

Paragraph (h)(1)(ii) provides an alternate leakage test pressure for an MC 330 or MC 331 cargo tank in dedicated liquefied petroleum gas service. Consistent with paragraph (h)(1)(iii), PHMSA proposes to include non-specification cargo tank motor vehicle authorized under § 173.315(k) in this paragraph. In addition, PHMSA proposes an editorial amendment to correct the spelling of “liquified” to “liquefied.”

Paragraph (h)(1)(iii)

This paragraph authorizes a leakage test pressure exception for an MC 330 or MC 331 cargo tank, and a non-specification cargo tank authorized under § 173.315(k) equipped with a meter. PHMSA proposes a minor editorial revision consistent with other proposals to specify this paragraph applies to “cargo tank motor vehicles” instead of “cargo tanks.”

Paragraph (h)(1)(iv)

This paragraph provides an alternate leakage test pressure for an MC 330 or MC 331 cargo tank in dedicated service for anhydrous ammonia. PHMSA proposes minor editorial revisions to specify this paragraph applies to “specification MC 330 or MC 331 cargo tank motor vehicles.”

Paragraph (h)(2)

Paragraph (h)(2) details leak test authorizations for cargo tanks used to transport petroleum distillate fuels that are equipped with vapor collection equipment. PHMSA proposes a minor editorial amendment to specify this paragraph applies to “cargo tank motor vehicles” instead of “cargo tanks” consistent with correct terminology and other proposals.

Paragraph (h)(3)

This paragraph requires that if a cargo tank fails to retain leakage test pressure, it may not be returned to service as a specification cargo tank, except under conditions specified in § 180.411(d). PHMSA proposes editorial amendments to indicate that this paragraph applies to “cargo tank motor vehicles” instead of “cargo tanks.” Furthermore, PHMSA proposes to include leaks as another reason why the cargo tank may not be returned to service. A cargo tank motor vehicle that is leaking would not pass a leakage test if one was conducted and thus, should be subject to this paragraph and subject to repair immediately. Therefore, a leakage test would not have to be performed on the leaking cargo tank motor vehicle before the cargo tank motor vehicle is subject to repair. The intent of this revision is to support the safe transportation of hazardous materials in cargo tank motor vehicles by allowing leaking tanks to be repaired more efficiently. Lastly, PHMSA proposes to remove the specific reference to § 180.411(d) as how a cargo tank motor vehicle is returned to service. Section 180.411(d) requires all sources of leakage must be repaired. Instead of requiring the reader to turn to another section with minimal instruction, PHMSA proposes to add plain language to indicate the cargo tank

motor vehicle must be repaired as required by this subpart before returning to service. PHMSA expects that this provides regulatory clarity and therefore, aids in increased safety.

Paragraph (h)(4)

This paragraph specifies the inspection requirements for delivery hose assembly and piping systems of specification MC 330 and MC 331 cargo tank motor vehicles and non-specification cargo tank motor vehicles authorized under § 173.315(k). PHMSA proposes editorial amendments in this paragraph. First, PHMSA proposes to remove the July 1, 2000, reference as this date has passed and is no longer needed. PHMSA also proposes to specify this paragraph applies to Registered Inspectors “conducting a leakage test” to reinforce the general applicability of paragraph (h). Lastly, PHMSA proposes to revise all references of “cargo tanks” to “cargo tank motor vehicles,” consistent with other proposals. These proposed editorial amendments help to increase regulatory clarity and ultimately, increase safety.

On August 1, 2012, in response to various incidents and NTSB Safety Recommendations H-12-1 through H-12-6, FMCSA issued a notice⁵⁸ regarding hoses used for the transfer of Anhydrous Ammonia and Liquefied Petroleum Gas from cargo tank motor vehicles to storage tanks, and vice versa. This notice reinforced the potential hazards and importance of safety requirements for these hoses, which are subject to emergency discharge control requirements in § 173.315(n). Therefore, to reinforce the need to have these hoses tested and inspected, PHMSA proposes to specify the applicability of the requirements for delivery hose assembly and piping systems in this paragraph includes any delivery hose assembly used to meet § 173.315(n). PHMSA expects that codifying this information in the HMR will increase compliance and therefore, increase safety.

PHMSA also proposes to add a sentence to indicate “the test pressure of the delivery hose assembly must be at least 80 percent of the MAWP of the cargo tank.” This provides regulatory clarity to increase safety and is not intended to revise current inspection requirements.

Lastly, in review of this paragraph, PHMSA and FMCSA identified that the sentence “[d]elivery hose assemblies not

⁵⁸ See the August 1, 2012, notice at: https://www.fmcsa.dot.gov/sites/fmcsa.dot.gov/files/docs/Important%20Notice%20Regarding%20Anhydrous%20Ammonia%20and%20Liquefied%20Petroleum%20Gas%20Hoses_508CLN.pdf.

permanently attached to the cargo tank motor vehicle may be inspected separately from the cargo tank motor vehicle” may potentially be confusing language. As currently required in § 180.416(e), a delivery hose assembly that is not permanently attached to a cargo tank is required to be annually tested in accordance with § 180.407(h)(4). However, because § 180.407(h)(4) only uses the term “inspection” without the term “testing,” there is potential ambiguity on how a person tests a delivery hose assembly that is not permanently attached to a cargo tank. To remove this ambiguity, PHMSA proposes to revise “separately from the cargo tank motor vehicle” to “and tested while not attached to the cargo tank motor vehicle.” By reducing any potential ambiguity, PHMSA expects this will increase compliance and ultimately, safety.

Paragraph (i)(4)(v)

This paragraph requires thickness testing be performed on the areas around shell reinforcements. PHMSA proposes to add emphasis that the areas around shell reinforcements include the areas “around all ring stiffeners and the areas in the bottom half of the cargo tank.” PHMSA expects this proposed language will aid in regulatory understanding to ultimately increase safety, without altering the intent of this section.

Paragraph (i)(6)

Paragraph (i)(6)(ii) requires that the cargo tank motor vehicle nameplate must reflect revised service limits as one of the conditions to continue using a cargo tank that no longer conforms to the minimum thickness prescribed in the original design of a cargo tank motor vehicle.

PHMSA proposes to clarify that the cargo tank DCE must supply the part 178 supplemental Certificate of Compliance (currently required by § 180.407(i)(6)(i)) that includes the revised minimum thickness to the cargo tank motor vehicle owner. This proposal establishes an additional record beyond the name plate or specification to assist with traceability of the cargo tank motor vehicle. In addition, this ensures these revised service limits can be identified if there is degradation of the name plate or specification, which will increase future safe transportation and maintenance of the cargo tank motor vehicle. Additionally, PHMSA is proposing an editorial revision to include marking the “certification plate” for older 300-series CTMVs.

Section 180.409

This section details minimum qualifications for inspectors and testers. Paragraph (a) includes introductory language for this section. PHMSA proposes minor editorial revisions to paragraph (a) for ease of reading. This includes removing “except as otherwise provided in this section” and replacing the § 180.407(e) reference with a general reference to this subpart. PHMSA expects that by increasing the readability, it increases compliance and therefore, safety.

Additionally, PHMSA proposes to add paragraph (a)(4) to reinforce that a registered inspector must meet the training requirements of part 172 subpart H. The second highest number of FMCSA enforcement violations each year occur from Registered Inspectors not having met the general hazmat employee training requirements. Therefore, in an effort to improve compliance and reinforce the current HMR requirements, PHMSA proposes to add paragraph (a)(4) to state that Registered Inspectors must meet the training requirements in part 172 subpart H.

Section 180.411

Section 180.411 details the acceptable results of the test and inspections of cargo tank motor vehicles required by the HMR. Paragraph (b) provides introductory language and requires use of CGA C-6 for evaluation procedures of dents, cuts, digs, and gouges. Paragraph (b)(1) provides acceptable results for dents. In review of the HMR, PHMSA noted in addition to dents, cuts, digs, and gouges, CGA C-6 also includes evaluation procedures for bulges. Similar to dents, bulges are a feature of a cargo tank that should be evaluated to ensure the cargo tank motor vehicle operates properly. Therefore, to increase safety and align with CGA C-6, PHMSA proposes to add bulges in the list of defects in the introductory title to paragraph (b) and in paragraph (b)(1).

Paragraph (g) specifies that any tank that fails to meet pressure test requirements must be properly repaired. As a minor editorial amendment, in the introductory text, PHMSA proposes to add the word “cargo” to clarify the testing is for the “cargo tank.”

Lastly, PHMSA proposes to add paragraph (h) to specify when a cargo tank motor vehicle must be removed from service and how that removal must be communicated to the cargo tank motor vehicle owner. This proposed language specifies that if a Registered Inspector determines the cargo tank motor vehicle does not meet the

applicable design specification, it may not be represented as a DOT specification cargo tank motor vehicle. Furthermore, the cargo tank motor vehicle must be removed from service until it is in compliance with the specification requirements and has been successfully tested and inspected as required by § 180.407(c). This aligns with current regulatory requirements, but provides additional clarity, specifically for scenarios where a non-conforming cargo tank motor vehicle may not be marked as a DOT specification cargo tank until it has been repaired and can pass the appropriate § 180.407(c) test and inspections. Therefore, PHMSA expects this proposal to increase safety and ensure cargo tank motor vehicles are removed from hazardous materials service when they do not conform to the HMR.

Section 180.413

Section 180.413 specifies requirements for the repair, modification, stretching, rebarrelling, or mounting of specification cargo tanks. Paragraph (b)(6) requires that MC 330 and MC 331 cargo tanks must be repaired in accordance with CGA Technical Bulletin TB-2 and the National Board Inspection Code. PHMSA proposes to update the IBR of CGA Technical Bulletin TB-2 to CGA Technical Bulletin P26 (formerly TB-2) in § 171.8. See “Section IV. Section-by-Section Review; Part 171; Section 171.7” for a discussion on the proposed change to this IBR. Therefore, PHMSA proposes to revise the name of the CGA Technical Bulletin in this paragraph.

Section 180.415

This section includes requirements for test and inspection markings for cargo tanks and cargo tank motor vehicles. Paragraph (b) details cargo tank marking requirements after completion of a test or inspection. PHMSA proposes to require that after a test or inspection, the cargo tank facility mark their cargo tank registration number on the cargo tank. As proposed, this marking must be placed immediately adjacent to other required markings and does not need to be replicated if the registration number is already marked on the cargo tank. FMCSA identified some cargo tanks that display current test or inspection markings but found safety concerns with the cargo tank. However, without the cargo tank registration number marked on the cargo tank, it is difficult to trace those safety concerns back to the testing and inspection facility who repaired, tested, or inspected the cargo tank. PHMSA and FMCSA expect that

having the cargo tank facility's registration number marked on the cargo tank will also aid in correcting noncompliance and increase the safety of cargo tank motor vehicles being operated on the highway.

Section 180.416

This section specifies inspection and maintenance requirements of discharge systems for cargo tanks transporting liquefied compressed gases. Paragraph (a) details the applicability of § 180.416. PHMSA proposes to revise editorially "nonspecification cargo tanks" to "nonspecification cargo tank motor vehicles," which aligns with other references to these cargo tank motor vehicles in the HMR.

Paragraph (b) details hose identification requirements. PHMSA proposes to remove the compliance date of July 1, 2000, as this date has passed, and all hoses are now subject to this requirement. This editorial revision helps to provide regulatory clarity and increase safety.

Paragraph (c) states the operator of a cargo tank motor vehicle must visually check that portion of the hose assembly that has been deployed during unloading. PHMSA proposes to specify that the rejection criteria in § 180.416(g) should be used when an operator visually checks the portion of the delivery hose assembly that was deployed during the unloading process. While not currently specified in paragraph (c), the rejection criteria in § 180.416(g) applies to hose assemblies; therefore, this proposal provides clarity and aids in additional regulatory compliance. Ultimately, PHMSA expects this proposal will increase safety.

Paragraph (f) specifies requirements for new or repaired delivery hose assemblies and PHMSA proposes minor editorial amendments, with paragraph (f)(3) specifying record requirements following the test and inspection. PHMSA proposes to revise the introductory text of paragraph (f) to specify the requirements apply to a "cargo tank motor vehicle" instead of a "cargo tank." PHMSA also proposes to remove the compliance date of July 1, 2000, in paragraph (f)(3), as this date has passed. Both of these proposed editorial amendments align with other proposals and provide regulatory clarity, which is anticipated to increase safety.

Section 180.501

Section 180.501 contains the general requirements for continued use of tank cars. In this NPRM, PHMSA proposes to replace the phrase "owner's qualification program" with "owner's

qualification and maintenance program" similar to other references to the owner's qualification and maintenance program in §§ 179.7, 180.503, and 180.513. The intent of this change is to maintain consistency and clarity within the HMR, and to ensure there is no confusion over the scope of part 180, subpart F, titled "Qualification and Maintenance of Tank Cars."

Section 180.503

Section 180.503 contains definitions relevant to the qualification and maintenance of tank cars. PHMSA proposes to revise the definitions of *coating/lining owner*, *service equipment owner* and *tank car owner*, to convey more clearly and accurately the intended application of these definitions in part 180 subpart F. These definitions are revised as "the person responsible for the development or approval, and execution of the qualification and maintenance program" for the coating/lining, service equipment, or tank car owner, as appropriate. This change identifies the responsible parties more accurately throughout subpart F, particularly by removing confusion about financial responsibility that can arise with complex multi-dimensional business arrangements, agreements, contracts, and organization. This proposed change was approved by HMIWG during the January 10–11, 2017 meeting. The proposed language was approved by consensus vote at the May 25, 2017, RSAC meeting and offered to PHMSA and FRA for consideration.

PHMSA also proposes to amend the following definitions:

- **Maintenance:** PHMSA proposes to remove "upkeep, or preservation" from the definition of *maintenance* and replace it with "performance of functions." PHMSA and FRA consider "upkeep" and "preservation" too vague to be useful, especially for service equipment. *Maintenance* of service equipment that triggers qualification is an activity that meets the conditions requiring a leakage pressure test in accordance with § 180.509(j) (e.g., breaking the seal between the service equipment and the tank car tank). Actions on service equipment that don't require the service equipment to be removed from the tank do not meet the definition of *maintenance* and don't trigger qualification, unless the owner's qualification and maintenance program specifically requires qualification after certain activities. See "Section II.B.4. Tank Car Facility Definition" for additional information. Lastly, PHMSA proposes to revise "proper" to

"appropriate" as an editorial amendment.

- **Modification:** PHMSA proposes to replace "certificate of construction" with "design approval certificate" for tank cars constructed after the effective date of a final rule. Tank cars constructed under AAR-approved certificates of construction must receive DCE approval for any modification. See "Section II.B.2. Tank Car Design Approval" for additional information.

- **Qualification:** PHMSA proposes to replace the phrase "applicable requirements of the AAR Specifications for Tank Cars (IBR, see § 171.7 of this subchapter)" with "approved design." This amendment conforms to PHMSA's proposal to remove AAR approval requirements.

- **Service equipment:** PHMSA proposes to revise this definition to align with the current industry standard and is intended to provide more clarity than the current definition. Service equipment is pressure or lading retaining equipment and therefore performs a critical safety function. See "Section II.B.4. Tank Car Facility Definition" for additional information related to entities who operate and qualify service equipment. PHMSA and FRA emphasize that service equipment must continue to be included in the tank car owner's qualification and maintenance plan.

Section 180.509

Section 180.509 details requirements for inspection and testing of specification tank cars. Paragraph (i)(1) requires inspections of tank car internal linings and coatings used to transport a material that is corrosive or reactive to the tank car. PHMSA proposes to revise paragraph (i)(1) to indicate more clearly that the inspection requirements only apply to those linings and coatings used to protect the tank from corrosion or reactivity.

Paragraph (k)(2) contains qualification requirements for service equipment. PHMSA proposes to remove the phrase "[e]ach tank car facility must qualify" from § 180.509(k) because PHMSA does not require tank car facilities to qualify service equipment. Additionally, PHMSA proposes to replace "qualified in accordance with" with "must conform to" as an amendment to better align the paragraph with the definition of "tank car facility" being proposed in this rulemaking. See "Section II.B.4. Tank Car Facility Definition" for additional information.

Section 180.513

This section includes requirements for repairs, alterations, conversions, and

modifications of tank cars, with paragraph (b) specifying the responsibilities of a tank car facility. PHMSA proposes to revise paragraph (b) editorially to replace “Quality Assurance Program” with “qualification and maintenance program.” This proposal clarifies the tank car owner’s responsibility to provide tank car facilities with qualification and maintenance information. See “Section II.B.8. Editorial Revision to §§ 180.501 and 180.513” for additional information.

Section 180.517

Section 180.517 contains reporting and record retention requirements for tank car qualification. PHMSA proposes to remove reference to the “certification of construction” and replace it with the proposed “Design Approval Certificate” for tank cars constructed after the effective date of a final rule. See “Section IV. Section-by-Section Review; Part 179; Section 179.5” for more information. Tank cars constructed with AAR-approved certificates of construction will remain subject to the same recordkeeping requirements for the rest of their service lives. In paragraph (a), PHMSA also proposes to replace references to the builder of the car with references to the tank car facility, replace references to the certificate of construction with references to qualification reports, and add a reference to paragraph 179.7(b)(12). The revisions to paragraph (a) are intended to accommodate the proposed replacement of AAR TCC approval with tank car DCE approval of tank car and service equipment designs. We propose to replace the phrase “related papers” with “related qualification reports,” to clarify that we expect tank car owners to retain the reports issued by tank car facilities at the time of manufacture and maintenance qualification. Additionally, PHMSA proposes to add a requirement to record the tank car facilities’ registration number on the inspection and test report in new paragraph (b)(9).

Appendix D to Part 180

This appendix discusses materials considered corrosive to the tank or service equipment. PHMSA proposes to remove reference to the AAR TCC from the second paragraph, in conformance with the proposal to replace AAR TCC approval with tank car DCE approval. Therefore, PHMSA proposes to state that the list in Appendix D may be modified based on an analysis of the test results by the car owner or the Department of Transportation.

V. Regulatory Analyses and Notices

A. Statutory/Legal Authority

This NPRM is published under the authority of Federal Hazardous Materials Transportation Act (HMTA; 49 U.S.C. 5101–5127). Section 5103(b) of the HMTA authorizes the Secretary of Transportation to “prescribe regulations for the safe transportation, including security, of hazardous materials in intrastate, interstate, and foreign commerce.” The Secretary has delegated the authority granted in the HMTA to the PHMSA Administrator at 49 CFR 1.97(b).

B. Executive Order 12866, 14094, and DOT Regulatory Policies and Procedures

Executive Order 12866 (“Regulatory Planning and Review”)⁵⁹ as amended by Executive Order 14094 (“Modernizing Regulatory Review”),⁶⁰ requires that agencies “should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.” Agencies should consider quantifiable measures and qualitative measures of costs and benefits that are difficult to quantify. Further, Executive Order 12866 requires that “agencies should select those [regulatory] approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.” Similarly, DOT Order 2100.6A (“Rulemaking and Guidance Procedures”) requires that regulations issued by PHMSA, and other DOT Operating Administrations should consider an assessment of the potential benefits, costs, and other important impacts of the proposed action and should quantify (to the extent practicable) the benefits, costs, and any significant distributional impacts, including any environmental impacts.

Executive Order 12866 and DOT Order 2100.6A require that PHMSA submit “significant regulatory actions” to the Office of Management and Budget (OMB) for review. This rulemaking is not considered a significant regulatory action under section 3(f) of Executive Order 12866 (as amended) and, therefore, was not formally reviewed by OMB. A PRIA with estimates of the costs and benefits of the rulemaking is available in the docket.

PHMSA solicits comment on this analysis. Overall, the issues discussed in this rulemaking promote the continued safe transportation of

hazardous materials while producing a net cost savings. Cost savings are derived from certain modal specific provisions, including expanding allowance of UN ID number marking on cargo tank motor vehicles that transport different petroleum distillate fuels within the same day and reduction in the number of anticipated OTMAs for rail tank cars.

Based on the discussions of benefits and costs provided above, PHMSA estimates annualized net benefits at a two percent discount rate of approximately \$97.3 million per year. Details on the estimated costs, cost savings, and benefits of this rulemaking can be found in the PRIA, which is available in the public docket.

C. Executive Order 13132

PHMSA analyzed this rulemaking in accordance with the principles and criteria in Executive Order 13132 (“Federalism”)⁶¹ and the Presidential Memorandum (“Preemption”) that was published in the **Federal Register** on May 22, 2009.⁶² Executive Order 13132 requires agencies to assure meaningful and timely input by state and local officials in the development of regulatory policies that may have “substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.”

This rulemaking may preempt state, local, and Native American tribe requirements, but does not propose any regulation that has substantial direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government.

The Federal Hazmat Law contains an express preemption provision, 49 U.S.C. 5125 (b), that preempts state, local, and tribal requirements on certain covered subjects, unless the non-federal requirements are “substantively the same” as the federal requirements, including:

- (1) Designation, description, and classification of hazardous materials;
- (2) Packing, repacking, handling, labeling, marking, and placarding of hazardous materials;
- (3) Preparation, execution, and use of shipping documents related to hazardous materials and requirements related to the number, contents, and placement of those documents;

⁵⁹ 58 FR 51735 (Oct. 4, 1993).

⁶⁰ 88 FR 21879 (Apr. 11, 2023).

⁶¹ 64 FR 43255 (Aug. 10, 1999).

⁶² 74 FR 24693 (May 22, 2009).

(4) Written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) Design, manufacture, fabrication, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

This rule addresses subject items (3) and (5) above, which are covered subjects, and, therefore, non-federal requirements that fail to meet the “substantively the same” standard are vulnerable to preemption under the Federal Hazmat Law. Moreover, PHMSA will continue to make preemption determinations applicable to specific non-federal requirements on a case-by-case basis, using the obstacle, dual compliance, and covered subjects tests provided in Federal Hazmat Law.

This rule also incorporates certain FRA requirements under the former Federal Railroad Safety Act of 1970, as repealed, revised, reenacted, and recodified (FRSA; 49 U.S.C. 20106), and the former Safety Appliance Acts, as repealed, revised, reenacted, and recodified (SAA; 49 U.S.C. 20301–20302, 20306) that may potentially preempt certain state requirements. Such FRSA and SAA requirements would apply to transportation by rail.

D. Executive Order 13175

PHMSA analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13175 (“Consultation and Coordination with Indian Tribal Governments”)⁶³ and DOT Order 5301.1 (“Department of Transportation Policies, Programs, and Procedures Affecting American Indians, Alaska Natives, and Tribes”). Executive Order 13175 and DOT Order 5301.1 requires DOT Operating Administrations to assure meaningful and timely input from Native American tribal government representatives in the development of rules that significantly or uniquely affect tribal communities by imposing “substantial direct compliance costs” or “substantial direct effects” on such communities or the relationship and distribution of power between the federal government and Native American tribes. Because this rulemaking does not have Native American tribal implications, and does not impose substantial direct compliance costs, the funding and consultation requirements of Executive Order 13175 do not apply. However, PHMSA solicits comments from Native American tribal governments and

communities on potential impacts of this proposed rulemaking.

E. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires agencies to consider whether a rulemaking would have a “significant economic impact on a substantial number of small entities” to include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000. The Regulatory Flexibility Act directs agencies to establish exceptions and differing compliance standards for small businesses, where possible to do so and still meet the objectives of applicable regulatory statutes. Executive Order 13272 (“Proper Consideration of Small Entities in Agency Rulemaking”)⁶⁴ requires agencies to establish procedures and policies to promote compliance with the Regulatory Flexibility Act and to “thoroughly review draft rules to assess and take appropriate account of the potential impact” of the rules on small businesses, governmental jurisdictions, and small organizations. The DOT posts its implementing guidance on a dedicated web page.⁶⁵

This rulemaking has been developed in accordance with Executive Order 13272 and DOT’s procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts of draft rules on small entities are properly considered. PHMSA has developed an initial regulatory flexibility analysis (IRFA), which is included in the docket. As detailed in the IRFA, the impact of this rulemaking on small business is not expected to be significant. The proposed changes are generally intended to provide regulatory flexibility and cost savings to industry members, while increasing safety. However, PHMSA solicits comment on the anticipated economic impacts to small entities and the IRFA.

F. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), no person is required to respond to any information collection unless it has been approved by OMB and displays a valid OMB control number. Pursuant to 44 U.S.C. 3506(c)(2)(B) and 5 CFR

1320.8(d), PHMSA must provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests.

PHMSA has analyzed this NPRM in accordance with the Paperwork Reduction Act. PHMSA proposes to revise the approved information collections under the following OMB Control Numbers: OMB Control No. 2137–0014, “Cargo Tank Specification Requirements;” OMB Control No. 2137–0559, “Rail Carrier and Tank Car Tanks Requirements, Rail Tank Car Tanks—Transportation of Hazardous Materials by Rail;” and OMB Control No. 2137–0612 “Hazardous Materials Security Plans.”

OMB Control No. 2137–0014, “Cargo Tank Specification Requirements”

PHMSA estimates that this rulemaking will result in an increase in burden due to the proposed requirements in § 180.407(f)(2) for a cargo tank owner to provide paperwork to the Registered Inspector prior to lining inspection and § 180.415(b) for an inspector or tester to mark the cargo tank with their registration number. A total overview of the proposed changes in this OMB Control Number are detailed in the table below.

For the proposed requirement in § 180.407(f)(2) for a cargo tank owner to provide paperwork to the Registered Inspector for lining inspection, PHMSA estimates 1,333 cargo tank owners will provide paperwork for approximately 60 cargo tanks per year. It is estimated to take five minutes per response, for a total of 6,665 annual burden hours. PHMSA does not estimate that there are any out-of-pocket expenses.

The new proposed requirement in § 180.415(b) for a cargo tank inspector to mark the cargo tank with their registration number is expected to increase information collection burden. PHMSA estimates 3,400 cargo tank inspectors will mark each cargo tank approximately 61 times per year. The marking is anticipated to take five minutes per inspection, resulting in a total of 17,283 annual burden hours. PHMSA does not estimate any out-of-pocket expenses. PHMSA notes that after the first year of this requirement, there will be a significant reduction in this burden as the registration number does not need to be remarked on the cargo tank if it is being tested and inspected at the same location. Therefore, PHMSA plans to update this burden one year after the effective date of this rulemaking.

Lastly, PHMSA acknowledges that there are proposed amendments that

⁶⁴ 67 FR 53461 (Aug. 16, 2002).

⁶⁵ DOT, “Rulemaking Requirements Related to Small Entities,” <https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities> (last visited Jun. 17, 2021).

⁶³ 65 FR 67249 (Nov. 6, 2000).

impact the burden but are not included in this estimate. PHMSA does not estimate a significant change in the current burden due to the proposed changes to cargo tank registration including requiring an email address on the registration statement, providing for online submission, and expanding the types of certificates that must be

provided in an application. Additionally, PHMSA does not expect that there will be more than ten respondents who will submit a written response, request for reconsideration, or request appeal following the modification, suspension, or termination of their cargo tank registration. PHMSA and FMCSA also

expect that there will not be more than ten respondents per year who will replace a missing specification plate and prepare and maintain paperwork, as proposed in new § 180.503(b)(3). Therefore, PHMSA is not including a new information collection for this requirement.

Information collection details	Increase in number of respondents	Response per respondent	Increase in number of responses	Minutes per response	Increase in annual burden hours	Increase in annual burden costs
Obtain and Provide Paperwork for Lining Inspection—§ 180.407(f)(2)	1,333	60	79,980	5	6,665	\$0
Registration Number on Cargo Tank—§ 180.415(b)	3,400	61	207,400	5	17,283	0

Annual Increase in Number of Respondents: 4,733.
Annual Increase in Number of Responses: 287,380.
Annual Increase in Burden Hours: 23,948.
Annual Increase in Burden Costs: \$0.

OMB Control No. 2137-0559, “Rail Carrier and Tank Car Tanks Requirements, Rail Tank Car Tanks—Transportation of Hazardous Materials by Rail”

PHMSA estimates that this rulemaking will result in an increase in burden due to various tank car proposed changes, including: new tank car facility and DCE registration, including reporting and recordkeeping requirements; development of procedures for closing and securing all openings on tank cars; record requirements for a tank car being held more than 48 hours; OTMA recordkeeping requirements; DCE written procedures to verify compliance of tank cars; and requirement for the DCE to provide a DAC to the tank car or service equipment owner. However, this rulemaking will also lead to a decrease in burden, particularly in the removal of AAR reporting to Bureau of Explosives under § 174.20 and reduction in the number of OTMA applications under § 174.50. A total overview of the proposed changes in this OMB Control Number are detailed in the below table.

PHMSA estimates that 280 tank car facilities will register for the proposed new tank car facility registration requirements in § 107.905. Each registration is anticipated to take two hours, for a total of 560 annual burden hours. PHMSA does not estimate that there are any out-of-pocket expenses associated with this information collection.

PHMSA estimates that 25 DCEs will register under the proposed new

requirement in § 107.907 for DCE registration. Each registration is anticipated to take two hours to complete, for a total of 50 annual burden hours. PHMSA does not estimate any out-of-pocket expenses associated with this information collection.

For both tank car facility and DCE registration, PHMSA does estimate that this number will significantly reduce after the first year of initial tank car facility and DCE registration. However, after the first initial registration period, PHMSA estimates there will be a burden associated with registration renewal and updating the requirements in §§ 107.909(c) and 107.909(d). As tank car facility and DCE registration are new requirements, PHMSA does not estimate the renewal and updating requirements in the first year. However, PHMSA plans to estimate that to renew or update a tank car facility or DCE registration, it will take approximately 30 minutes to complete. One year after the effective date of this rulemaking, PHMSA will update the burden for initial registration and renewal and updating a registration.

PHMSA also estimates an increase in burden based on tank car facility and DCE registration recordkeeping proposed requirements in § 107.909(e). PHMSA estimates that most of the requests for a registration copy will occur during FRA inspections, which occur approximately 45 times per year. It is anticipated that it will take five minutes to produce the paperwork, resulting in total of approximately four annual burdens hours. PHMSA does not estimate any out-of-pocket expenses.

Additionally, PHMSA proposes requirements for the modification, suspension, and termination of tank cargo facility and DCE registrations, including provisions for registrants to submit a written response, request for

reconsideration, and appeal of the decision. However, PHMSA has not estimated this burden, as PHMSA estimates that there will be less than ten registrants per year who may choose to respond, request reconsideration, or appeal their modification, suspension, and termination of their registration.

PHMSA proposes to revise the approval process in § 173.31(a)(2) from AAR approval to DCE approval. Accordingly, PHMSA will revise the name of the information collection from “AAR Approval Required when a Tank Car is Proposed for Commodity Service other than Specified on a Certificate of Construction” to “DCE Approval when a Tank Car Carries a Commodity other than Specified on a Certificate of Construction or DAC.” However, PHMSA does not expect a change in the burden associated with this collection because the required information for the change request does not change; only the approval entity is proposed to be changed.

PHMSA proposes to revise § 173.31(d)(1) to require written procedures for closure and securement of all openings on a tank car prior to shipment. PHMSA estimates that there are 4,619 tank car offerors who will be subject to this requirement. PHMSA estimates that 95 percent of these offerors already have some form of procedures and thus the burden to review and update these procedures is limited to 16 hours resulting in a total of 70,209 annual burden hours. The other five percent of offerors will need to create new procedures, which is estimated to take 40 hours to develop, resulting in a total of 9,238 annual burden hours. Therefore, PHMSA estimates that there will be an increase of 79,447 total burden hours for this new requirement. PHMSA does not estimate any out-of-pocket expenses. Following the initial year of this

rulemaking, PHMSA estimates that the burdens associated with developing these procedures will be significantly reduced, as only new tank car offerors will be subject to this requirement. Additionally, after the first year, PHMSA estimates that there will be a new burden for existing offerors to update their written procedures. PHMSA estimates that five percent of tank car offerors will take eight hours to update the procedures on an annual basis. PHMSA plans to add this burden after the rulemaking has been effective for one year.

PHMSA proposes a new requirement in § 174.14(a) to create a record when a tank car is being held beyond 48 hours. PHMSA estimates that there are 100 railroads who create this record 100 times per year. Each record takes approximately five seconds, resulting in a total of 14 annual burden hours. PHMSA does not estimate any out-of-pocket expenses.

PHMSA proposes to remove § 174.20(b), which requires reporting to the AAR Bureau of Explosives regarding any restrictions over any portion of its lines. PHMSA currently accounts for 34

offerors submitting 1.5 reports a year. Each report takes 20 minutes resulting in a reduction of 17 hours of annual burden.

PHMSA proposes to revise § 174.50 for OTMA requirements, including adding exceptions from needing an OTMA. Because of these reductions, PHMSA estimates a reduction of approximately three OTMA per year for each applicant for a total reduction of 575 OTMAs per year. As each application takes approximately 24 minutes to complete an OTMA, this revision results in an estimated reduction of 202 annual burden hours. PHMSA does not estimate any out-of-pocket expenses.

In § 174.50(d), PHMSA proposes to specify recordkeeping requirements for OTMAs. PHMSA estimates that these recordkeeping requests, which will mostly be through enforcement requests, occur 56 times per year. It takes approximately five minutes to produce the OTMA documentation, for a total of five annual burden hours. PHMSA does not estimate any out-of-pocket expenses.

PHMSA proposes a new requirement in § 179.3(b) for a DCE to develop

written procedures to verify compliance with tank car design. PHMSA estimates that it takes eight hours for each of the 25 DCEs to develop written procedures, resulting in a total of 200 annual burden hours. PHMSA does not estimate any out-of-pocket expenses. Furthermore, as this is a one-time requirement, PHMSA plans to reduce this information collection one year after the effective date of this rulemaking.

Lastly, PHMSA proposes a recordkeeping requirement in §§ 179.3(d) and 179.5 that the DCE provide a copy of the DAC to the tank car or service equipment owner following approval. PHMSA estimates that the 25 DCEs will review and approve approximately 14 tank cars or service equipment designs per year, resulting in a total of 350 DACs produced. PHMSA estimates it will take 10 hours to develop the DAC resulting in 3,500 annual burden hours. PHMSA estimates that there are no out-of-pocket expenses for development of the DAC.

The following table outlines the total change in information collection burden:

Information collection request	Change in number of respondents	Responses per respondent	Change in number of responses	Time per response	Change in total burden hours	Change in annual burden costs
Tank Car Facility Registration—§ 107.905	280	1	280	2 hours	560	\$0
DCE Registration—§ 107.907	25	1	25	2 hours	50	0
Tank Car Facility & DCE Registration Record Retention—§ 107.909(e)	45	1	45	5 minutes	4	0
Tank Car Tank Car Facility & DCE Registration—Renew or Update Registration—§ 107.909(e)	0	0	0	30 minutes	0	0
DCE Approval when a Tank Car Carries a Commodity other than Specified on a Certificate of Construction or DAC—§ 173.31(a)(2)	0	48	0	10 minutes	0	0
Procedures for Closing and Securing All Openings on a Tank Car—§ 173.31(d)(1)—NEW	4,619	1	4,619	16 hours	70,280	0
Procedures for Closing and Securing All Openings on a Tank Car—§ 173.31(d)(1)—UPDATES	231	1	231	40 hours	9,240
Record Required for Car Being Held—§ 174.14(a)	100	100	10,000	5 seconds	14	0
Reporting to the Bureau of Explosives Regarding any Restrictions Over Any Portion of its Lines—§ 174.20(b)	-34	1.5	-51	20 minutes	-17	0
OTMA Application—§ 174.50(c)	-54	9	-575	24 minutes	-202	0
OTMA Documentation—§ 174.50(d)	56	1	56	5 minutes	5	0
DCE Written Procedure to Verify Compliance—§ 179.3(b)	25	1	25	8 hours	200	0
DCE Providing DAC Requirements—§§ 179.3(d), 179.5	25	14	350	10 hours	3,500	0

Annual Increase in Number of Respondents: 5,318.

Annual Increase in Number of Responses: 15,005.

Annual Increase in Burden Hours: 83,634.

Annual Increase in Burden Costs: \$0.

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PHMSA estimates this rulemaking will result in a change in the current estimated burden based on the new

exception from alternate route analysis. Specifically, PHMSA proposes to add § 172.820(d)(3) to provide an exception where no alternate route exists. PHMSA estimates that approximately 10 percent of Class II and III railroad routes will no longer have to develop alternate route analysis. This leads to a reduction of 1,400 total burden hours for both Class II and III railroads. However, § 172.820(d)(3) requires that to take the alternate route analysis exception, the railroad must develop remediation or

mitigation measures and certify that no alternative route exists. Therefore, PHMSA estimates that there will be 132 railroads (32 Class II and 100 Class III railroads), with 47 routes where no alternate route exists. PHMSA estimates it will take 30 minutes to develop the written measures and certification and this new requirement will result in a total of 24 annual burden hours. Because there is no change in the number of Class II and III railroads who are subject to alternate route analysis

requirements, there is an increase in respondents and responses, but there is an overall decrease in burden hours and

salary costs. The below table details the estimated change in burden associated

with this new exception. PHMSA does not estimate any out-of-pocket expenses.

Information collection details—alternate route analysis—§ 172.820(d)	Change in number of railroads	Change in number of routes per railroad	Change in number of routes	Burden hours per route	Change in total burden hours	Change in total burden cost
Class II Railroads	0	-0.3	-10	120	-1,200	\$0
Class III Railroads	0	-0.05	-5	40	-200	0
Where No Practicable Route Exists	132	0.35	47	0.5	24	0

Annual Increase in Number of Respondents: 132.

Annual Increase in Number of Responses: 32.

Annual Decrease in Burden Hours: 1,376.

Annual Decrease in Burden Costs: \$0.

PHMSA requests comments on any information collection and recordkeeping burden associated with the proposed changes under this rulemaking. Address written comments to the DOT Dockets Operations Office as identified in the ADDRESSES section of this rulemaking. Comments regarding information collection burdens must be received prior to the close of the comment period identified in the DATES section of this rulemaking. Requests for a copy of this information collection should be directed to Steven Andrews or Glenn Foster, 202-366-8553, OHMSPRA@dot.gov, Standards and Rulemaking Division (PHH-10), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590-0001. If these proposed requirements are adopted in a final rule, PHMSA will submit the revised information collection and recordkeeping requirements to OMB for approval.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA; 2 U.S.C. 1501 et seq.) requires agencies to assess the effects of federal regulatory action on state, local, or tribal governments, and the private sector. For any NPRM or final rule that includes a federal mandate that may result in the expenditure by state, local, and tribal governments, or by the private sector of \$100 million or more in 1996 dollars in any given year, an agency must prepare, amongst other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the federal mandate.

This proposed rulemaking does not impose unfunded mandates under URMA. As explained in the PRIA, it is not expected to result in costs of \$100 million or more in 1996 dollars on

either state, local, or tribal governments, in the aggregate, or to the private sector in any one year, and is the least burdensome alternative that achieves the objective of the rule.

H. Draft Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 et seq), requires that federal agencies analyze proposed actions to determine whether the action will have a significant impact on the human environment. When the effects of a proposed action are unknown, CEQ implementing regulations (40 CFR 1500-1508) require federal agencies to conduct an environmental review and prepare an environmental assessment to consider (1) the need for the proposed action, (2) alternatives to the action, (3) probable environmental impacts of the action and alternatives, and (4) the agencies and persons consulted during the consideration process. DOT Order 5610.1C ("Procedures for Considering Environmental Impacts") establishes DOT procedures for evaluation of environmental impacts under NEPA and its implementing regulations.

1. Need for the Action

This NPRM would amend the HMR to revise provisions specific to the highway, rail, and vessel transportation of hazardous materials. This proposed action is necessary to increase regulatory clarity and consistency, update requirements to reflect changing conditions and trends, and improve the safe transportation of hazardous materials.

2. Alternatives

In proposing this rulemaking, PHMSA considered the following alternatives:

No Action Alternative

If PHMSA were to select the No Action Alternative, current regulations would remain in place and no new provisions would be amended or added.

Proposed Action Alternative

The proposed alternative for this NPRM includes adoption of RSAC

proposals for rail transportation, revision to the approval process for tank car designs and QAPs, miscellaneous amendments to highway cargo tank specification and requalification requirements, and an amendment to cargo tank marking requirements for the transportation of petroleum distillate fuels that will be discussed in further detail below.

This alternative is the current proposal as it appears in this NPRM, applying to the transportation of hazardous materials by highway, rail, and vessel. The proposed amendments included in this alternative are more fully described in the preamble and regulatory text sections of this NPRM.

3. Reasonably Foreseeable Environmental Impacts of the Alternatives

No Action Alternative

The No Action Alternative would not adopt enhanced and clarified regulatory requirements expected to maintain or increase the high level of safety in transportation of hazardous materials provided by the HMR. For example, creation of reliable and repeatable closure instructions for tank cars in § 173.31 is intended to decrease the number of leaking or improperly closed tank cars entering transportation, which will decrease the quantity of hazardous materials released into the environment. Not adopting the proposed environmental and safety requirements in the NPRM under the No Action Alternative would result in a lost opportunity for reducing safety-related incidents.

If PHMSA were to select the No Action Alternative, the HMR would remain unchanged, and no new provisions would be amended or added. Additionally, any economic benefits and additional regulatory clarity gained through these amendments would not be realized.

Proposed Alternative

The changes under the Proposed Action Alternative will maintain or increase the high safety standards

currently achieved under the HMR. The following details significant proposed amendments and their impact:

1. Adoption of Rail Safety Advisory Committee (RSAC) Proposals for Rail Transportation

Adoption of RSAC proposals includes updating the IBR edition of the AAR Specifications for Tank Cars to the 2014 edition from the 2000 edition; creating closure instruction requirements for tank car offerors; codifying long-standing FRA guidance on OTMAs; and revising tank car use requirements found in part 174 to reflect the current industry best practices in tank car loading and unloading.

The RSAC proposals are designed to improve regulatory clarity, and therefore encourage compliance with the requirements of the HMR. Creation of closure instruction requirements for tanks cars will decrease the number of non-compliant tank cars offered for transportation and the number of non-accidental releases of hazardous materials. Based on a review of non-accident release data, PHMSA and FRA estimate that the implementation of the closure instruction requirement could reduce the number of non-accidental releases by 15 percent, primarily by reducing releases associated with improperly closed hinged-and-bolted manways. Codifying FRA's One Time Movement Approval procedures in the HMR will have no impact on releases of hazardous materials to the environment, because these procedures are already in place as FRA policy. Revisions to part 174, including clarification of the applicability of the term "residue" for tank cars in § 174.58, authorizing additional types of packages for COFC/TOFC service without FRA approval in § 174.63, and revising transloading requirements in § 174.67 are intended to remove unnecessarily prescriptive and outmoded requirements and replace them with performance based standards that maintain the current level of safety. PHMSA and FRA do not anticipate any increase in the release of hazardous materials or other negative environmental impacts from these changes. Increased compliance with the HMR's requirements for hazardous materials containment in particular through proper closure instructions and transloading procedures, decreases the release of hazardous materials to the environment and improve the ability of emergency responders to appropriately respond to accidents and incidents involving hazardous materials in transportation.

Greenhouse gas emissions would remain the same under this proposed amendment.

Based on this analysis adopting RSAC proposals will have a positive impact on human health and the environment.

2. Revision to the Approval Process for Tank Car Designs and Quality Assurance Programs (QAPs)

PHMSA proposes changes to remove the role of the AAR TCC in tank car design approval, to be replaced with design review by a DCE. This process will mirror the current procedure for cargo tank motor vehicles. PHMSA additionally proposes to remove the role of the AAR TCC from the approval process of a tank car facility's QAP, to be replaced with a registration requirement for tank car facilities and increased governmental oversight. Finally, PHMSA proposes to revise the definition of *tank car facility* to narrow the scope of the definition to only cover facilities that qualify tank cars for service.

PHMSA and FRA anticipate that the proposal to replace the role of the AAR TCC with tank car DCEs, registered with PHMSA and subject to PHMSA and FRA oversight will ensure at least an equivalent level of safety oversight due to improved visibility into the design approval process. PHMSA and FRA have limited oversight and control over the current AAR TCC tank car design approval and QAP approval process. The procedures proposed for the design review in Part 179 are intended to create an accountable, auditable, criteria-based tank car design approval system. Similarly, the tank car facility registration program is designed to create increased visibility of tank car facilities with increased government oversight through the registration program, including possible suspension or termination of a registration. Therefore, there will be no change to the suitability of tank car designs, or to the construction, maintenance, and qualification of tank cars conducted by tank car facilities.

PHMSA does not anticipate any impact to greenhouse gas emissions under this proposed amendment.

3. Miscellaneous Amendments to Highway Cargo Tank Specification and Requalification Requirements

PHMSA proposes to amend a variety of highway cargo tank specification and requalification requirements. While a majority of the intended provisions are for editorial and regulatory clarity, they also include the following substantive revisions:

- Updating the IBR edition of CGA P-26 (formerly TB-2) to the 1997 edition;
- Allowing for the use of a Midland PRD for chlorine gases in cargo tanks and portable tanks;
- Requiring post-weld heat treatment on newly manufactured nurse tanks;
- Requiring combustible liquids and flammable liquids reclassified as combustible liquids to be bonded and grounded prior to and during transfer of lading;
- Allowing the DOT Specification 331 and 338 cargo tank motor vehicle specification plate to be applied to the vehicle instead of the rail chassis;
- Ensuring the mechanical means of remote closure on a cargo tank motor vehicle is not obstructed;
- Requiring that all equipment and instruments be calibrated;
- Allowing the use of video camera or fiber optics equipment for any visual test or inspection;
- Requiring inspection of all pad attachments;
- Limiting the need to remove the upper coupler during inspection; and
- Requiring the cargo tank facility registration number to be marked on the cargo tank following inspection.

These highway amendments are designed to improve regulatory clarity, and therefore encourage compliance with the requirements of the HMR. The HMR's cargo tank construction, maintenance, and qualification regulations have not kept up with technological changes, *e.g.*, the availability of small, high quality video cameras capable of producing images of the interior of a cargo tank shell equivalent to human vision. Revising and updating these cargo tank requirements will improve construction, maintenance, and qualification practices for cargo tanks used to transport hazardous materials. These revisions are intended to decrease the release of hazardous materials to the environment during transportation.

Greenhouse gas emissions would remain the same under this proposed amendment.

4. Cargo Tank Marking Requirements for Petroleum Distillate Fuels

PHMSA proposes to revise the marking requirements for cargo tanks transporting multiple petroleum distillate fuels in the current or previous business day (defined as a day that the operator of the cargo tank motor vehicle is open and operating in commerce). The proposal authorizes a carrier to display the marking of the UN ID number for the petroleum distillate fuel with the lowest flashpoint transported

in that cargo tank during the current or previous business day. For example, a cargo tank used to transport gasoline on Day 1, and diesel fuel only on Day 2, may display “1203” on Day 2, because gasoline has a lower flash point than diesel fuel.

PHMSA’s analysis of this proposed amendment indicates that for NA1993, UN1202, UN1203, UN1223, and other petroleum distillate fuels, the ERG directs the reader to the same guide page for initial emergency response measures, and PHMSA further requests information from emergency responders describing how emergency response would differ for an accident involving a cargo tank motor vehicle marked “1993,” “1202,” “1203,” “1223,” or another UN ID number associated with a petroleum distillate fuel. PHMSA requests information on any known incidents where emergency response was impacted negatively due to a cargo tank motor vehicle displaying “1203” when it was transporting a petroleum distillate fuel with a higher flash point.

The substantial time saved during fuel deliveries due to the removal of the requirement to change the ID number displayed inside the placard may provide environmental benefits, including a reduction in greenhouse gases due to a reduction in time cargo tank motors vehicles spend idling while the driver changes the ID number displayed in the placard. PHMSA seeks comment on this, and any other environmental impacts associated with this amendment.

4. Agencies and Persons Consulted During the Consideration Process

PHMSA has coordinated with the FAA, FMCSA, FRA, and the USCG, in the development of this proposed rulemaking. The NPRM has also been made available to other federal agencies within the interagency review process contemplated under Executive Order 12866. PHMSA solicits, and will consider, comments on the NPRM’s potential impacts on safety and the environment submitted by members of the public, state and local governments, tribal communities, and industry.

5. Executive Order 12898

Executive Orders 12898 (“Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations”),⁶⁶ 13985 (“Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”),⁶⁷ 13990 (“Protecting Public Health and the

Environment and Restoring Science To Tackle the Climate Crisis”),⁶⁸ 14008 (“Tackling the Climate Crisis at Home and Abroad”),⁶⁹ and DOT Order 5610.2C (“Department of Transportation Actions to Address Environmental Justice in Minority Populations and Low-Income Populations”) require DOT agencies to achieve environmental justice as part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects, including interrelated social and economic effects of their programs, policies, and activities on minority populations, low-income populations, and disadvantaged communities.

PHMSA has evaluated this proposed rulemaking under the above Executive Orders and DOT Order 5610.2C and expects it would not cause disproportionately high and adverse human health and environmental effects on minority, low-income, underserved, and other disadvantaged populations and communities. The rulemaking is facially neutral and national in scope; it is neither directed toward a particular population, region, or community, nor is it expected to adversely impact any particular population, region, or community. And because PHMSA expects the rulemaking would not adversely affect the safe transportation of hazardous materials generally, PHMSA does not expect the proposed revisions would entail disproportionately high adverse risks for minority populations, low-income populations, or other underserved and other disadvantaged communities.

The proposed rulemaking could reduce risks to minority populations, low-income populations, or other underserved and other disadvantaged communities. Insofar as the proposed HMR amendments could avoid the release of hazardous materials, the proposed rule could reduce risks to populations and communities—including any minority, low-income, underserved and other disadvantaged populations and communities—in the vicinity of interim storage sites and transportation arteries and hubs. Additionally, as explained in the above discussion of NEPA, PHMSA anticipates that its proposed HMR amendments will yield modest GHG emissions reductions, thereby reducing the risks posed by anthropogenic climate change to minority, low-income, underserved, and other disadvantaged populations and communities.

PHMSA solicits comment on potential impacts to minority, low-income, underserved, and other disadvantaged populations and communities of the proposed rulemaking.

6. Proposed Finding of No Significant Impact

PHMSA anticipates the adoption of the Proposed Action Alternative’s regulatory amendments will maintain the HMR’s current high level of safety for shipments of hazardous materials transported by highway, rail, and vessel, and as such proposes the HMR amendments in the NPRM would have no significant impact on the human environment. The environmental review outlines the Proposed Action Alternative will avoid adverse safety, environmental justice, and greenhouse gas (GHG) emissions impacts of the proposed action. Furthermore, based on the environmental analysis of provisions described above, PHMSA proposes to find the codification and implementation of this rulemaking would not result in a significant impact to the human environment.

PHMSA welcomes any views, data, or information related to safety or environmental impacts that may result from the NPRM’s proposed requirements, the No Action Alternative, and other viable alternatives and their environmental impacts.

I. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>. DOT’s complete Privacy Act Statement in the **Federal Register** published on April 11, 2000,⁷⁰ or on DOT’s website at <http://www.dot.gov/privacy>.

J. Executive Order 13609 and International Trade Analysis

Executive Order 13609 (“Promoting International Regulatory Cooperation”)⁷¹ requires that agencies must consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally. In meeting shared

⁶⁶ 59 FR 7629 (Feb. 16, 1994).

⁶⁷ 86 FR 7009 (Jan. 25, 2021).

⁶⁸ 86 FR 7037 (Jan. 25, 2021).

⁶⁹ 86 FR 7619 (Feb. 1, 2021).

⁷⁰ 65 FR 19475 (Apr. 11, 2000).

⁷¹ 77 FR 26413 (May 4, 2012).

challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to the Trade Agreements Act, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA participates in the establishment of international standards in order to protect the safety of the American public. PHMSA has assessed the effects of this rulemaking to ensure that it does not cause unnecessary obstacles to foreign trade. While the rulemaking would clarify and elaborate on existing PHMSA regulations, PHMSA expects the rulemaking will result in cost savings and greater regulatory flexibility for entities engaged in international commerce. Accordingly, this rulemaking is consistent with Executive Order 13609 and PHMSA's obligations under the Trade Agreement Act, as amended.

K. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) directs federal agencies to use voluntary consensus standards in their regulatory activities unless doing so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specification of materials, test methods, or performance requirements) that are developed or adopted by voluntary consensus standard bodies. This rulemaking involves multiple voluntary consensus standards that are discussed at length in the discussion on § 171.7. See “Section IV. Section-by-Section

Review; Part 171; Section 171.7” for further details.

L. Executive Order 13211

Executive Order 13211 (“Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use”)⁷² requires federal agencies to prepare a Statement of Energy Effects for any “significant energy action.” Executive Order 13211 defines a “significant energy action” as any action by an agency (normally published in the **Federal Register**) that promulgates, or is expected to lead to the promulgation of, a final rule or regulation that (1)(i) is a significant regulatory action under Executive Order 12866 or any successor order and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy (including a shortfall in supply, price increases, and increased use of foreign supplies); or (2) is designated by the Administrator of the Office of Information and Regulatory Affairs (OIRA) as a significant energy action.

Although this proposed rule is a significant regulatory action under Executive Order 12866, this action is not likely to have a significant adverse effect on the supply, distribution, or use of energy in the United States. For additional discussion of the anticipated economic impact of this rulemaking, please review the PRIA in the rulemaking docket.

M. Cybersecurity and Executive Order 14082

Executive Order 14082 (“Improving the Nation’s Cybersecurity”)⁷³ expressed the Administration policy that “the prevention, detection, assessment, and remediation of cyber incidents is a top priority and essential to national and economic security.” Executive Order 14082 directed the Federal Government to improve its efforts to identify, deter, and respond to “persistent and increasingly sophisticated malicious cyber campaigns.” Consistent with Executive Order 14082, TSA in October 2022 issued a Security Directive to reduce the risk that cybersecurity threats pose to critical railroad operations and facilities through implementation of layered cybersecurity measures that provide defense-in-depth.⁷⁴

PHMSA has considered the effects of the NPRM and has preliminarily determined that its proposed regulatory amendments would not materially affect

the cybersecurity risk profile for rail transportation of hazardous materials.

PHMSA seeks comment on any other potential cybersecurity impacts of the proposed amendments.

N. Severability

The purpose of this proposed rule is to operate holistically in addressing different issues related to safety and environmental hazards associated with the transportation of hazardous materials. However, PHMSA recognizes that certain provisions focus on unique topics. Therefore, PHMSA preliminarily finds that the various provisions of this proposed rule are severable and able to function independently if severed from each other; thus, in the event a court were to invalidate one or more of this proposed rule’s unique provisions, the remaining provisions should stand and continue in effect. PHMSA seeks comment on which portions of this rule should or should not be severable.

List of Subjects

49 CFR Part 107

Administrative practice and procedure, Hazardous materials transportation, Penalties, Reporting and recordkeeping requirements.

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting, and recordkeeping requirements.

49 CFR Part 172

Education, Hazardous materials transportation, Hazardous waste, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Incorporation by reference, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

49 CFR Part 174

Hazardous materials transportation, Radioactive materials, Railroad safety.

49 CFR Part 176

Hazardous materials transportation, Incorporation by reference, Maritime carriers, Radioactive materials, Reporting and recordkeeping requirements.

49 CFR Part 177

Hazardous materials transportation, Incorporation by reference, Motor carriers, Radioactive materials,

⁷² 66 FR 28355 (May 22, 2001).

⁷³ 86 FR 26633 (May 17, 2021).

⁷⁴ TSA, Security Directive No. 1580/82–2022–01, “Rail Cybersecurity Mitigation Actions and Testing” (Oct. 24, 2022).

Reporting and recordkeeping requirements.

49 CFR Part 178

Hazardous materials transportation, Incorporation by reference, Motor vehicle safety, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 179

Hazardous materials transportation, Incorporation by reference, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 180

Hazardous materials transportation, Incorporation by reference, Motor carriers, Motor vehicle safety, Packaging and containers, Railroad safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA proposes to amend 49 CFR chapter I as follows:

PART 107—HAZARDOUS MATERIALS PROGRAM PROCEDURES

■ 1. The authority citation for part 107 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 Section 4; Pub. L. 104–121 Sections 212–213; Pub. L. 104–134 Section 31001; Pub. L. 114–74 Section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97; 33 U.S.C. 1321.

■ 2. In § 107.1, revise the definition of “registration” to read as follows:

§ 107.1 Definitions.

* * * * *

Registration means a written acknowledgment from the Associate Administrator that a registrant is authorized to perform a function for which registration is required under subchapter C of this chapter (e.g., registration in accordance with 49 CFR 178.503 regarding marking of packagings). For purposes of subparts A through E, “registration” does not include registration under subpart F, G, or J of this part.

* * * * *

■ 3. In 107.105, revise paragraph (a)(5) to read as follows:

§ 107.105 Application for special permit.

(a) * * *

(5) For persons required to be registered in accordance with Subpart F, G, or J of this part, in addition to the information listed in paragraph (a)(2) of this section, the application must provide the registration number or the name of the company to which the registration number is assigned if

different from the applicant. For persons not required to be registered in accordance with Subpart F, G, or J of this part, in addition to the information listed in paragraph (a)(2) of this section, the application must provide a statement indicating that registration is not required.

* * * * *

■ 4. In § 107.502:

■ a. Revise paragraphs (a)(3), (b), (d), and (e); and

■ b. Add paragraphs (a)(4) through (9) and (f).

The revisions and additions read as follows:

§ 107.502 General registration requirements.

(a) * * *

(3) The terms cargo tank wall, component, and manufacturer are defined in § 178.320(a) of this chapter. The terms maintenance, modification, and repair are defined in § 180.403 of this chapter.

(4) Fixed test and inspection facility means a single, permanent, and specific geographical location with a physical address where cargo tanks or cargo tank motor vehicles are housed, stored, and maintained for repair or tests and inspections, in accordance with subpart E of part 180 of this chapter.

(5) FMCSA Agency Decisionmaker means Assistant Administrator, Federal Motor Carrier Safety Administration, or another FMCSA official authorized to make a final agency decision as specified in this subchapter.

(6) FMCSA Agency Official means the official(s) authorized by FMCSA order of delegation to take the actions specified in this subchapter.

(7) Mobile tester means a person qualified in accordance with § 180.409 of this chapter to perform repair or test and inspection at a location other than a fixed test and inspection facility.

(8) Mobile testing means the conduct of repairs or tests and inspections by a mobile tester in accordance with subpart E of part 180 of this chapter for the continuing qualification, maintenance, or periodic testing of cargo tanks or cargo tank motor vehicles at a location other than at a fixed test and inspection facility.

(9) Mobile test and inspection unit means a motor vehicle used by a mobile tester to perform mobile testing.

(b) No person may engage in the manufacture, assembly, certification, inspection, or repair of a cargo tank or cargo tank motor vehicle manufactured under the terms of a DOT specification under subchapter C of this chapter or a special permit issued under this part unless the person is registered with the

Department in accordance with the provisions of this subpart. A person employed as a Registered Inspector or Design Certifying Engineer is considered to be registered if the person’s employer is registered. The requirements of this paragraph (b) do not apply to a person engaged in the repair of a DOT specification cargo tank used in the transportation of hazardous materials in the United States in accordance with § 180.413(a)(1)(iii) of this chapter.

* * * * *

(d) Persons registering with the Department may submit their registration statement and all of the information required by this subpart, in English, electronically at https://portal.fmcsa.dot.gov/UrsRegistrationWizard/, or in hard copy form to: FMCSA Hazardous Materials Division—MC–ECH, 1200 New Jersey Ave., Washington, DC 20590–0001.

(e) Upon determination that a registration statement contains all the information required by this subpart, the Department will send the registrant a letter or provide electronic confirmation verifying receipt of the registration application and assigning a registration number to that person.

(f) A separate registration number will be assigned for each cargo tank manufacturing, assembly, repair facility, or other place of business identified by the registrant.

■ 5. In § 107.503:

■ a. Revise paragraphs (a)(2), (a)(4), and (c); and

■ b. Add paragraph (d).

The revisions and addition read as follows:

§ 107.503 Registration statement.

(a) * * *

(2) Street address, mailing address, telephone number, and email address, if available, for each facility or place of business;

* * * * *

(4) A statement signed by the person responsible for compliance with the applicable requirements of this chapter, certifying knowledge of those requirements and that each employee who is a hazmat employee, including a Registered Inspector or Design Certifying Engineer, meets the minimum qualification requirements set forth in § 171.8 of this chapter, has been trained in accordance with § 172.704, and is knowledgeable and trained in the functions the employee performs. The following language may be used:

I certify that all hazmat employees, including Registered Inspectors and Design Certifying Engineers, performing any function have met the minimum

qualification requirements set forth in 49 CFR 171.8 and/or 180.403 and the training requirements of 49 CFR 172.704; that all persons are knowledgeable and trained in the functions they perform; that I am the person responsible for ensuring compliance with the applicable requirements of this chapter; that I maintain all required documentation to verify compliance; and that I have knowledge of the requirements applicable to the functions to be performed.

* * * * *

(c) In addition to the information required under paragraph (a) of this section, each person who repairs a cargo tank or cargo tank motor vehicle must submit a copy of the repair facility's current National Board Certificate of Authorization for the use of the "R" stamp or ASME Certificate of Authorization for the use of the ASME "U" stamp.

(d) In addition to the information required under paragraph (a) of this section, each person who performs the wet fluorescent magnetic particle exam must submit a copy of the ASME Code training certificate.

■ 6. Add § 107.505 to read as follows:

§ 107.505 Modification, suspension or termination of registration.

(a) The FMCSA Agency Official may modify, suspend, or terminate a registration, as appropriate, on finding that:

(1) Because of a change in circumstances, the registration requires modification, is no longer needed, or would no longer be granted if applied for;

(2) The application contained inaccurate or incomplete information, and the registration would not have been granted had the application been accurate and complete;

(3) The application contained deliberately inaccurate or incomplete information; or

(4) The holder knowingly has violated the terms of the registration or an applicable requirement of this chapter in a manner demonstrating lack of fitness to conduct the activity for which registration is required.

(b) Except as provided in paragraph (c) of this section, before a registration is modified, suspended, or terminated, the FMCSA Agency Official notifies the holder in writing or by electronic means of the proposed action and the reasons for it, and provides an opportunity to show cause why the proposed action should not be taken.

(1) The holder may file a response in writing or by electronic means with the

FMCSA Agency Official within 30 days of service of notice of the proposed action.

(2) After considering the holder's written response, or after 30 days have passed without response since service of the notice, the FMCSA Agency Official notifies the holder in writing or by electronic means of the decision with a brief statement of reasons and the effective date of the action.

(c) The rules for service and computation of time in §§ 386.6 and 386.8 of this title shall apply to this section, except that electronic service is permitted.

(d) If FMCSA determines that a violation of a provision of the federal hazardous material transportation law, or a regulation or order prescribed under that law, or an unsafe condition or practice, constitutes or is causing an imminent hazard, as defined in § 109.1 of this subchapter, FMCSA may issue an immediately effective emergency order to the registration holder in accordance with § 109.17 of this subchapter. Petitions for review of the emergency order shall be governed by § 109.19 of this subchapter.

■ 7. Add § 107.506 to read as follows:

§ 107.506 Reconsideration.

(a) A registration holder may request that the FMCSA Agency Official reconsider a decision under § 107.505 of this part. The request for reconsideration must:

(1) Be in writing or by electronic means and served within twenty days of service of the decision;

(2) State in detail any alleged errors of fact, law, or procedure;

(3) Explain any corrective actions taken;

(4) Enclose any additional information needed to support the request to reconsider; and

(5) State in detail the modification of the final decision sought.

(b) A decision issued under § 107.505 of this part remains effective pending a decision on reconsideration. The FMCSA Agency Official will consider requests to stay the decision using the criteria set forth in § 107.507(b)(1)–(4) of this part.

(c) The FMCSA Agency Official may request additional information or documents and, to ensure that the deficiencies identified as the basis for the action have been corrected, may conduct additional investigation. If the registration holder does not provide the information requested, the FMCSA Agency Official may deny the petition for reconsideration. The FMCSA Agency Official considers all information and

documentation submitted on reconsideration.

(d) The FMCSA Agency Official grants or denies, in whole or in part, the relief requested and informs the requesting person in writing or by electronic means of the decision.

(e) The rules for service and computation of time in §§ 386.6 and 386.8 of this title shall apply to this section, except that electronic service is permitted.

■ 8. Add § 107.507 to read as follows:

§ 107.507 Appeal.

(a) A person who requested reconsideration under § 107.506 and is denied the relief requested may appeal to the FMCSA Agency Decisionmaker. The appeal must be in writing and served on the Agency Decisionmaker, ATTN: Adjudications Counsel, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE Washington, DC 20590-0001, or by submitting the documents electronically to *fmcsa.adjudication@dot.gov*. The appeal must also be served on all parties to the proceeding. The appeal must:

(1) Be served within 30 days of service of the FMCSA Agency Official's decision on reconsideration;

(2) State in detail any alleged errors of fact, law, or procedure;

(3) Enclose any additional information needed to support the appeal; and

(4) State in detail the modification of the final decision sought.

(b) The FMCSA Agency Official's action remains effective pending a decision on appeal. Requests for a stay of the FMCSA Agency Official's action will be considered using the following criteria:

(1) There is a substantial likelihood that the requesting party will prevail on the merits;

(2) The requesting party will suffer irreparable injury absent the stay;

(3) The threatened injury outweighs whatever damage the stay may cause the opposing party; and

(4) The stay will not harm the public interest.

(c) The FMCSA Agency Official files a response to the appeal no later than 30 days following service of the appeal. The FMCSA Agency Official addresses each assignment of error by producing evidence or legal argument that supports the Agency Official's determination on that issue. The Agency Official's determination may be supported by circumstantial or direct evidence and the reasonable inferences drawn therefrom. The burden of proof shall be on the FMCSA Agency Official.

(d) The FMCSA Agency Decisionmaker may ask the parties to

submit additional information. If the registration holder does not provide the information requested, the Agency Decisionmaker may dismiss the petition for review. The FMCSA Agency Decisionmaker grants or denies, in whole or in part, the relief requested and informs the appellant in writing of the decision on appeal. The FMCSA Agency Decisionmaker decision on the appeal is the final agency action.

(e) The rules for service, filing of documents, and computation of time in §§ 386.6, 386.7, and 386.8 of this title shall apply to this section, except that electronic service is permitted.

■ 9. In § 107.701, revise paragraph (c) to read as follows:

§ 107.701 Purpose and scope.

* * * * *

(c) Registration under subpart F, G, or J of this part is not subject to the procedures of this subpart.

■ 10. In part 107, subpart J is added to read as follows:

Subpart J—Registration of Tank Car Facilities and Design Certifying Engineers

§ 107.901 Purpose and Scope.

§ 107.903 Definitions.

§ 107.905 Tank car facility registration.

§ 107.907 Tank car design certifying engineer registration.

§ 107.909 Period of registration, updates, and record retention.

§ 107.911 Modification, suspension, or termination of registration.

§ 107.913 Reconsideration.

§ 107.915 Appeal.

§ 107.901 Purpose and scope.

(a) This subpart establishes a registration procedure for tank car facilities and tank car Design Certifying Engineers.

(b) Persons who apply for registration in accordance with this subpart must be familiar with the requirements set forth in part 179 and part 180, subpart F of this chapter.

§ 107.903 Definitions.

The following definitions apply for the purpose of this subpart:

Associate Administrator for Safety, *FRA* means the Federal Railroad Administration, Associate Administrator for Safety.

Design Certifying Engineer is defined in § 171.8 of this chapter.

FRA Administrator means the Administrator of the Federal Railroad Administration.

Qualification is defined in § 180.503 of this chapter.

Tank car is defined in § 179.2 of this chapter.

Tank car facility is defined in § 179.2 of this chapter.

Tank car tank is defined in § 180.503 of this chapter.

§ 107.905 Tank car facility registration.

(a) No person may engage in the qualification of a tank car manufactured and maintained under the terms of a DOT specification under subchapter C of this chapter or a special permit issued under this part unless the person is registered with the Department in accordance with the provisions of this subpart.

(b) A person who performs functions subject to the provisions of this subpart may perform only those functions that have been identified to the Department in accordance with the procedures of this subpart.

(c) Persons registering a tank car facility may submit their registration statements and all the information required by this subpart, in English, electronically at www.phmsa.dot.gov or in hard copy form to: Associate Administrator of Hazardous Materials Safety (Attention: General Approvals and Permits, PHH-13) Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, 1200 New Jersey Avenue SE, Washington, DC 20590-0001.

(d) Each person must submit a separate registration statement and each tank car facility will be assigned a unique registration number.

(e) Upon determination that a tank car facility registration statement contains all the information required by this subpart, the Department will send the registrant a letter or provide electronic confirmation verifying receipt of the registration application and assigning a registration number to that facility.

(f) Each tank car facility registration statement must contain the following information:

(1) Name of business;

(2) Street address, mailing address, telephone number, and email address, if available, for the facility or place of business;

(3) A statement indicating whether the facility uses mobile testing/inspection equipment to perform manufacturing, maintenance, or qualification at a location other than the address listed in paragraph (f)(2) of this section;

(4) A statement signed by the principal, officer, partner, or employee of the facility responsible for compliance with the applicable requirements of this chapter, certifying knowledge of those requirements and that each employee who is a hazmat employee has been trained in accordance with § 172.704 of this

chapter and is knowledgeable and trained in the functions the employee performs, and that the facility's quality assurance program complies with the requirements of § 179.7 of this chapter. The following statement may be used:

I certify that this facility operates in conformance with minimum requirements set forth in this chapter; that all persons are knowledgeable and trained in the functions they perform; that I am the person responsible for ensuring compliance with the applicable requirements of this chapter; that I maintain all required documentation to verify compliance; that I have knowledge of the requirements applicable to the functions to be performed; and that this tank car facility's quality assurance program is in compliance with the requirements of 49 CFR 179.7.

(5) A description of the specific qualification functions to be performed on tank cars. For example:

(i) External visual inspection;

(ii) Leakproofness testing; or

(iii) Ultrasonic examination.

(6) A description of any other tank car-related functions performed at the facility. For example:

(i) Manufacture; or

(ii) Maintenance.

(7) An identification of the types of DOT specification and special permit tank cars that the registrant intends to qualify and manufacture or maintain, if applicable;

(8) Each tank car facility must submit an executive summary of the facility's current quality assurance program, sufficient to demonstrate compliance with the required elements of § 179.7(b) of this chapter; and

(9) If the registrant is not a resident of the United States, the name and address of a permanent resident of the United States designated in accordance with § 105.40 of this subchapter to serve as agent for service of process.

§ 107.907 Tank car Design Certifying Engineer registration.

(a) No person may approve the design of a tank car or service equipment manufactured in accordance with subchapter C of this chapter or a special permit issued under this part unless the person is registered with the Department in accordance with the provisions of this subpart.

(b) A person who performs functions subject to the provisions of this subpart may perform only those functions that have been identified to the Department in accordance with the procedures of this subpart.

(c) Persons registering a tank car Design Certifying Engineer may submit

their registration statements and all the information required by this subpart, in English, electronically at www.phmsa.dot.gov or in hard copy form to: Associate Administrator of Hazardous Materials Safety (Attention: General Approvals and Permits, PHH-13), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, 1200 New Jersey Avenue SE Washington, DC 20590-0001.

(d) Each registration statement must be in English and contain the following information:

(1) Name of business;

(2) Street address, mailing address, telephone number, and email address, if available, for each person or place of business;

(3) A statement signed by the person responsible for compliance with the applicable requirements of this chapter, certifying knowledge of those requirements and that each employee who is a hazmat employee, including a Design Certifying Engineer, meets the minimum qualification requirements set forth in § 171.8 of this chapter; has been trained in accordance with § 172.704 of this chapter; and is knowledgeable and trained in the functions the employee performs. The following statement may be used:

I certify that all hazmat employees performing any hazardous materials transportation function have met the training requirements of 49 CFR 172.704; that any Design Certifying Engineer hazmat employees have met the minimum qualification requirements set forth in 49 CFR 171.8 for Design Certifying Engineers; that all persons are knowledgeable and trained in the hazardous materials transportation functions they perform; that I am the person responsible for ensuring compliance with the applicable requirements of this chapter; that I maintain all required documentation to verify compliance; and that I have knowledge of the requirements applicable to the hazardous materials transportation functions to be performed.

(4) A description of the specific functions to be performed, *e.g.*:

(i) New tank car design;

(ii) Tank car modification;

(iii) New service equipment design;

and

(iv) Service equipment modification.

(5) An identification of the types of DOT specification and special permit tank cars and service equipment whose designs the registrant intends to review;

(6) The names and a description of the experience meeting the definition in § 171.8 of this chapter for each

individual engineer employed as a Design Certifying Engineer; and

(7) If the registrant is not a resident of the United States, the name and address of a permanent resident of the United States designated in accordance with § 105.40 of this subchapter to serve as an agent for service of process.

(e) Upon determination that a registration statement contains all of the information required by this subpart, the Department will send the registrant a letter or provide electronic confirmation verifying receipt of the registration application and assigning a registration number to that person. A separate registration number will be assigned to each individual employed as a Design Certifying Engineer and identified in the registration statement by the registrant.

§ 107.909 Period of registration, updates, and record retention.

(a) The period of registration for both tank car facilities and tank car Design Certifying Engineers will be for a maximum of six years from the date of the original registration and for six-year renewal periods thereafter.

(b) Any correspondence with the Department must contain the registrant's name and registration number.

(c) A registration must be renewed prior to expiration of the period of registration to ensure continued authorization to perform authorized duties by submitting an up-to-date registration statement containing the information prescribed by §§ 107.905 or 107.907 of this subpart. Any person initially registered under the provisions of §§ 107.905 or 107.907 of this subpart and who is in good standing is eligible for renewal.

(d) A registrant shall provide notification to PHMSA within 30 days of any of the following occurrences:

(1) Any change in the registration information submitted under §§ 107.905 or 107.907 of this subpart, (*e.g.*, change of company name, address, ownership, or names and description of the experience meeting the definition in § 171.8 of this chapter for each individual engineer employed as a Design Certifying Engineer);

(2) Replacement of the person responsible for compliance with the requirements in §§ 107.905(f)(4) or 107.907(d)(3) of this subpart. If this occurs, the registrant shall resubmit the required certification;

(3) A change in function, such as from maintenance to manufacture, an addition of a function, or a change to the types of qualifications or certifications of tank cars conducted by the facility; or

(4) The facility or Design Certifying Engineer no longer performs any functions requiring a registration under this subpart.

(e) Each registrant shall maintain a current copy of the registration information submitted to the Department and a current copy of the registration number received from the Department at the location identified in §§ 107.905(f)(2) or 107.907(d)(2) of this subpart during such time the person is registered with the Department and for two (2) years thereafter.

§ 107.911 Modification, Suspension, or Termination of Registration.

(a) The Associate Administrator for Safety, FRA may modify, suspend, or terminate a tank car facility or tank car Design Certifying Engineer registration, as appropriate, on finding that:

(1) Because of a change in circumstances, the registration is no longer needed or would no longer be granted if applied for;

(2) The application contained inaccurate or incomplete information, and the registration would not have been granted had the application been accurate and complete;

(3) The application contained deliberately inaccurate or incomplete information; or

(4) The holder knowingly has violated the terms of the registration or an applicable requirement of this chapter in a manner demonstrating lack of fitness to conduct the activity for which registration is required.

(b) Except as provided in paragraph (c) of this section, before a registration is modified, suspended, or terminated, the Associate Administrator for Safety, FRA notifies the holder of the proposed action and the reasons for it, and provides an opportunity to show cause why the proposed action should not be taken.

(1) The holder may file a response with the Associate Administrator for Safety, FRA within 30 days of receipt of notice of the proposed action in accordance with the procedures of 49 CFR 209.9 via FRAlegal@dot.gov.

(2) After considering the holder's response, or after 30 days have passed without response since receipt of the notice, the Associate Administrator for Safety, FRA notifies the holder of the final decision with a brief statement of reasons.

(c) The Associate Administrator for Safety, FRA, if necessary to avoid a risk of significant harm to persons or property, may, in the notification, declare the proposed action immediately effective.

§ 107.913 Reconsideration.

(a) A registration holder may request that the Associate Administrator for Safety, FRA reconsider a decision under § 107.911 of this subpart. The request must:

- (1) Be filed in accordance with the procedures of 49 CFR 209.9 with *FRALegal@dot.gov* within twenty days of receipt of the decision;
- (2) State in detail any alleged errors of fact and law;
- (3) Enclose any additional information needed to support the request to reconsider; and
- (4) State in detail the modification of the final decision sought.

(b) The Associate Administrator for Safety, FRA considers newly submitted information on a showing that the information could not reasonably have been submitted during application processing.

(c) The Associate Administrator for Safety, FRA grants or denies, in whole or in part, the relief requested and

informs the requesting person of the decision.

§ 107.915 Appeal.

(a) A person who requested reconsideration under § 107.913 of this subpart and is denied the relief requested may appeal to the FRA Administrator. The appeal must:

- (1) Be filed in accordance with the procedures of 49 CFR 209.9 with *FRALegal@dot.gov* within 30 days of receipt of the Associate Administrator for Safety, FRA’s decision on reconsideration;
- (2) State in detail any alleged errors of fact and law;
- (3) Enclose any additional information needed to support the appeal; and
- (4) State in detail the modification of the final decision sought.

(b) The FRA Administrator, if necessary to avoid a risk of significant harm to persons or property, may declare that the Associate Administrator

for Safety, FRA’s action remain effective pending a decision on appeal.

(c) The FRA Administrator grants or denies, in whole or in part, the relief requested and informs the appellant of the decision on appeal. The FRA Administrator’s decision on the appeal is the final administrative action.

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 11. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–134, section 31001; Pub. L. 114–74 section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

■ 12. In § 171.6, revise the table in paragraph (b)(2) to read as follows:

§ 171.6 Control numbers under the Paperwork Reduction Act.

*	*	*	*	*
(b)	*	*	*	
(2)	*	*	*	

Current OMB control number	Title	Title 49 CFR part or section where identified and described
2137–0014	Cargo Tank Specification Requirements	§§ 107.503, 107.504, 107.505, 107.506, 107.507, 178.320, 178.337, 178.338, 178.345, 180.405, 180.407, 180.409, 180.413, 180.415, 180.417.
2137–0018	Inspection and Testing of Portable Tanks and Intermediate Bulk Containers.	§§ 173.24, 173.32, 178.3, 178.255, 178.273, 178.274, 178.703, 178.801, 180.352, 180.605.
2137–0022	Testing, Inspection, and Marking Requirements for Cylinders.	§§ 173.5b, 173.302a, 173.303, 173.304, 173.309, 178.2, 178.3, 178.35, 178.44, 178.45, 178.46, 178.57, 178.59, 178.60, 178.61, 178.68, 180.205, 180.207, 180.209, 180.211, 180.213, 180.215, 180.217, Appendix C to part 180.
2137–0034	Hazardous Materials Shipping Papers and Emergency Response Information.	§§ 172.200, 172.201, 172.202, 172.203, 172.204, 172.505, 172.600, 172.602, 172.604, 172.606, 173.6, 173.7, 173.22, 173.56, 174.24, 174.26, 174.114, 175.30, 175.31, 175.33, 176.24, 176.27, 176.30, 176.36, 176.89, 177.817.
2137–0039	Hazardous Materials Incidents Reports	§§ 171.15, 171.16, 171.21.
2137–0051	Rulemaking and Special Permit Petitions.	§§ 105.30, 105.40, 106.95, 106.110, 107.105, 107.107, 107.109, 107.113, 107.117, 107.121, 107.123, 107.125, 107.205, 107.211, 107.215, 107.217, 107.219, 107.221, 107.223.
2137–0510	RAM Transportation Requirements	Part 173, subpart I, §§ 173.22, 173.411, 173.415, 173.416, 173.417, 173.457, 173.471, 173.472, 173.473, 173.476.
2137–0542	Flammable Cryogenic Liquids	§§ 173.318, 177.816, 177.840, 180.405.
2137–0557	Approvals for Hazardous Materials	§§ 107.402, 107.403, 107.405, 107.705, 107.713, 107.715, 107.717, 107.803, 107.805, 107.807, 110.30, 172.101, 172.102, Special Provisions 19, 26, 53, 55, 60, 105, 118, 121, 125, 129, 131, 133, 136, B45, B55, B61, B69, B77, B81, N10, N72, 173.2a, 173.4, 173.7, 173.21, 173.22, 173.24, 173.31, 173.38, 173.51, 173.56, 173.58, 173.59, 173.124, 173.128, 173.159, 173.166, 173.171, 173.214, 173.222, 173.224, 173.225, 173.245, 173.301, 173.305, 173.306, 173.314, 173.315, 173.316, 173.318, 173.334, 173.340, 173.411, 173.433, 173.457, 173.471, 173.472, 173.476, 174.50, 174.63, 175.8, 175.85, 175.701, 175.703, 176.168, 176.340, 176.704, 178.3, 178.35, 178.47, 178.53, 178.273, 178.274, 178.503, 178.509, 178.605, 178.606, 178.608, 178.801, 178.813, 180.213.
2137–0559	Rail Carrier and Tank Car Tanks Requirements, Rail Tank Car Tanks—Transportation of Hazardous Materials by Rail.	§§ 107.905, 107.907, 107.909, 107.911, 107.913, 107.915, 172.102, Special provisions: B45, B46, B55, B61, B69, B77, B78, B81; 173.10, 173.31, 174.14, 174.50, 174.63, 174.104, 174.114, 174.204, 179.3, 179.4, 179.5, 179.6, 179.7, 179.11, 179.18, 179.22, 179.100–9, 179.100–12, 179.100–13, 179.100–16, 179.100–17, 179.102–4, 179.102–17, 179.103–1, 179.103–2, 179.103–3, 179.103–5, 179.200–10, 179.200–14, 179.200–15, 179.200–16, 179.200–17, 179.200–19, 179.201–3, 179.201–8, 179.201–9, 179.220–4, 179.220–7, 179.220–8, 179.220–13, 179.220–15, 179.220–17, 179.220–18, 179.220–20, 179.220–22, 179.300–3, 179.300–7, 179.300–9, 179.300–12, 179.300–13, 179.300–15, 179.300–20, 179.400–3, 179.400–4, 179.400–11, 179.400–13, 179.400–16, 179.400–17, 179.400–19, 179.400–20, 179.500–5, 179.500–8, 179.500–12, 179.500–18, 180.505, 180.509, 180.515, 180.517.
2137–0572	Testing Requirements for Non-bulk Packages.	§§ 173.168, 178.2, 178.601, Appendix C to part 178, Appendix D to part 178.

Current OMB control number	Title	Title 49 CFR part or section where identified and described
2137-0582 2137-0586	Container Certification Statement Hazardous Materials Public Sector Training and Planning Grants.	§§ 176.27, 176.172. Part 110.
2137-0591 2137-0595	Response Plans for Shipments of Oil ... Cargo Tank Motor Vehicles in Liquefied Compressed Gas Service.	Part 130. §§ 173.315, 178.337-8, 178.337-9, 180.405, 180.416.
2137-0612 2137-0613	Hazardous Materials Security Plans Subsidiary Hazard Class and Number/ Type of Packagings.	Part 172, subpart I, §§ 172.800, 172.802, 172.804. §§ 172.202, 172.203.
2137-0620	Inspection and Testing of Meter Provers.	Part 173, subpart A, § 173.5a.
2137-0621	Requirements for United Nations (UN) Cylinders.	§§ 173.301, 173.304, 173.304b, 178.69, 178.70, 178.74, 178.75, 180.207, 180.209, 180.212, 180.215, 180.217.
2137-0628	Flammable Hazardous Materials by Rail Transportation.	§§ 130.120, 171.16, 173.41, 173.145, 173.150, 174.310, 174.312.

- 13. In § 171.7:
 - a. Revise paragraphs (h)(39), (k), and (l)(3);
 - b. Remove and reserve paragraph (l)(4); and
 - c. Revise paragraph (n)(21).
- The revisions read as follows:

§ 171.7 Reference material.

* * * * *

(h) * * *

(39) ASTM D 1838-64 Copper Strip Corrosion by Liquefied Petroleum (LP) Gases, 1964 (Reapproved 1968), into § 173.315.

* * * * *

(k) *Association of American Railroads*, American Railroads Building, Suite 1000, 425 Third Street SW, Washington, DC 20024; telephone 877-999-8824, <http://www.aarpublications.com/>

(1) AAR Manual of Standards and Recommended Practices, Section C—II Specifications for Design, Fabrication, and Construction of Freight Cars, Chapter 5, Paragraph 5.1, Workmanship, April 2011, into § 179.16.

(2) AAR Manual of Standards and Recommended Practices, Section C—II Specifications for Design, Fabrication, and Construction of Freight Cars, Chapter 6, June 2015, into § 179.400-6.

(3) AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars), Chapter 1, November 2014, into § 180.517.

(4) AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars), Chapter 2, November 2014, into § 179.102-3.

(5) AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars), Chapter 3,

November 2014, into §§ 173.241, 173.242, 173.247.

(6) AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars), Chapter 5, November 2014, into § 179.16.

(7) AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars), Chapter 6, November 2014, into § 179.10.

(8) AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars), Appendix A, November 2014, into §§ 173.314; 179.15; 179.300-15; 179.300-17; 179.400-20.

(9) [Reserved]

(10) AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars), Appendix C, November 2014, into §§ 179.22; 179.220-26; 179.400-25.

(11) AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars), Appendix D, November 2014, into § 180.509.

(12) AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars), Appendix E, November 2014, into §§ 173.31; 179.20; 179.100-12; 179.100-14; 179.101-1; 179.103-5; 179.200-9; 179.200-13; 179.200-17; 179.220-14; 179.220-18.

(13) [Reserved]

(14) AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars,

Specification M-1002 (AAR Specifications for Tank Cars), Appendix M, November 2014, into §§ 179.200-7; 179.201-6; 179.220-6; 179.220-7; 179.400-5; 179.400-8.

(15) AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars), Appendix R, November 2014, except paragraphs 1.1, 1.2, 3.2, 3.3, 3.4, 5.5 into § 179.6.

(16) [Reserved]

(17) [Reserved]

(18) AAR Manual of Standards and Recommended Practices, Section C—III, Specifications for Tank Cars, Specification M-1002 (AAR Specifications for Tank Cars), Appendix W, November 2014, except paragraph 1.2 into §§ 179.11; 179.100-9; 179.100-10; 179.100-13; 179.100-18; 179.102-1; 179.102-4; 179.102-17; 179.200-10; 179.200-11; 179.200-22; 179.220-10; 179.220-11; 179.300-9; 179.300-10; 179.400-5; 179.400-11; 179.400-12; 179.400-15; 179.400-18.

(19) AAR Manual of Standards and Recommended Practices, Section I, Specially Equipped Freight Car and Intermodal Equipment, 1988, into §§ 174.55; 174.63.

(20) AAR Standard 286; AAR Manual of Standards and Recommended Practices, Section C, Car Construction Fundamentals and Details, Standard S-286, Free/Unrestricted Interchange for 286,000 lb. Gross Rail Load Cars (Adopted 2002; Revised: 2003, 2005, 2006, 2016), into § 179.13.

* * * * *

(l) * * *

(3) Pamphlet 49, Recommended Practices for Handling Chlorine Bulk Highway Transport, Edition 10, December 2016, into § 173.315.

(4) [Reserved]

* * * * *

(n) * * *

(21) CGA Technical Bulletin P-26, Guidelines for Inspection and Repair of MC-330 and MC-331 Anhydrous Ammonia Cargo Tanks (formerly TB-2), 1997, into §§ 180.407; 180.413.

■ 14. In § 171.8, revise the definitions of “cargo tank” and “design certifying engineer” to read as follows:

§ 171.8 Definitions and abbreviations.

Cargo tank means a bulk packaging that:

(1) Is a tank intended primarily for the carriage of liquids, gases, solids, or semi-solids and includes appurtenances, closures, components, and reinforcements (for cargo tank specifications, see 49 CFR 178.320, 178.337-1, or 178.338-1, 178.345-1, as applicable);

(2) Is permanently attached to or forms a part of a motor vehicle, or is not permanently attached to a motor vehicle but which, by reason of its size, construction or attachment to a motor vehicle is loaded or unloaded without being removed from the motor vehicle; and

(3) Is not fabricated under a specification for cylinders, intermediate bulk containers, multi-unit tank car tanks, portable tanks, or tank cars.

Design Certifying Engineer means a person registered with the Department, in accordance with subparts F or J of part 107 of this chapter, who has the knowledge and ability to perform stress analysis of pressure vessels and otherwise determine whether a cargo tank or tank car design and construction meets the applicable DOT specification. A Design Certifying Engineer meets the knowledge and ability requirements by meeting any one of the following requirements:

(1) For cargo tanks:

(i) Has an engineering degree and at least one year of work experience in cargo tank structural or mechanical design;

(ii) Is currently registered as a professional engineer by appropriate authority of a state of the United States or a province of Canada; or

(iii) Has at least three years' experience in performing the duties of a Design Certifying Engineer prior to September 1, 1991.

(2) For tank cars:

(i) Has an engineering degree and at least one year of work experience in tank car structural or mechanical design; or

(ii) Is currently registered as a professional engineer by an appropriate

authority of a state of the United States or a province of Canada.

■ 15. In § 171.22, revise paragraph (f)(4) to read as follows:

§ 171.22 Authorization and conditions for the use of international standards and regulations.

(f) * * *

(4) Each person who provides for transportation or receives for transportation (see §§ 174.24, 175.30, 176.24, and 177.817 of this subchapter) a shipping paper must retain a copy of the shipping paper or an electronic image thereof that is accessible at or through its principal place of business in accordance with § 172.201(e) of this subchapter. The shipping paper shall be made readily accessible for inspection to an authorized official of a federal, state, or local government agency.

■ 16. In § 171.23, revise paragraphs (b)(5) introductory text and (b)(5)(iii) to read as follows:

§ 171.23 Requirements for specific materials and packagings transported under the ICAO Technical Instructions, IMDG Code, Transport Canada TDG Regulations, or the IAEA Regulations.

(b) * * *

(5) Hazardous substances. A material meeting the definition of a hazardous substance, as defined in § 171.8, must conform to the shipping paper requirements in § 172.203(c) of this subchapter. Non-bulk packages must be marked in accordance with the requirements in § 172.324 of this subchapter:

(iii) The letters “RQ” must be entered on the shipping paper either before or after the basic description and marked on a non-bulk package in association with the proper shipping name for each hazardous substance listed.

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, TRAINING REQUIREMENTS, AND SECURITY PLANS

■ 17. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101-5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 18. In § 172.101, revise paragraph (j) introductory text to read as follows:

§ 172.101 Purpose and use of the hazardous materials table.

(j) Column 9: Quantity limitations. Columns 9A and 9B specify the maximum quantities that may be offered for transportation in one package by passenger-carrying aircraft or passenger-carrying rail (Column 9A) or by cargo aircraft only (Column 9B), subject to the following:

■ 19. In § 172.102, revise paragraph (c)(1), special provision 13 and paragraph (c)(3), special provision B45 to read as follows:

§ 172.102 Special provisions.

(c) * * *

(1) * * *

13 The words “Inhalation Hazard” shall be entered on each shipping paper in association with the shipping description, shall be marked on each non-bulk package in association with the proper shipping name and identification number, and shall be marked on two opposing sides of each bulk package. The size of a marking on a bulk package must conform to § 172.302(b) of this subchapter. In addition, security plan requirements in part 172, subpart I, apply. The requirements of §§ 172.203(m) and 172.505 of this subchapter do not apply.

(3) * * *

B45 Each tank must have a reclosing combination pressure relief device, equipped with stainless steel or platinum rupture discs, approved by a tank car Design Certifying Engineer.

■ 20. In § 172.303, add paragraph (b)(4) to read as follows:

§ 172.303 Prohibited marking.

(b) * * *

(4) The display of a BIOHAZARD marking, a “HOT” marking, or a sour crude oil hazard marking in accordance with §§ 172.323(c), 172.325(c), or 172.327(a), of this part, respectively.

■ 21. In § 172.328, revise paragraph (d) to read as follows:

§ 172.328 Cargo tanks.

(d) Emergency shutoff marking. For all cargo tank motor vehicles subject to emergency remote shutoff device requirements in accordance with this subchapter, each on-vehicle manually-activated remote shutoff device for closure of the internal or external self-closing stop valve must be identified by marking “Emergency Shutoff” in letters

at least 0.75 inches in height, in a color that contrasts with its background, and

located in an area immediately adjacent to the means of closure.

§ 172.336 Identification numbers; special provisions.

* * * * *

* * * * *

■ 22. In § 172.336, revise the table in paragraph (c) to read as follows:

(c) * * *

Packaging:	When:	Then the alternative marking requirement is:
On the ends of portable tanks, cargo tanks, or tank cars.	They have more than one compartment and hazardous materials with different identification numbers are being transported therein.	The identification numbers on the sides of the tank are displayed in the same sequence as the compartments containing the materials they identify.
On cargo tanks	They contain only gasoline	The tank is marked "Gasoline" on each side and rear in letters no less than 50 mm (2 inches) high or is placarded in accordance with § 172.542(c).
On cargo tanks	They contain only fuel oil	The cargo tank is marked "Fuel Oil" on each side and rear in letters no less than 50 mm (2 inches) high, or is placarded in accordance with § 172.544(c).
On one end of nurse tanks if that end contains valves, fittings, regulators or gauges when those appurtenances prevent the markings and placard from being properly placed and visible.	They meet the provisions of § 173.315(m) of this subchapter.	N/A.
On each compartment of compartmented cargo tanks or compartmented tank cars.	The cargo tank or tank car contains more than one petroleum distillate fuel.	The identification number for the liquid petroleum distillate fuel having the lowest flash point in any one compartment is displayed. However, if a cargo tank or tank car compartment contains gasoline and alcohol fuel blends consisting of more than 10% ethanol the identification number "3475" or "1987," as appropriate, must also be displayed for that compartment.
On cargo tanks (including compartmented cargo tanks).	They transport more than one petroleum distillate fuel in different trips on the previous or current business day.	The identification number for the liquid petroleum distillate fuel having the lowest flash point transported in that previous or current business day is displayed. If the cargo tank contains gasoline and alcohol fuel blends consisting of more than 10% ethanol, the identification number "3475" or "1987," as appropriate, must also be displayed, and the identification numbers "3475" or "1987," may only be displayed if the material is present in the cargo tank during transportation.

* * * * *

■ 23. In § 172.504, revise paragraph (b) to read as follows:

§ 172.504 General placarding requirements.

* * * * *

(b) DANGEROUS placard. A freight container, unit load device, transport vehicle, or rail car that contains non-bulk packages with two or more categories of hazardous materials that require different placards specified in table 2 of paragraph (e) of this section may be placarded with a DANGEROUS placard instead of the separate placarding specified for each of the materials in table 2 of paragraph (e) of this section. However, the DANGEROUS placard may not be used under the following conditions:

(1) When 1,000 kg (2,205 pounds) aggregate gross weight or more of one category of material is loaded therein at one loading facility on a freight container, unit load device, transport vehicle, or rail car, the placard specified in table 2 of paragraph (e) of this section for that category must be applied; or

(2) When a hazardous material is transported by vessel.

* * * * *

■ 24. In § 172.516, revise paragraph (d) to read as follows:

§ 172.516 Visibility and display of placards.

* * * * *

(d) Recommended specifications for a placard holder are set forth in Appendix C of this part. Except for a placard holder similar to that contained in Appendix C to this part or contained in Appendix C to this part prior to [EFFECTIVE DATE OF THE FINAL RULE], the means used to attach a placard may not obscure any part of its surface other than the borders.

* * * * *

■ 25. In § 172.704:

- a. Add paragraph (a)(2)(iii); and
- b. Revise paragraph (e)(1). The revision and addition read as follows:

§ 172.704 Training requirements.

- (a) * * *
- (2) * * *

(iii) For hazardous materials employees transporting hazardous

materials by highway, function specific training must include the training requirements of § 177.816, as applicable.

* * * * *

(e) * * *

(1) A hazmat employee who manufactures, repairs, modifies, reconditions, or tests packagings, as qualified for use in the transportation of hazardous materials, and who does not perform any other function subject to the requirements of this subchapter, is not subject to the training requirements of paragraphs (a)(3) and (a)(4) of this section.

* * * * *

■ 26. In § 172.820, add paragraph (d)(3) to read as follows:

§ 172.820 Additional planning requirements for transportation by rail.

* * * * *

(d) * * *

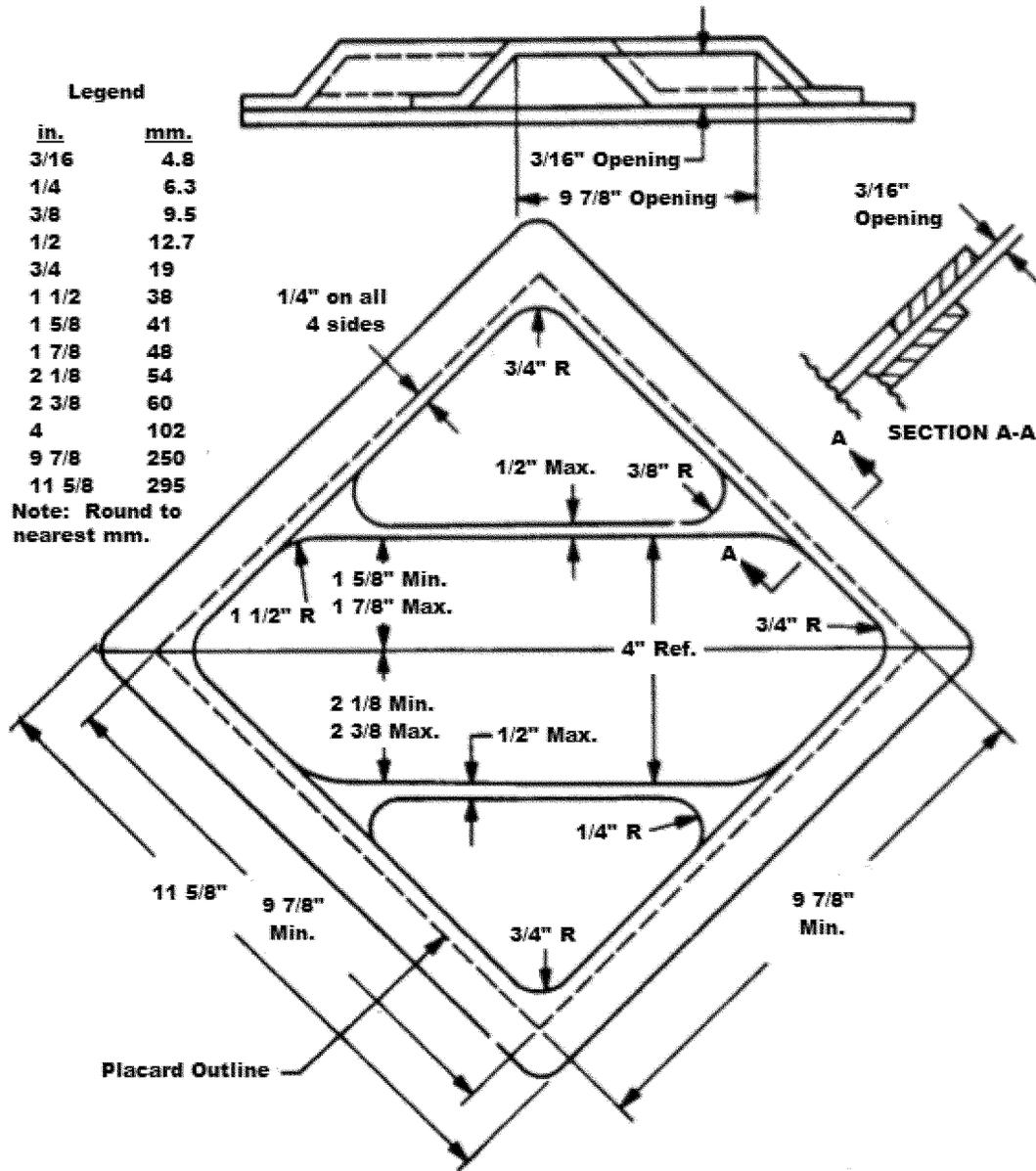
(3) If the rail carrier determines that no practicable alternative route exists, including consideration of interchange agreements, the requirements of paragraphs (d)(1) and (d)(2) do not apply. The rail carrier must describe, in

writing, the remediation or mitigation measures to be implemented, if any, on the primary route in conformance with § 172.820(d)(1)(iii) and certify that an

alternative route does not exist for a given primary route.

- * * * * *
- 27. Revise appendix C to part 172 to read as follows:

Appendix C to Part 172—Dimensional Specifications for Recommended Placard Holder



PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

- 28. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

- 29. In § 173.31, revise paragraphs (a)(2), (d) and (g)(1) to read as follows:

§ 173.31 Use of tank cars.

- (a) * * *

(2) Tank cars and appurtenances may be used for the transportation of any commodity for which they are authorized in this part and specified on the Design Approval Certificate or for tank cars constructed prior to [DATE ONE YEAR FROM EFFECTIVE DATE], the certificate of construction (AAR Form 4–2 or by addendum on Form R–1). See § 179.5 of this subchapter. Transfer of a tank car from one specified service on its certificate of construction or Design Approval Certificate to another may be made only by the owner

or with the owner’s authorization. A tank car proposed for a commodity service other than specified on its certificate of construction or Design Approval Certificate must be approved for such service by a Design Certifying Engineer.

* * * * *

- (d) *Pre-transportation closure, securement, and examination of tank cars.* Prior to transportation, each person who offers a tank car carrying hazardous material must ensure the tank

car is closed, secured, and inspected in accordance with this section.

(1) *Securement of closures on tank cars.* The offeror must have and follow a written procedure for closing and securing all openings on a tank car prior to shipment. The person responsible for developing or updating the procedure must consider available best practices and guidance from each packaging and component supplier, such as service equipment manufacturer, gasket manufacturer, tank car owner, or other product-specific closure manufacturer. The procedure must be periodically reviewed and updated to reflect changes or modifications that impact the securement of closures, but not later than every two years.

(2) *Pre-trip Inspection.* No person may offer for transportation a tank car containing a hazardous material or a residue of a hazardous material unless that person determines that the tank car is in proper condition and safe for transportation. As a minimum, each person offering a tank car for transportation must perform an external visual inspection that includes:

(i) Except where insulation or a thermal protection system precludes an inspection, the tank shell and heads for abrasion, corrosion, cracks, dents, distortions, defects in welds, or any other condition that makes the tank car unsafe for transportation;

(ii) The piping, valves, fittings, and gaskets for corrosion, damage, or any other condition that makes the tank car unsafe for transportation;

(iii) For missing or loose bolts, nuts, or elements that make the tank car unsafe for transportation;

(iv) All closures on tank cars and determine that the closures and all fastenings securing them are properly tightened in place by the use of a bar, wrench, or other suitable tool;

(v) Protective housings for proper securement;

(vi) The pressure relief device, including a careful inspection of the rupture disc in non-reclosing pressure relief devices, for corrosion or damage that may alter the intended operation of the device. The rupture disc is not required to be removed prior to visual inspection if the tank car contains the residue, as defined in § 171.8 of this subchapter, of a Class 8, PG II or PG III material with no subsidiary hazard or the residue of a Class 9 elevated temperature material;

(vii) Each tell-tale indicator after filling and prior to transportation to ensure the integrity of the rupture disc;

(viii) The external thermal protection system, tank-head puncture resistance system, coupler vertical restraint

system, and bottom discontinuity protection for conditions that make the tank car unsafe for transportation;

(ix) The required markings on the tank car for legibility; and

(x) The periodic inspection date markings to ensure that the inspection and test intervals are within the prescribed intervals.

(3) *Design of Closures.* Closures on tank cars are required, in accordance with this subchapter, to be designed and closed so that under conditions normally incident to transportation, including the effects of temperature and vibration, there will be no identifiable release of a hazardous material to the environment. In any action brought to enforce this section, the lack of securement of any closure to a tool-tight condition, detected at any point, will establish a rebuttable presumption that a proper inspection was not performed by the offeror of the car. That presumption may be rebutted by any evidence indicating that the lack of securement resulted from a specific cause not within the control of the offeror.

* * * * *

(g) * * *
(1) Except as provided in (g)(1)(i), each hazmat employee who is responsible for loading or unloading a tank car must ensure the track is secure to prevent access by other rail equipment, including motorized service vehicles. The mechanism used to satisfy this requirement must be under direct control of the hazmat employee responsible for the loading or unloading operation and must be locked so that only the employee responsible for the product transfer operation may remove it. The means of protection under this section must be capable of stopping or diverting rail equipment to prevent contact with the tank car or equipment that is part of the transfer operation. This requirement must be satisfied by lining each switch providing access to the loading/unloading area away from the unloading operation and securing each switch with an effective locking device; using a derail when locked in a derailing position with an effective locking device on the track providing direct access to the tank car that is being loaded or unloaded; by using other means that provide an equivalent level of security; or, a combination of the above.

(i) Equipment may be used to reposition rolling equipment on this track after the protection has been removed under the following conditions:

(A) The equipment is operated by an authorized employee under the

direction of the hazmat employee who is responsible for loading or unloading the tank car;

(B) The hazmat employee who is responsible for loading or unloading the tank car on the affected track has been notified;

(C) The rolling equipment must not couple into the tank car being loaded/unloaded; and

(D) The protection must be restored immediately after the repositioning has been completed.

(ii) [Reserved]

* * * * *

■ 30. In § 173.150, revise paragraph (f)(3)(viii) to read as follows:

§ 173.150 Exceptions for Class 3 (flammable and combustible liquids).

* * * * *

(f) * * *

(3) * * *

(viii) The requirements of §§ 173.1, 173.21, 173.24, 173.24a, 173.24b, 174.1, 177.804, 177.817, 177.834(j), 177.837(c) and 177.837(d) of this subchapter;

* * * * *

■ 31. In § 173.159, revise paragraphs (e)(2), (e)(4), and (e)(5), and add paragraph (e)(6) to read as follows:

§ 173.159 Batteries, wet.

* * * * *

(e) * * *

(2) The batteries must be loaded or braced so as to prevent damage and short circuits while in transit, in a manner that secures the batteries against shifting, including relative motion between packages, under conditions normally incident to transportation;

* * * * *

(4) Except for the purpose of consolidating shipments of batteries for recycling, the transport vehicle may not carry material shipped by any person other than the shipper of the batteries;

(5) The offeror must inform persons loading the batteries and the operator of the vehicle transporting batteries of the requirements of this paragraph; and

(6) Shipments made under this paragraph are subject to the incident reporting requirements in § 171.15.

* * * * *

■ 32. In § 173.241, revise paragraph (a) introductory text to read as follows:

§ 173.241 Bulk packagings for certain low hazard liquid and solid materials.

* * * * *

(a) *Rail cars:* Class DOT 103, 104, 105, 109, 111, 112, 114, 115, 117, or 120 tank car tanks; and Class 106 or 110 multi-unit tank car tanks. AAR Class 203W, 206W, and 211W tank car tanks are also authorized. AAR Class 203W, 206W, and 211W tank car tanks built after

[DATE ONE YEAR FROM EFFECTIVE DATE] must be as prescribed in AAR Specifications for Tank Cars Chapter 3 (IBR, see § 171.7 of this subchapter). Additional operational requirements apply to high-hazard flammable trains (see § 171.8 of this subchapter) as prescribed in § 174.310 of this subchapter. Except as otherwise provided in this section, DOT Specification 111 tank cars and DOT Specification 111 tank cars built to the CPC-1232 industry standard are no longer authorized to transport Class 3 (flammable) liquids in Packing Group III, unless retrofitted to the DOT Specification 117R retrofit standards or the DOT Specification 117P performance standards provided in part 179, subpart D of this subchapter.

■ 33. In § 173.242, revise paragraph (a) introductory text to read as follows:

§ 173.242 Bulk packagings for certain medium hazard liquids and solids, including solids with dual hazards.

(a) *Rail cars*: Class DOT 103, 104, 105, 109, 111, 112, 114, 115, 117, or 120 tank car tanks and Class 106 or 110 multi-unit tank car tanks. AAR Class 206W tank car tanks are also authorized. AAR Class 206W tank car tanks built after [DATE ONE YEAR FROM EFFECTIVE DATE] must be as prescribed in AAR Specifications for Tank Cars Chapter 3 (IBR, see § 171.7 of this subchapter). Additional operational requirements apply to high-hazard flammable trains (see § 171.8 of this subchapter) as prescribed in § 174.310 of this subchapter. Except as otherwise provided in this section, DOT Specification 111 tank cars and DOT Specification 111 tank cars built to the CPC-1232 industry standard are no longer authorized to transport unrefined petroleum products, ethanol, and other

Class 3 (flammable) liquids in Packing Group II or III, unless retrofitted to the DOT Specification 117R retrofit standards, or the DOT Specification 117P performance standards provided in part 179, subpart D of this subchapter.

■ 34. In § 173.247, revise paragraph (a) introductory text to read as follows:

§ 173.247 Bulk packaging for certain elevated temperature materials.

(a) *Rail cars*: Class DOT 103, 104, 105, 109, 111, 112, 114, 115, or 120 tank car tanks; Class DOT 106, 110 multi-unit tank car tanks; AAR Class 203W, 206W, 211W tank car tanks; and non-DOT specification tank car tanks equivalent in structural design and accident damage resistance to specification packagings. AAR Class 203W, 206W, and 211W tank car tanks constructed after [DATE ONE YEAR FROM EFFECTIVE DATE] must be as prescribed in AAR Specifications for Tank Cars Chapter 3 (IBR, see § 171.7 of this subchapter).

§ 173.314 [Amended]

■ 35. In § 173.314, remove and reserve paragraph (b)(4).

■ 36. In § 173.315:

- a. Revise the first sentence of paragraph (h) introductory text, paragraphs (i)(13), (j)(1) introductory text, (m)(1)(vi), (m)(1)(vii);
- b. Add paragraph (m)(1)(viii); and
- c. Revise the table in paragraph (n)(1).

The revisions and addition read as follows:

§ 173.315 Compressed gases in cargo tanks and portable tanks.

(h) Each cargo tank and portable tank, except a tank filled by weight (see

paragraph (e) of this section), must be equipped with one or more of the gauging devices described in the following table which indicate accurately the maximum permitted liquid level (for purposes of the following table, a column entry with “do” indicates “same as above”).

(13) A pressure relief device on a chlorine cargo tank must conform to one of the drawings in The Chlorine Institute, Inc. Pamphlet 49, “Recommended Practices for Handling Chlorine Bulk Highway Transports” (IBR, see § 171.7 of this subchapter).

(1) Storage containers for liquefied petroleum gas charged to five percent of their capacity or less and intended for permanent installation on consumer premises may be shipped by private motor carrier under the following conditions:

- (m) (1) Is securely mounted on a farm wagon or meets paragraph (m)(3) of this section;
- (vii) Is in conformance with the requirements of part 172 of this subchapter except that shipping papers are not required; and it need not be marked or placarded on one end if that end contains valves, fittings, regulators, or gauges when those appurtenances prevent the markings and placard from being properly placed and visible; and
- (viii) For tanks manufactured after [DATE 90 DAYS FROM EFFECTIVE DATE], the cargo tank must be subjected to full post weld heat treatment.

§ 173.315(n)(1)(*)	Hazardous material	Delivery service	Required emergency discharge control capability	Obstructed view deliveries under § 177.840(p) of this subchapter
(iii)	Anhydrous ammonia either Division 2.2 or 2.3.	Other than metered delivery service.	Paragraph (n)(2) of this section.	
	Anhydrous Ammonia, either Division 2.2 or 2.3.	Metered delivery service, 13,247 L (3,500 water gallons) or less.	Paragraph (n)(3) of this section.	
	Anhydrous Ammonia, either Division 2.2 or 2.3.	Metered delivery service, over 13,247 L (3,500 water gallons).	Paragraph (n)(3) of this section; and	Paragraph (n)(2) or (n)(4) of this section.
	Anhydrous Ammonia, either Division 2.2 or 2.3.	Both metered delivery service and other than metered delivery service, over 13,247 L (3,500 water gallons).	Paragraph (n)(2) of this section, provided the system operates for both metered and other than metered delivery service; or (n)(2) and (n)(3).	

§ 173.315(n)(1)(*)	Hazardous material	Delivery service	Required emergency discharge control capability	Obstructed view deliveries under § 177.840(p) of this subchapter
(iv)	Division 2.2 with a subsidiary hazard.	Other than metered delivery service.	Paragraph (n)(2) of this section.	
	Division 2.2 with a subsidiary hazard.	Metered delivery service, 13,247 L (3,500 water gallons) or less.	Paragraph (n)(3) of this section.	
	Division 2.2 with a subsidiary hazard.	Metered delivery service, over 13,247 L (3,500 water gallons).	Paragraph (n)(3) of this section; and	Paragraph (n)(2) or (n)(4) of this section.
(v)	Division 2.1	Other than metered delivery service.	Paragraph (n)(2) of this section.	
	Division 2.1	Metered delivery service, 13,247 L (3,500 water gallons) or less.	Paragraph (n)(3) of this section.	
	Division 2.1	Metered delivery service, over 13,247 L (3,500 water gallons).	Paragraph (n)(3) of this section;	Paragraph (n)(2) or (n)(4) of this section.

* * * * *

■ 37. In § 173.320, revise paragraphs (a) introductory text and (b) introductory text to read as follows:

§ 173.320 Cryogenic liquids; exceptions.

(a) Cryogenic liquids authorized to use this section by Column 8(A) of the § 172.101 Hazardous Materials Table of this subchapter, which are transported in Dewar flasks, insulated cylinders, insulated portable tanks, insulated cargo tank motor vehicles, and insulated tank cars that have been designed and constructed so that the pressure in such packagings will not exceed 25.3 psig under ambient temperature conditions during transportation, are not subject to the requirements of this subchapter when transported by motor vehicle or railcar except for:

* * * * *

(b) The requirements of this subchapter do not apply to cryogenic liquids authorized to use this section by Column 8(A) of the § 172.101 Hazardous Materials Table of this subchapter:

* * * * *

PART 174—CARRIAGE BY RAIL

■ 38. The authority citation for part 174 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 33 U.S.C. 1321; 49 CFR 1.81 and 1.97.

■ 39. In § 174.9, revise paragraph (a) and add paragraph (e) to read as follows:

§ 174.9 Safety and security inspection and acceptance.

(a) At each location where a hazardous material is accepted for transportation or placed in a train, the carrier must inspect each rail car containing the hazardous material, at ground level, for required markings, labels, placards, securement of closures, and leakage. These inspections may be

performed in conjunction with inspections required under 49 CFR parts 215 and 232.

* * * * *

(e) In an action brought to enforce this section, a train found departing a location where the hazardous material is accepted for transportation or placed in a train with improper hazard communication, unapplied closures, or leaking hazardous material, which is readily apparent from the ground level, will establish a rebuttable presumption that a proper inspection was not performed by the carrier. The presumption may be rebutted by any evidence indicating that the improper hazard communication, unapplied closures, or leaking hazardous material resulted from a specific cause not identifiable by the carrier during the inspection.

■ 40. In § 174.14, revise paragraph (a) to read as follows:

§ 174.14 Movements to be expedited.

(a) A carrier must forward each shipment of hazardous materials promptly and within 48 hours (Saturdays, Sundays, and holidays excluded), after acceptance at the originating point or receipt at any yard or interchange point. Exceptions from the requirement to forward a shipment within 48 hours are as follows and the carrier must keep a record of the delay of a shipment in accordance with one of these exceptions:

(1) When only biweekly or weekly service is performed, a shipment of hazardous materials must be forwarded on the first available train;

(2) Where circumstances preclude delivery to the consignee destination listed on the shipping paper (e.g., excessive railcar congestion on private track), railcars may be temporarily held until alternative disposition is obtained,

or the circumstances precluding delivery are resolved; or

(3) Where the shipment contains only the residue of a hazardous material.

* * * * *

§§ 174.16 and 174.20 [Remove and Reserve]

■ 41. Remove and reserve §§ 174.16 and 174.20.

■ 42. In § 174.24, revise paragraph (b) to read as follows:

§ 174.24 Shipping papers.

* * * * *

(b) Each person receiving a shipping paper required by this section must retain a copy or an electronic image thereof, that is accessible at or through its principal place of business and must make the shipping paper available, upon request, to an authorized official of a Federal, State, or local government agency at reasonable times and locations. In non-emergency circumstances, the shipping paper must be made available no later than close of business the following business day from the time of the request. For a hazardous waste, each shipping paper copy must be retained for three years after the material is accepted by the initial carrier. For all other hazardous materials, each shipping paper copy must be retained for one year after the material is accepted by the initial carrier. Each shipping paper copy must include the date of acceptance by the initial carrier. The date on the shipping paper may be the date a shipper notifies the rail carrier that a shipment is ready for transportation, as indicated on the waybill or bill of lading, as an alternative to the date the shipment is picked up, or accepted, by the carrier.

■ 43. Revise § 174.50 to read as follows:

§ 174.50 Nonconforming or leaking packages.

(a) *Applicability.* (1) Except as otherwise provided in paragraph (b) of this section, a rail car in hazardous material service that is not able to retain its contents in accordance with § 173.24 of this subchapter or a DOT specification tank car that does not conform to this subchapter may not be moved in transportation unless approved for movement by the Associate Administrator for Safety, Federal Railroad Administration.

(2) A leaking non-bulk package may not be forwarded until repaired, reconditioned, or overpacked in accordance with § 173.3 of this subchapter.

(b) *Exceptions.* (1) A leaking bulk package containing hazardous material may be moved without repair or approval only so far as necessary to reduce or eliminate an immediate threat of harm to human health or the environment when it is determined its movement would provide greater safety than allowing the bulk package to remain in place. In the case of a liquid leak, the company in possession of the bulk package must take measures to prevent the spread of the liquid.

(2) A non-conforming rail car that does not contain any hazardous material may be moved without repair or approval, provided the non-conforming condition does not affect the structural integrity of the rail car.

(3) A rail car containing a hazardous material that is found during the course of transportation to be overloaded by weight by 3,000 pounds or less of the maximum gross weight on rail (MGWR) when weighed on a weigh-in-motion scale, or a rail car containing a hazardous material that is found to be overloaded by weight by 1,000 pounds or less of the rail car's MGWR when weighed on a static scale. These tolerances apply to a rail car that the railroad operator discovers to be loaded above the rail car's MGWR during the course of transportation. This does not authorize the original offeror to knowingly offer a rail car for transportation when the pre-transportation calculations or scale weight exceed the MGWR of the rail car.

(4) For cross-border movements to or from Canada, a rail car in hazardous material service that is not able to retain its contents in accordance with § 173.24 of this subchapter or a DOT specification tank car moved in accordance with the TDG Regulations (see § 171.12), or a Temporary Certificate issued by the Competent Authority of Canada, as applicable.

(c) *Approval Process.* To apply for a One-Time Movement Approval, follow the guidance in FRA's guide for requesting a One-Time Movement Approval (HMG-127) and the requirements set forth in this section, as applicable.

(d) *General One-Time Movement Approval Requirements.* These general requirements apply to the grantee of an approval for a non-conforming rail car for transportation under the terms of a One-Time Movement Approval issued by FRA in accordance with this section.

(1) *Marking.* Prior to moving a non-conforming rail car, regardless of the lading, the rail car must have the following or similar wording applied to both sides of the rail car in a stencil, decal, or tag that is readily visible. This requirement does not apply to tank cars moved under a One-Time Movement Approval issued for rail cars that are overloaded by weight. The stencil, decal, or tag required by this paragraph must not be removed until appropriate repairs are made to the rail car. Rail cars with defective service equipment must also tag the specific equipment (e.g., valve or fitting) with the following wording or alternative wording that conveys a similar message.

<p>HOME SHOP FOR REPAIRS DO NOT LOAD or MOVING FOR DISMANTLING DO NOT LOAD</p>

(2) *Notification.* Each approval grantee must:

(i) Notify the owner of the rail car that it is being moved under the terms of a One-Time Movement Approval;

(ii) Ensure the consignee or final destination facility has been notified and will accept the non-conforming rail car and be willing and capable of unloading the lading, if necessary, to perform the required maintenance. For tank cars, a tank car facility, either fixed or mobile, must perform the required maintenance at the destination indicated in the application;

(iii) Ensure that the cleaning facility is capable of cleaning the rail car if the non-conforming rail car contains a hazardous material and requires movement to a cleaning facility prior to movement for repair;

(iv) Ensure that each rail carrier that will handle the defective rail car in transportation has been notified and will accept the non-conforming rail car for transportation; and

(v) Ensure that shipping documentation transmitted to the initial rail carrier involved in the movement of

the non-conforming shipment identifies that the rail car is moving under a One-Time Movement Approval.

(3) *Recordkeeping.* The approval grantee is required to maintain a copy or an electronic image of the One-Time Movement Approval and must make the information available upon request to FRA personnel. The One-Time Movement Approval must be retained for one year from the date of issuance of the approval.

(4) *Routing.* The approval grantee and the rail carrier(s) involved in the movement of the non-conforming rail car must consider the nature of the non-conformance and select the most appropriate route to the nearest cleaning facility and rail car repair facility capable of performing the required cleaning and/or repairs.

(5) *Root Cause Analysis.* A recommended format for a root cause analysis report is provided as an Appendix in the FRA guidance on applying for a One-Time Movement Approval.

(i) If FRA requires a root cause analysis for a non-conforming rail car, the grantee is responsible for notifying the rail car owner of the requirement and coordinating with the rail car owner to determine disposition of the rail car.

(ii) If FRA requires a root cause analysis for an overloaded rail car, the grantee is responsible for notifying the facility that loaded and offered the rail car of the requirement to provide FRA with a root cause analysis.

(e) *Compliance Responsibility.* (1) The person who offers the rail car into transportation and the grantee of the One-Time Movement Approval are responsible for ensuring compliance with all applicable requirements specified in this section and the One-Time Movement Approval.

(2) FRA may issue written notification to any entity found to be non-compliant with the requirements of this section or the conditions of the One-Time Movement Approval. This written notification may require the entity to submit all future One-Time Movement Approval requests as a Category 1 One-Time Movement Approval regardless of the identified non-conforming condition with the rail car. This limitation will apply to the particular entity until otherwise notified in writing by the FRA.

■ 44. Add § 174.58 to read as follows:

§ 174.58 Residue shipment.

As referenced in the § 171.8 definition of *residue*, the phrase "extent practicable" means an unloading facility has unloaded a bulk package using

properly functioning service equipment and plant process equipment.

■ 45. Revise § 174.59 to read as follows:

§ 174.59 Marking and placarding of rail cars.

No person may transport a rail car carrying hazardous materials unless it is marked and placarded as required by this subchapter. Required placards lost in transit must be replaced at the nearest inspection point in the direction of travel where mechanical personnel responsible for inspections related to 49 CFR parts 215 and 232 are on duty, and non-compliant placards must be removed at the next terminal in the direction of travel where the train is classified. For Canadian shipments, required placards lost in transit must be replaced either by those required by part 172 of this subchapter or by those authorized under § 171.12.

■ 46. In § 174.63, revise the section heading, and paragraphs (b), (c)(1), and (c)(2) to read as follows:

§ 174.63 Requirements for rail transport of Portable tanks, IM portable tanks, IBCs, Large Packagings, cargo tanks, and multi-unit tank car tanks in TOFC/COFC Service.

* * * * *

(b) A bulk packaging containing a hazardous material (including IM 101 and IM 102 portable tanks when appropriate according to dimensions and weight distribution) may be transported inside a fully closed transport vehicle or fully closed freight container provided it is properly secured with a restraint system that will prevent it from changing position, sliding into other packages, or contacting the side or end walls (including doors) under conditions normally incident to transportation.

(c) * * *

(1)(i) The bulk packaging contains a material packaged in accordance with §§ 173.240, 173.241, 173.242, 173.243, or 173.247; or

(ii) The bulk packaging contains a Division 2.2 material not specifically provided for in the § 173.315(a)(2) table and packaged in accordance with § 173.315;

(2) The bulk packaging must comply with the applicable requirements of the HMR concerning its specification, if applicable for the material it contains, and the rail car must comply with the applicable regulatory requirements for the type of rail car being used.

* * * * *

■ 47. Revise § 174.67 to read as follows:

§ 174.67 Tank car transloading.

(a) *General requirements.* (1) Transloading operations must be

performed by hazmat employees who are properly trained in the loading and unloading of hazardous materials and are made responsible for compliance with this section and §§ 173.31(d) and (g) of this subchapter.

(2) When placed for transloading and before unsecuring any closure, a tank car must be protected against motion or coupling in accordance with § 173.31(g).

(3) [Reserved]

(4) [Reserved]

(5) The transloading facility operator must maintain and adhere to written safety procedures—such as those it may already be required to maintain pursuant to the Department of Labor’s Occupational Safety and Health Administration requirements in 29 CFR 1910.119 and 1910.120—in a location where they are immediately available to hazmat employees responsible for the transloading operation. The procedures must include measures to address the safe handling and operation of the tank car and tank car service equipment, as well as account for physical and chemical properties of the lading being transloaded. At a minimum, the transloading procedures required by this paragraph must include provisions that address the following:

(i) Temperature monitoring and pressure relief;

(ii) Safe operation of the tank car for product loading or unloading;

(iii) Proper disposal of used seals and other debris;

(iv) Measures to avoid spillage of contents outside the tank;

(v) Operation of tank car service equipment;

(vi) Proper removal of product plugs that prevent adequate operation of the valves and equipment; and

(vii) Proper tool maintenance measures including the types of tools to use, calibration, cleanliness, and instructions on use.

(6) [Reserved]

(7) [Reserved]

(8) [Reserved]

(9) [Reserved]

(10) [Reserved]

(11) [Reserved]

(12) [Reserved]

(h) Connections for transloading equipment must be securely attached before any valves are opened.

(i) Throughout the entire period of transloading and while a tank car has transloading equipment attached, the facility operator must assure that the tank car is:

(1) Attended by a designated hazmat employee who is physically present and who has an unobstructed view of the transloading operation; or

(2) Monitored by a signaling system (e.g., video system, sensing equipment,

or mechanical equipment) that is observed by a designated hazmat employee located either in the immediate area of the tank car or at a remote location within the facility, such as a control room. The signaling system must—

(i) Provide a level of surveillance equivalent to that provided in paragraph (i)(1) of this section; and

(ii) Provide immediate notification to a designated hazmat employee of any system malfunction or other emergency so that, if warranted, responsive actions may be initiated immediately.

(j) Attendance is not required when piping is attached to a top outlet of a tank car, equipped with a protective housing required under § 179.100–12 of this subchapter, for transfer of lading under the following conditions:

(1) All valves are tightly closed.

(2) The piping is not connected to hose or other product transfer equipment and is fitted with a cap or plug of appropriate material and construction.

(3) The piping extends no more than 15.24 centimeters (6 inches) from the outer edge of the protective housing.

(k) In the absence of the transloader, a tank car may stand with transloading connections attached when no product is being transferred under the following conditions:

(1) The facility operator must designate a hazmat employee responsible for on-site monitoring of the transfer facility. The designated hazmat employee must be made familiar with the nature and properties of the product contained in the tank car; procedures to be followed in the event of an emergency; and, in the event of an emergency, have the ability and authority to take responsible actions.

(2) When a signaling system is used in accordance with paragraph (i) of this section, the system must be capable of alerting the designated hazmat employee in the event of an emergency and providing immediate notification of any monitoring system malfunction. If the monitoring system does not have self-monitoring capability, the designated hazmat employee must check the monitoring system hourly for proper operation.

(3) The tank car and facility shutoff valves must be secured in the closed position.

(4) Brakes must be set, and wheels locked, in accordance with § 173.31(g) of this subchapter.

(5) Access to the track must be secured in accordance with § 173.31(g) of this subchapter.

(l) Once the transloading operation is complete, all tank car valves and

closures must be secured in accordance with § 173.31(d) of this subchapter. The tank car then must be inspected by a designated hazmat employee in accordance with § 173.31(d) of this subchapter before it is released to the rail carrier for continued movement.

(m) Railroad defect cards may not be removed.

(n) [Reserved]

(o) [Reserved]

■ 48. In § 174.81, revise paragraph (g)(3)(iv) to read as follows:

§ 174.81 Segregation of hazardous materials.

* * * * *

(g) * * *

(3) * * *

(iv) "4" means detonators, detonating assemblies, and boosters with detonators may not be loaded in the same car with Division 1.1 and 1.2 (explosive) materials (except other detonators, detonating assemblies, and boosters with detonators).

* * * * *

PART 176—CARRIAGE BY VESSEL

■ 49. The authority citation for part 176 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 50. In § 176.2, revise the definition for "Commandant" to read as follows:

§ 176.2 Definitions.

* * * * *

Commandant (CG-ENG), USCG means the Chief, Office of Design and Engineering Standards, United States Coast Guard, Washington, DC 20593–7509.

* * * * *

■ 51. In § 176.84, revise paragraph (a) to read as follows:

§ 176.84 Other requirements for stowage, cargo handling, and segregation for cargo vessels and passenger vessels.

(a) General. When Column 10B of the § 172.101 Table refers to a numbered or alpha-numeric stowage provision for water shipments, the meaning and requirements of that provision are set forth in this section. Terms in quotation marks are defined in § 176.83. Other terms used in the table in this section—such as "acids," "chlorates," and "permanganates"—indicate different chemical groups referred to here as segregation groups. Materials falling within a segregation group are considered to have certain similar chemical properties and, although not exhaustive in nature, the materials belonging to each group include those substances identified in section 3.1.4 of

the IMDG Code (IBR, see § 171.7 of this subchapter), as set forth in § 176.83(m). Hazardous materials offered for transportation as limited quantities are not subject to the stowage codes assigned by Column 10B of the § 172.101 Table (see § 172.101(k)).

* * * * *

■ 52. In § 176.340, revise paragraph (c) to read as follows:

§ 176.340 Combustible liquids in portable tanks.

* * * * *

(c) Portable tanks approved by the Commandant (CG-ENG), USCG.

■ 53. In § 176.905, add paragraph (i)(7) to read as follows:

§ 176.905 Stowage of vehicles.

* * * * *

(i) * * *

(7) The vehicle is stored incident to movement on shore within a single port area, including contiguous harbors.

* * * * *

PART 177—CARRIAGE BY PUBLIC HIGHWAY

■ 54. The authority citation for part 177 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; sec. 112 of Pub. L. 103–311, 108 Stat. 1673, 1676 (1994); sec. 32509 of Pub. L. 112–141, 126 Stat. 405, 805 (2012); 49 CFR 1.81 and 1.97.

■ 55. Revise § 177.801 to read as follows:

§ 177.801 Unacceptable hazardous materials shipments.

(a) No person may accept for transportation or transport by motor vehicle a forbidden material (see § 173.21).

(b) No person may accept for transportation or transport a hazardous material that is not classified, packaged, marked, labeled, or placarded, as applicable, in accordance with the requirements of this subchapter or by special permit.

■ 56. In § 177.804, revise paragraph (a) to read as follows:

§ 177.804 Compliance with Federal Motor Carrier Safety Regulations.

(a) General. Motor carriers and other persons subject to this part must comply with 49 CFR part 383 and 49 CFR parts 390 through 397 (excluding §§ 397.3 and 397.9) when operating vehicles subject to those regulations.

* * * * *

■ 57. In § 177.816, revise paragraphs (c) and (d) to read as follows:

§ 177.816 Driver Training.

* * * * *

(c) The training required by paragraphs (a) and (b) of this section may be satisfied by compliance with the current requirements for a Commercial Driver's License (CDL) with a tank vehicle or hazardous materials endorsement if it appropriately covers the requirements in paragraph (a) and (b) of this section.

(d) Training required by paragraphs (a) and (b) of this section must conform to the requirements of § 172.704(c) and (d) of this subchapter with respect to frequency and recordkeeping.

■ 58. In § 177.835, revise paragraph (d) to read as follows:

§ 177.835 Class 1 (explosive) materials.

* * * * *

(d) Multipurpose bulk trucks. When § 172.101 of this subchapter specifies that Class 1 (explosive) materials may be transported in accordance with § 173.66 of this subchapter (per special provision 148 in § 172.102(c)(1)), these materials may be transported on the same vehicle with Division 5.1 (oxidizing) materials, or Class 8 (corrosive) materials, and/or Combustible Liquid, n.o.s., NA1993, only under the conditions and requirements set forth in IME Standard 23 (IBR, see § 171.7 of this subchapter) and paragraph (g) of this section. A multipurpose bulk truck may not be transported with any cargo tank that is required to be marked or placarded under § 177.823. In addition, the segregation requirements in § 177.848 do not apply.

* * * * *

■ 59. In § 177.837, revise paragraph (c) introductory text to read as follows:

§ 177.837 Class 3 (flammable liquid) materials.

* * * * *

(c) Bonding and grounding cargo tanks before and during transfer of lading. A cargo tank motor vehicle that is preparing to transfer or is transferring any flammable liquid, combustible liquid, or a flammable liquid reclassified as a combustible liquid must be bonded and grounded as follows:

* * * * *

■ 60. In § 177.840, revise paragraphs (n), (r)(2), and (t) to read as follows:

§ 177.840 Class 2 (gases) materials.

* * * * *

(n) Emergency shut down. If there is an unintentional release of product to the environment during unloading of a liquefied compressed gas, the qualified person unloading the cargo tank motor vehicle must promptly shut the internal or external self-closing stop valve or other primary means of closure, and

shut down all motive and auxiliary power equipment.

* * * * *

(r) * * *

(2) The qualified person monitoring unloading must remain within arm's reach of the mechanical means of closure for the internal or external self-closing stop valve when the self-closing stop valve is open except for short periods when it is necessary to activate controls or monitor the receiving container. For chlorine cargo tank motor vehicles, the qualified person must remain within arm's reach of a means to stop the flow of product except for short periods when it is necessary to activate controls or monitor the receiving container.

* * * * *

(t) *Unloading without appropriate emergency discharge control equipment.* Until a cargo tank motor vehicle is equipped with emergency discharge control equipment in conformance with §§ 173.315(n)(2) and 180.405(m)(1) of this subchapter, the qualified person attending the unloading operation must remain within arm's reach of a means to close the internal or external self-closing stop valve when the self-closing stop valve is open except during short periods when the qualified person must activate controls or monitor the receiving container. For chlorine cargo tank motor vehicles, the qualified person must remain within arm's reach of a means to stop the flow of product except for short periods when it is necessary to activate controls or monitor the receiving container.

* * * * *

■ 61. In § 177.841, revise paragraphs (e)(1) introductory text and (e)(2) to read as follows:

§ 177.841 Division 6.1 (poisonous materials and Division 2.3 (poisonous gas) materials.

* * * * *

(e) * * *

(1) Except as provided in paragraph (e)(3) of this section, bearing or required to bear a POISON, POISON GAS, or POISON INHALATION HAZARD label or placard in the same motor vehicle with material that is marked as or known to be foodstuffs, feed, or edible material intended for consumption by humans or animals unless the poisonous material is packaged in accordance with this subchapter and is:

* * * * *

(2) Bearing or required to bear a POISON, POISON GAS, or POISON INHALATION HAZARD label in the driver's compartment (including a sleeper berth) of a motor vehicle,

including enclosed van trucks with no permanent barrier separating the driver from the cargo compartment; or

* * * * *

PART 178—SPECIFICATIONS FOR PACKAGINGS

■ 62. The authority citation for part 178 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 63. In § 178.320, paragraph (a);
■ a. Revise definitions of “cargo tank”, “cargo tank motor vehicle”, and “minimum thickness”; and
■ b. In alphabetical order, add definitions for “cargo tank motor vehicle certification date”, “component”, “flexible connector”, “lading retention system”, “lining”, “name plate”, “original test date”, “sacrificial device”, “shear section”, and “specification plate”.

The revisions and additions read as follows:

§ 178.320 General requirements applicable to all DOT Specification cargo tank motor vehicles.

(a) * * *

* * * * *

Cargo tank: See § 171.8 of this subchapter for the definition.

Cargo tank motor vehicle: See § 171.8 of this subchapter for the definition.

* * * * *

Cargo tank motor vehicle certification date means the date stamped on the cargo tank motor vehicle specification plate, and represents the date the cargo tank motor vehicle manufacturer certifies that the cargo tank motor vehicle conforms in all respects with the specification requirements (including, but not limited to: rear-end protection devices, overturn protection devices, all other accident damage protection, and attachment to the vehicle), and the ASME Code, if applicable.

* * * * *

Component means any attachment to the cargo tank or cargo tank motor vehicle, including valves, piping, fittings, and hoses, that contain lading during loading, unloading, or transportation, or are required to be pressure- or leak-tested in accordance with the requirements of part 180 of this subchapter.

* * * * *

Flexible connector means a short component of a piping system, not exceeding 36 inches (.91 m) overall length, fabricated of flexible material, and equipped with suitable connections on both ends. Liquefied petroleum gas resistant rubber and fabric or metal, or

a combination thereof, or all metal may be used.

* * * * *

Lading retention system means the cargo tank wall and any associated components or equipment that, if damaged, could result in the release of the contents of the package.

Lining means an internal layer of different material covering the inside surface of the cargo tank.

* * * * *

Minimum thickness means the minimum required shell and head (and baffle and bulkhead when used as tank reinforcement) thickness needed to meet the specification. The minimum thickness is the greatest of the following values: (1)(i) For MC 330, MC 331, and MC 338 cargo tanks, the specified minimum thickness found in the applicable specification(s); or

(ii) For DOT 406, DOT 407 and DOT 412 cargo tanks, the specified minimum thickness found in Tables I and II of the applicable specification(s); or

(iii) For MC 300, MC 301, MC 302, MC 303, MC 304, MC 305, MC 306, MC 307, MC 310, MC 311, and MC 312 cargo tanks, the in-service minimum thickness prescribed in Tables I and II of § 180.407(i)(5) of this subchapter, for the minimum thickness specified by Tables I and II of the applicable specification(s); or

(2) The thickness necessary to meet with the structural integrity and accident damage requirements of the applicable specification(s); or

(3) The thickness as computed per the ASME Code requirements (if applicable).

* * * * *

Name plate means a data plate permanently attached to the cargo tank by the cargo tank manufacturer for the purpose of displaying the minimum information required by the ASME Code prescribed in §§ 178.337–17(b), 178.338–18(b), or 178.345–14(b) of this part, as appropriate.

* * * * *

Original test date means the date when the cargo tank manufacturer performed the pressure test, as required in part 178 of this subchapter, to verify the structural integrity of the cargo tank in accordance with the requirements for new construction prescribed in this part.

* * * * *

Sacrificial device means an element, such as a shear section, designed to fail under a load in order to prevent damage to any lading retention part or device. The device must break under strain at no more than 70 percent of the strength of the weakest piping element between

the cargo tank and the sacrificial device. Operation of the sacrificial device must leave the remaining piping and its attachment to the cargo tank intact and capable of retaining lading.

* * * * *

Shear section means a sacrificial device fabricated in such a manner as to abruptly reduce the wall thickness of the adjacent piping or valve material by at least 30 percent.

* * * * *

Specification plate means a data plate containing the applicable markings prescribed in §§ 178.337–17(c), 178.338–18(c), or 178.345–14(c) of this part, as appropriate, and permanently attached to the cargo tank or the cargo tank motor vehicle chassis by the manufacturer. The markings on this plate are certification by the manufacturer that the cargo tank or the cargo tank motor vehicle conforms in all respects with the specification requirements of this subchapter.

* * * * *

- 64. In § 178.337–1:
 - a. Revise paragraph (d); and
 - b. Remove the definition of “internal self-closing stop valve” in paragraph (g).
The revision reads as follows:

§ 178.337–1 General Requirements.

* * * * *

(d) *Reflective design.* Every uninsulated cargo tank permanently attached to a cargo tank motor vehicle shall, unless covered with a jacket made of aluminum, stainless steel, or other bright non-tarnishing metal, be white, aluminum, or a similar reflecting color on the upper two-thirds of area of the cargo tank.

* * * * *

- 65. In § 178.337–2, revise paragraph (b)(2)(i) to read as follows:

§ 178.337–2 Material.

* * * * *

(b) * * *

(2) * * *

(i) Material shall conform to ASTM A 612 or ASTM A 516/A 516M (IBR, see § 171.7 of this subchapter), Grade 65 or 70;

* * * * *

- 66. In § 178.337–3, revise paragraphs (g)(3) introductory text and (g)(3)(iii) to read as follows:

§ 178.337–3 Structural integrity.

* * * * *

(g) * * *

(3) Except as prescribed in paragraphs (g)(1) and (g)(2) of this section, the welding of any appurtenance to the cargo tank wall, internal or external, must be made by attachment of a

mounting pad so that there will be no adverse effect upon the lading retention integrity of the cargo tank if any force less than that prescribed in paragraph (b)(1) of this section is applied from any direction. The thickness of the mounting pad may not be less than that of the shell wall or head wall to which it is attached, and not more than 1.5 times the shell or head thickness. However, a pad with a minimum thickness of 0.25 inch may be used when the shell or head thickness is over 0.25 inch. If weep holes or tell-tale holes are used, the pad must be drilled or punched at the lowest point before it is welded to the tank. Each pad must—

* * * * *

(iii) Extend at least two inches in each direction from any point of attachment of an appurtenance.

* * * * *

- 67. In § 178.337–8, add paragraph (a)(4)(vii) to read as follows:

§ 178.337–8 Openings, inlets, and outlets.

(a) * * *

(4) * * *

(vii) Mechanical means of remote closure for manual operation must not be obstructed by equipment or appurtenances in a manner that prevents access to or operation of the remote means in an emergency.

* * * * *

- 68. In § 178.337–9:
 - a. Revise paragraphs (a)(3), (b) introductory text, (b)(1), and (b)(6);
 - b. Remove and reserve paragraph (b)(7); and
 - c. Add paragraph (e).

The revisions and addition read as follows:

§ 178.337–9 Pressure relief devices, piping, valves, hoses, and fittings.

(a) * * *

(3) Each pressure relief device must be designed, constructed, and marked for a rated pressure not less than the cargo tank design pressure at the temperature expected to be encountered.

(b) *Components and other pressure parts.* The cargo tank motor vehicle manufacturer must ensure that all components meet the following requirements:

(1) The burst pressure of all piping, pipe fittings, hose, and other pressure parts, except for pump seals and pressure relief devices, must be at least four times the MAWP of the cargo tank. Additionally, the burst pressure may not be less than four times any higher pressure to which each pipe, pipe fitting, hose, or other pressure part may be subjected to in service. For chlorine

service, see paragraph (b)(8) of this section.

* * * * *

(6) Cargo tank motor vehicle manufacturers must demonstrate that all piping, valves, and fittings on a cargo tank are free from leaks. To meet this requirement, the piping, valves, and fittings must be tested after installation at not less than 80 percent of the MAWP marked on the name plate after the piping is installed on the cargo tank motor vehicle.

(7) [Reserved].

* * * * *

(e) *Hose assembler requirements.* A hose assembler must:

(1) Permanently mark each hose assembly with a unique identification number.

(2) Demonstrate that each hose assembly is free from leaks by performing the tests and inspections and issuing a written report as required by § 180.416(f) of this subchapter.

(3) Mark each hose assembly with the month and year of its original pressure test.

- 69. In § 178.337–10, revise paragraph (c)(1) to read as follows:

§ 178.337–10 Accident damage protection.

* * * * *

(c) * * *

(1) Consist of at least one rear bumper designed to protect the cargo tank and all components located at the rear of the cargo tank from damage that could result in loss of lading in the event of a rear-end collision. The bumper design must transmit the force of the collision directly to the chassis of the vehicle.

The rear bumper and its attachments to the chassis must be designed to withstand a load equal to twice the weight of the loaded cargo tank motor vehicle and attachments, using a safety factor of four based on the tensile strength of the materials used, with such load being applied horizontally and parallel to the major axis of the cargo tank. The rear bumper dimensions must also meet the requirements of § 393.86 of this title. The exception in § 393.86 for wheels back vehicles does not apply; or

* * * * *

- 70. In § 178.337–17, revise paragraphs (a) introductory text and (a)(4) to read as follows:

§ 178.337–17 Marking.

(a) *General.* The manufacturer shall permanently attach to each cargo tank a corrosion-resistant metal name plate (ASME Plate), if applicable, and a specification plate permanently attached by brazing, welding, or other

suitable means on the left side of the vehicle near the front, in a place accessible for inspection. If the specification plate is attached directly to the cargo tank wall by welding, it must be welded to the tank before the cargo tank is postweld heat treated.

* * * * *

(4) The specification plate must be permanently attached to the cargo tank or its integral supporting structure by brazing, welding, or other suitable means on the left side of the vehicle near the front head, in a place accessible for inspection. If the specification plate is attached to an integral supporting structure, then the cargo tank serial number assigned by the cargo tank manufacturer must be included on the plate.

* * * * *

■ 71. Revise § 178.337–18, revise paragraphs (a) introductory text, (a)(1), (a)(3), and (a)(4) to read as follows:

§ 178.337–18 Certification.

(a) At or before the time of delivery, the cargo tank motor vehicle manufacturer must supply and the owner must obtain, a cargo tank’s ASME Form U–1A data report as required by Section VIII of the ASME Code (IBR, see § 171.7 of this subchapter), and a Certificate of Compliance stating that the completed cargo tank motor vehicle conforms in all respects to Specification MC 331 and the ASME Code. The registration numbers of the manufacturer, the Design Certifying Engineer, and the Registered Inspector, as appropriate, must appear on the Certificates of Compliance (see subpart F, part 107 in subchapter A of this chapter).

(1) For each design type, the Certificate of Compliance must be signed by an official of the manufacturer responsible for compliance and a Design Certifying Engineer; and

* * * * *

(3) When a cargo tank motor vehicle is manufactured in two or more stages, each manufacturer who performs a manufacturing operation on the incomplete cargo tank motor vehicle or portion thereof must provide to the succeeding manufacturer, at or before the time of delivery, a certificate that states the function performed by the manufacturer, including any certificates received from previous manufacturers, Registered Inspectors, and Design Certifying Engineers. When the cargo tank motor vehicle is brought into full compliance with the applicable DOT specification and the ASME Code, the final manufacturer must mark the specification plate with the cargo tank

motor vehicle certification date and attach the specification plate to the completed cargo tank motor vehicle in accordance with § 178.337–17(a) of this part.

(4) Specification shortages. When a cargo tank motor vehicle is manufactured in two or more stages, the manufacturer of the cargo tank must attach the name plate and specification plate as required by § 178.337–17(a) and (b) without the original date of certification stamped on the specification plate. Prior manufacturers must list the specification requirements that are not completed on the Certificate of Compliance. When the cargo tank motor vehicle is brought into full compliance with the applicable specification, the Registered Inspector shall stamp the date of certification on the specification plate and issue a Certificate of Compliance to the owner of the cargo tank motor vehicle. The Certificate of Compliance must list the actions taken to bring the cargo tank motor vehicle into full compliance. In addition, the certificate must include the date of certification and the person (manufacturer, carrier or repair organization) accomplishing compliance.

* * * * *

■ 72. In § 178.338–3, revise paragraphs (g)(3) introductory text and (g)(3)(iii) to read as follows:

§ 178.338–3 Structural integrity.

* * * * *

(g) * * *

(3) Except as prescribed in paragraphs (g)(1) and (g)(2) of this section, the welding of any appurtenance to the cargo tank wall, internal or external, must be made by attachment of a mounting pad so that there will be no adverse effect upon the lading retention integrity of the cargo tank if any force less than that prescribed in paragraph (b)(1) of this section is applied from any direction. The thickness of the mounting pad may not be less than that of the shell wall or head wall to which it is attached, and not more than 1.5 times the shell or head thickness. However, a pad with a minimum thickness of 0.187 inch may be used when the shell or head thickness is over 0.187 inch. If weep holes or tell-tale holes are used, the pad must be drilled or punched at the lowest point before it is welded to the tank. Each pad must:

* * * * *

(iii) Extend at least two inches in each direction from any point of attachment of an appurtenance.

* * * * *

■ 73. In § 178.338–10, revise paragraph (c)(1) to read as follows:

§ 178.338–10 Accident damage protection.

* * * * *

(c) * * *

(1) Consist of at least one rear bumper designed to protect the cargo tank and all components located at the rear of the cargo tank from damage that could result in loss of lading in the event of a rear-end collision. The bumper design must transmit the force of the collision directly to the chassis of the vehicle. The rear bumper and its attachments to the chassis must be designed to withstand a load equal to twice the weight of the loaded cargo tank motor vehicle and attachments, using a safety factor of four based on the tensile strength of the materials used, with such load being applied horizontally and parallel to the major axis of the cargo tank. The rear bumper dimensions must also meet the requirements of § 393.86 of this title. The exception in § 393.86 for wheels back vehicles does not apply; or

* * * * *

■ 74. In § 178.338–11, add paragraph (c)(2)(iii) to read as follows:

§ 178.338–11 Discharge control devices.

* * * * *

(c) * * *

(2) * * *

(iii) Mechanical means of remote closure for manual operation must not be obstructed by equipment or appurtenances in a manner that prevents access to or operation of the remote means in an emergency.

■ 75. In § 178.338–18, revise paragraphs (a) introductory text and (a)(4) to read as follows:

§ 178.338–18 Marking.

(a) General. The manufacturer shall permanently attach to each cargo tank a corrosion-resistant metal name plate (ASME Plate), if applicable, and a specification plate permanently attached by brazing, welding, or other suitable means on the left side of the vehicle near the front, in a place accessible for inspection. If the specification plate is attached directly to the cargo tank wall by welding, it must be welded to the tank before the cargo tank is postweld heat treated.

* * * * *

(4) The specification plate must be permanently attached to the cargo tank or its integral supporting structure, by brazing, welding, or other suitable means on the left side of the vehicle near the front head, in a place accessible for inspection. If the specification plate

is attached to an integral supporting structure, then the cargo tank serial number assigned by the cargo tank manufacturer must be included on the plate.

* * * * *

■ 76. Revise § 178.338–19 to read as follows:

§ 178.338–19 Certification.

(a) At or before the time of delivery, the cargo tank motor vehicle manufacturer must supply and the owner must obtain, a cargo tank’s ASME Form U–1A data report as required by Section VIII of the ASME Code (IBR, see § 171.7 of this subchapter), and a Certificate of Compliance stating that the completed cargo tank motor vehicle conforms in all respects to Specification MC 338 and the ASME Code. The registration numbers of the manufacturer, the Design Certifying Engineer, and the Registered Inspector, as appropriate, must appear on the Certificates of Compliance (see subpart F, part 107 in subchapter B of this chapter).

(1) For each design type, the Certificate of Compliance must be signed by an official of the manufacturer responsible for compliance and a Design Certifying Engineer; and

(2) A photograph, pencil rub, or other facsimile of the plates required by paragraphs (a) and (b) of § 178.338–18.

(3) When a cargo tank motor vehicle is manufactured in two or more stages, each manufacturer who performs a manufacturing operation on the incomplete cargo tank motor vehicle or portion thereof must provide to the succeeding manufacturer, at or before the time of delivery, a certificate that states the function performed by that manufacturer, including any certificates received from previous manufacturers, Registered Inspectors, and Design Certifying Engineers. When the cargo tank motor vehicle is brought into full compliance with the applicable DOT specification and the ASME Code, the final manufacturer must mark the specification plate with the cargo tank motor vehicle certification date and attach the specification plate to the completed cargo tank motor vehicle in accordance with § 178.338–18(a) of this part.

(b) The owner shall retain the data report, certificates, and related papers throughout his ownership of the cargo tank motor vehicle and for at least one year thereafter; and in the event of change of ownership, retention by the prior owner of non-fading photographically reproduced copies will be deemed to satisfy this requirement. Each motor carrier using

the cargo tank motor vehicle, if not the owner thereof, shall obtain a copy of the data report and the Certificate(s) of Compliance, and retain them during the time the carrier uses the cargo tank motor vehicle and for at least one year thereafter.

(c) [Reserved]

■ 77. In § 178.345–1, revise paragraph (c) to read as follows:

§ 178.345–1 General requirements.

* * * * *

(c) *Definitions.* See § 178.320(a) for the definition of certain terms used in §§ 178.345, 178.346, 178.347, and 178.348.

* * * * *

■ 78. In § 178.345–3, revise paragraphs (f) introductory text, (f)(3) introductory text, and (f)(3)(iii) to read as follows:

§ 178.345–3 Structural integrity.

* * * * *

(f) The design, construction, and installation of an attachment, appurtenance to a cargo tank, structural support member between the cargo tank and the vehicle of suspension component, or accident protection device must conform to the following requirements:

* * * * *

(3) Except as prescribed in paragraphs (f)(1) and (f)(2) of this section, the welding of any appurtenance to the cargo tank wall, internal or external, must be made by attachment of a mounting pad so that there will be no adverse effect upon the lading retention integrity of the cargo tank if any force less than that prescribed in paragraph (b)(1) of this section is applied from any direction. The thickness of the mounting pad may not be less than that of the shell wall or head wall to which it is attached, and not more than 1.5 times the shell or head thickness. However, a pad with a minimum thickness of 0.187 inch may be used when the shell or head thickness is over 0.187 inch. If weep holes or tell-tale holes are used, the pad must be drilled or punched at the lowest point before it is welded to the tank. Each pad must:

* * * * *

(iii) Extend at least two inches in each direction from any point of attachment of an appurtenance.

* * * * *

■ 79. In § 178.345–8, revise paragraph (d) to read as follows:

§ 178.345–8 Accident damage protection.

* * * * *

(d) *Rear-end tank protection.* Each cargo tank motor vehicle must be provided with a rear-end tank

protection device to protect the cargo tank and piping in the event of a rear-end collision and reduce the likelihood of damage that could result in the loss of lading. Nothing in this paragraph relieves the manufacturer of responsibility for complying with the requirements of § 393.86 of this title and, if applicable, paragraph (b) of this section. The rear-end tank protection device must conform to the following requirements:

(1) For cargo tanks constructed with any component at the rear of the cargo tank motor vehicle:

(i) For any component on the same horizontal plane as the rear-end protection device, the device must be designed so that it can deflect at least six inches horizontally forward from the device’s inboard surface without contacting the component;

(ii) For any component not on the same horizontal plane as the rear-end cargo tank protection device, the device must be designed so that it can deflect at least six inches horizontally forward from the device’s outboard surface or with a vertical plane passing through the device’s outboard surface without contacting the component.

(2) The dimensions of the rear-end cargo tank protection device shall conform to the following:

(i) The bottom surface of the rear-end protection device must be at least four inches below the lower surface of any part at the rear of the cargo tank motor vehicle that contains lading during transit and not more than 60 inches from the ground when the vehicle is empty.

(ii) The maximum width of a notch, indentation, or separation between sections of a rear-end cargo tank protection device may not exceed 24 inches. A notched, indented, or separated rear-end protection device may be used only when the piping at the rear of the cargo tank is equipped with a sacrificial device outboard of a shut-off valve.

(iii) The widest part of the motor vehicle at the rear may not extend more than 18 inches beyond the outermost ends of the device or (if separated) devices on either side of the vehicle.

(3) The structure of the rear-end protection device and its attachment to the cargo tank motor vehicle must be designed to satisfy the conditions specified in paragraph (d)(1) of this section when subjected to an impact of the cargo tank motor vehicle at the gross vehicle weight rating at a deceleration of two “g.” Such impact must be considered as being uniformly applied in the horizontal plane at an angle of 10 degrees or less to the longitudinal axis

of the vehicle. The structures supporting the rear-end protection device, including the frame and the attachments to the frame must also be capable of withstanding the two “g” load.

* * * * *

■ 80. In § 178.345–11:

- a. Revise paragraph (b)(1)(ii); and
- b. Add paragraph (b)(1)(iv).

The revision and addition read as follows:

§ 178.345–11 Tank outlets.

* * * * *

(b) * * *

(1) * * *

(ii) If the actuating system is accidentally damaged, sheared off during transportation, or fails, each loading/unloading outlet must remain securely closed and capable of retaining lading.

* * * * *

(iv) Mechanical means of remote closure for manual operation must not be obstructed by equipment or appurtenances in a manner that prevents access to or operation of the remote means in an emergency.

* * * * *

■ 81. In § 178.345–13, revise paragraph (a) to read as follows:

§ 178.345–13 Pressure and leakage tests.

(a) Cargo tank motor vehicle manufacturers must perform a pressure and leakage test in accordance with this section and §§ 178.346–5, 178.347–5, or 178.348–5. The leakage test shall be performed after the piping is installed on the cargo tank motor vehicle.

* * * * *

■ 82. In § 178.345–14, revise paragraphs (a), (b)(3), (c)(6), (c)(7), and (d) to read as follows:

§ 178.345–14 Marking.

(a) *General.* The manufacturer shall certify that each cargo tank motor vehicle has been designed, constructed, and tested in accordance with the applicable Specification DOT 406, DOT 407 or DOT 412 (§§ 178.345, 178.346, 178.347, 178.348) cargo tank requirements and, when applicable, with Section VIII of the ASME Code (IBR, see § 171.7 of this subchapter). The certification shall be accomplished by marking the cargo tank as prescribed in paragraphs (b) and (c) of this section, and by preparing the certificate prescribed in § 178.345–15. Metal plates prescribed by paragraphs (b), (c), (d), and (e) of this section must be permanently attached to the cargo tank or its integral supporting structure by brazing, welding, or other suitable means. These plates must be affixed on

the left side of the vehicle near the front of the cargo tank (or the front most cargo tank of a multi-cargo tank motor vehicle), in a place readily accessible for inspection. The plates must be permanently and plainly marked in English by stamping, embossing, or other means in characters at least 3/16 inch high. If the information required by this section is displayed on a name plate, the information need not be repeated on the specification plate. The information required by paragraphs (b) and (c) of this section may be combined on one plate.

(b) * * *
(3) Cargo tank MAWP in psig.

* * * * *

(c) * * *

(6) Maximum loading rate in gallons per minute (Max. Load rate, GPM). “NONE” may be used to indicate no limit.

(7) Maximum unloading rate in gallons per minute (Max. Unload rate). “OPEN MH” or “NONE” may be used to indicate no limit.

* * * * *

(d) *Multi-cargo tank motor vehicle.* For a multi-cargo tank motor vehicle having all its cargo tanks not separated by any void, the information required by paragraphs (b) and (c) of this section may be combined on one specification plate. When separated by a void, each cargo tank must have an individual name plate as required in paragraph (b) of this section, unless all cargo tanks are made by the same manufacturer using the same design type, as defined in § 178.320. The cargo tank motor vehicle may have a combined name plate and specification plate. When only one plate is used, the plate must be visible and not covered by insulation. The required information must be listed on the plate from front to rear in the order of the corresponding cargo tank location.

* * * * *

■ 83. In § 178.345–15, revise paragraphs (a), (b)(1), and (e) to read as follows:

§ 178.345–15 Certification.

(a) At or before the time of delivery, the cargo tank motor vehicle manufacturer must supply and the owner must obtain, a cargo tank’s ASME Form U–1A data report as required by Section VIII of the ASME Code (IBR, see § 171.7 of this subchapter), and a Certificate of Compliance stating that the completed cargo tank motor vehicle conforms in all respects to the DOT specification and the ASME Code. The registration numbers of the manufacturer, the Design Certifying Engineer, and the Registered Inspector, as appropriate, must appear on the

certificates (see subpart F, part 107 in subchapter A of this chapter).

(b) * * *

(1) For each design type, the Certificate of Compliance must be signed by an official of the manufacturer responsible for compliance and a Design Certifying Engineer; and

* * * * *

(e) *Specification shortages.* When a cargo tank motor vehicle is manufactured in two or more stages, the manufacturer of the cargo tank must attach the name plate and specification plate as required by §§ 178.345–14(b) and (c) without the original date of certification stamped on the specification plate. Prior manufacturers must list the specification requirements that are not completed on the Certificate of Compliance. When the cargo tank motor vehicle is brought into full compliance with the applicable specification, the Registered Inspector shall stamp the date of certification on the specification plate and issue a Certificate of Compliance to the owner of the cargo tank motor vehicle. The Certificate of Compliance must list the actions taken to bring the cargo tank motor vehicle into compliance. In addition, the certificate must include the date of compliance and person (manufacturer, carrier, or repair organization) accomplishing compliance.

■ 84. In § 178.348–1, revise paragraphs (d) and (e) to read as follows:

§ 178.348–1 General requirements.

* * * * *

(d) A cargo tank motor vehicle built to this specification with a MAWP greater than 15 psig must be constructed and certified in accordance with Section VIII of the ASME Code (IBR, see § 171.7 of this subchapter).

(e) A cargo tank motor vehicle built to this specification with a MAWP of 15 psig or less must be constructed in accordance with Section VIII of the ASME Code except as modified herein: (1) The recordkeeping requirements contained in Section VIII of the ASME Code do not apply. Parts UG–90 through 94 in Section VIII do not apply. Inspection and certification must be made by an inspector registered in accordance with subpart F of part 107.

(2) Loadings must be as prescribed in § 178.345–3 of this part.

(3) The knuckle radius of flanged heads must be at least three times the material thickness, and in no case less than 0.5 inch. Stuffed (inserted) heads may be attached to the shell by a fillet weld. The knuckle radius and dish radius versus diameter limitations of UG–32 do not apply for cargo tank

motor vehicles with a MAWP of 15 psig or less. Shell sections of cargo tanks designed with a non-circular cross section need not be given a preliminary curvature, as prescribed in UG-79(b).

(4) Marking, certification, data reports, and name plates must be as prescribed in §§ 178.345-14 and 178.345-15.

(5) Manhole closure assemblies must conform to § 178.345-5.

(6) Pressure relief devices must be as prescribed in § 178.348-4.

(7) The hydrostatic or pneumatic test must be as prescribed in § 178.348-5.

(8) The following paragraphs in parts UG and UW in Section VIII of the ASME Code do not apply: UG-11, UG-12, UG-22(g), UG-32(e), UG-34, UG-35, UG-44, UG-76, UG-77, UG-80, UG-81, UG-96, UG-97, UW-13(b)(2), UW-13.1(f), and the dimensional requirements found in Figure UW-13.1.

PART 179—SPECIFICATIONS FOR TANK CARS

■ 85. The authority citation for part 179 continues to read as follows:

Authority: 49 U.S.C. 5101-5128; 49 CFR 1.81 and 1.97.

■ 86. In § 179.2:

■ a. Revise paragraphs (a) introductory text, and (a)(2);

■ b. Add paragraphs (a)(4) and (a)(9); and

■ c. Revise paragraph (a)(10).

The revisions and addition read as follows:

§ 179.2 Definitions and abbreviations.

(a) In addition to the definitions in §§ 171.8 and 180.503 of this subchapter, the following definitions apply to part 179:

* * * * *

(2) *Approved* means approval by a Design Certifying Engineer registered in accordance with part 107, subpart J.

* * * * *

(4) *Component* means service equipment, safety systems, linings or coatings, other elements specifically required by this part, and any elements used to achieve a performance standard in this part.

* * * * *

(9) *Tank car* means a tank car tank and all of its components.

(10) *Tank car facility* means an entity that qualifies a tank car to ensure its conformance to part 179 or part 180 of this subchapter. A tank car facility must register with PHMSA in accordance with part 107, subpart J, of this chapter.

* * * * *

■ 87. Revise § 179.3 to read as follows:

§ 179.3 Design Approval.

(a) *General.* A Design Certifying Engineer registered in accordance with part 107, subpart J, must approve the following as conforming with the specifications in this part:

(1) Tank car designs, materials and construction, and modifications; and

(2) Service equipment designs, materials and construction, and modifications.

(b) *Procedure.* The Design Certifying Engineer must develop, maintain, and adhere to a written procedure that describes the process used to verify conformance with this subchapter. This procedure must be provided to a representative of the Department upon request. The procedure must include acceptance and rejection criteria for each element approved by the Design Certifying Engineer.

(c) *Approval.* When the Design Certifying Engineer determines such tank cars or service equipment are in compliance with the requirements of this subchapter, the Design Certifying Engineer will approve the design, material and construction, or modification.

(d) *Documentation.* Upon approval of the design, material and construction, or modification, the Design Certifying Engineer shall generate and provide to the tank car or service equipment owner a Design Approval Certificate (see § 179.5). A Design Approval Certificate certifies that the tank car or service equipment fully conforms to all requirements of the specification.

(1) A Design Approval Certificate covers all tank cars or service equipment built to an approved design, material and construction, or modification, provided the tank cars or service equipment are identical.

(2) When ownership of a tank car is transferred, the new owner must obtain the Design Approval Certificate from the previous owner or Design Certifying Engineer for the tank car to remain in service.

■ 88. Revise § 179.4 to read as follows:

§ 179.4 Changes in specifications for tank cars.

(a) Proposed changes in or additions to specifications for tanks must be submitted to a Design Certifying Engineer for review. Construction should not be started until the specification has been approved and a special permit has been issued. When proposing a new specification, the applicant shall furnish information to the Design Certifying Engineer to justify a new specification. This data should include the properties of the lading and the method of loading and unloading.

(b) The Design Certifying Engineer will review the proposed specifications at its earliest convenience and report its recommendations on the approval or disapproval of the specification to the designer of the new tank car specification. The recommendation will be considered by the Department in determining appropriate action.

■ 89. Revise § 179.5 to read as follows:

§ 179.5 Design Approval Certificate.

(a) *General.* Before a tank car is placed in service, the Design Certifying Engineer shall provide a Design Approval Certificate to the tank car or service equipment owner certifying that the tank or service equipment fully conforms to all requirements of the specification.

(b) *Tank car information.* The Design Approval Certificate for tank cars must include the following information, as applicable:

(1) Name, registration number, phone number, and mailing address of Design Certifying Engineer;

(2) Approval date;

(3) Tank specification;

(4) Tank car specification;

(5) Reporting marks and numbers;

(6) Commodity;

(7) Commodity density (lbs. per Gallon);

(8) Full water capacity (Gallons);

(9) Outage (Gallons);

(10) Tank head;

(i) Material type and grade heads;

(ii) Head material normalized

(Indicate Yes/No);

(iii) Tank head spliced (Indicate Yes/No);

(iv) Head Charpy test value;

(v) Material thickness heads (Inches);

and

(vi) Head radius, main (Inches if not 2:1).

(11) Tank shell;

(i) Material type and grade shell;

(ii) Tank shell material normalized

(Indicate Yes/No);

(iii) Shell Charpy test value;

(iv) Material thickness shell (Inches);

(v) Inside diameter—center (Inches);

and

(vi) Inside diameter—end rings

(Inches).

(12) Coating/lining type and

thickness;

(13) Tank test pressure (PSI);

(14) Insulation material;

(i) Insulation type;

(ii) Insulation thickness (Inches); and

(iii) Thermal conductivity (BTU—in/

hr.—ft sq.—degree F).

(15) Thermal protection;

(i) Thermal protection material type;

(ii) Thermal protection material

thickness (Inches);

(iii) Thermal protection material conductivity (BTU—in/hr.—ft sq.—degree F);

(iv) Jacket thickness; and

(v) Meets § 179.18 thermal protection standard (Indicate Yes/No).

(16) Safety relief devices;

(i) Type of safety relief device;

(ii) Number of safety relief devices;

(iii) Pressure relief device start-to-discharge (PSI);

(iv) Pressure relief device flow capacity (CFM Required); and

(v) Pressure relief device flow capacity (CFM Actual).

(17) Protective systems;

(i) Meets bottom fitting protection standard (Indicate Yes/No);

(ii) Meets top fittings protection standard (Indicate Yes/No); and

(iii) Meets tank head puncture resistance standard (Indicate Yes/No);

(A) Head shield thickness (Inches); and

(B) Head shield material type.

(18) Underframe or stub sill type; and

(19) Weight;

(i) Center of gravity loaded (Inches);

(ii) Estimated light weight (lbs.);

(iii) Rail load limit (lbs.); and

(iv) Truck capacity (Tons).

(20) *Signed Certification Statement.* A certification shall not be considered valid without a signature and certifying statement by a registered Design Certifying Engineer. The following statement may be used for tank car certifications:

“I, _____ [insert Design Certifying Engineer name], have reviewed the above design(s) for a DOT _____ [insert DOT specification] tank car(s) and certify compliance in all respects with the specification requirements found in 49 CFR part 179.

_____ [Design Certifying Engineer Signature]”

(c) *Tank Car Drawings.* The Design Approval Certificate must include the following detailed design drawings for tank cars:

(1) General arrangement;

(2) Tank arrangement;

(3) Reinforced openings, including calculations;

(4) Anchorage, including calculations;

(5) Fittings arrangement;

(6) Manway assembly;

(7) Manway cover;

(8) Protective housing;

(9) Venting, loading, and discharge valves;

(10) Pressure relief devices;

(11) Heater systems;

(12) Gauging devices;

(13) Bottom outlet valve;

(14) Design calculations;

(15) Gasket drawing; and

(16) Tank qualification drawing.

(d) *Service Equipment Information.* The Design Approval Certificate must include the following information for service equipment, as applicable:

(1) Description of device;

(i) Manufacturer;

(ii) Model; and

(iii) Design revision date.

(2) Approval date;

(3) Commodity;

(4) Construction;

(i) Material of construction;

(ii) Construction method; and

(iii) Seal material.

(5) Design operating temperature;

(6) Operating pressure range at design temperature (PSI); and

(7) *Signed Certification Statement.* A certification shall not be considered valid without a signature and certifying statement by a registered Design Certifying Engineer. The following statement may be used for service equipment certifications:

“I, _____ [insert Design Certifying Engineer name], have reviewed the above design for _____ [insert service equipment make and model] and it complies in all respects with the requirements found in 49 CFR part 179. _____ [Design Certifying Engineer Signature]”

(e) *Service Equipment Drawings.* The Design Approval Certificate must include the following detailed design drawings for service equipment:

(1) Dimensional drawing;

(2) Securement drawing; and

(3) Design calculations.

(f) *Service Equipment Validation.* The Design Approval Certificate must include the following service equipment validation reports:

(1) Life cycle testing results;

(2) Failure modes and effects analysis; and

(3) Other applicable laboratory testing results.

■ 90. Revise § 179.6 to read as follows:

§ 179.6 Repairs and alterations.

For procedures to make repairs or alterations, see Appendix R of the AAR Specifications for Tank Cars (IBR, see § 171.7 of this subchapter). Compliance with paragraphs 1.1; 1.2; 3.2; 3.3; 3.4; and 5.5 is not required. For all repairs not specifically described in Appendix R of the AAR Specifications for Tank Cars, approval by a Design Certifying Engineer is required.

■ 91. In § 179.7, revise paragraph (a) introductory text, (a)(2), (b) introductory text, (b)(3) through (5), (b)(8), (d) and (f) to read as follows:

§ 179.7 Quality assurance program.

(a) A tank car facility must register with PHMSA in accordance with part

107, subpart J, of this chapter. At a minimum, each tank car facility shall have a quality assurance program that—

* * * * *

(2) Has the means to detect any nonconformity in the manufacturing, inspection, testing, qualification, or maintenance of the tank car; and

* * * * *

(b) At a minimum, the quality assurance program must have the following elements:

* * * * *

(3) Procedures to ensure that the latest applicable drawings, design calculations, specifications, and instructions are used in manufacture, inspection, testing, qualification and maintenance.

(4) Procedures to ensure that all materials and components used in the fabrication and construction of a tank car are properly identified and documented, and meet applicable design requirements.

(5) A description of the manufacturing, inspection, testing, and qualification and maintenance program, including the acceptance criteria, so that an inspector can identify the characteristics of the tank car and the elements to inspect, examine, and test at each point.

* * * * *

(8) Provisions indicating that the applicable requirements of the AAR Specifications for Tank Cars (IBR, see § 171.7 of this subchapter), apply.

* * * * *

(d) Each tank car facility shall provide written procedures to its employees to ensure that the work on the tank car conforms to the specification, approval, and owner's acceptance criteria.

* * * * *

(f) No tank car facility may manufacture, inspect, test, qualify, or maintain tank cars subject to requirements of this subchapter, unless it is operating in conformance with a quality assurance program and written procedures required by paragraphs (a) and (b) of this section, and maintains a valid tank car facility registration in accordance with part 107, subpart J, of this chapter.

■ 92. In § 179.10, add paragraph (b) to read as follows:

§ 179.10 Tank mounting.

* * * * *

(b) Tank mounting arrangements must meet the requirements of AAR Specifications for Tank Cars Chapter 6 (IBR, see § 171.7 of this subchapter).

■ 93. In § 179.11, revise paragraph (a) to read as follows:

§ 179.11 Welding certification.

(a) Welding procedures, welders, and fabricators must meet the requirements in AAR Specifications for Tank Cars Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

* * * * *

■ 94. In § 179.24:

- a. Revise paragraph (a)(2); and
■ b. Remove and reserve paragraph (a)(3)(i).

The revision reads as follows:

§ 179.24 Stamping.

(a) * * *

(2) Each plate must be stamped, embossed, or otherwise marked by an equally durable method in letters 3/16-inch high with the following information (parenthetical abbreviations may be used):

(i) Tank Manufacturer (Tank MFG): Full name of the car builder.

(ii) Tank Manufacturer's Serial Number (SERIAL NO): For the specific car.

(iii) [Reserved]

(iv) Tank Specification (SPECIFICATION).

(v) Tank Shell Material/Head Material (SHELL MATL/HEAD MATL): ASTM or AAR specification of the material used in the construction of the tank shell and heads. For Class DOT-113W, DOT-115W, AAR-204W, and AAR-206W, the materials used in the construction of the outer tank shell and heads must be listed. Only list the alloy (e.g., 5154) for aluminum tanks and the type (e.g., 304L or 316L) for stainless steel tanks.

(vi) Insulation Material (INSULATION MATL): Generic names of the first and second layer of any thermal protection/insulation material applied.

(vii) Insulation Thickness (INSULATION THICKNESS): In inches.

(viii) Underframe/Stub Sill Type (UF/SS DESIGN)

(ix) Date of Manufacture (DATE OF MFR): The month and year of tank manufacture. If the underframe has a different built date than the tank, show both dates.

* * * * *

■ 95. In § 179.100-9, revise paragraph (a) to read as follows:

§ 179.100-9 Welding.

(a) All joints shall be fusion-welded in compliance with the requirements of AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

* * * * *

■ 96. In § 179.100-10, revise paragraph (a) to read as follows:

§ 179.100-10 Postweld heat treatment.

(a) After welding is complete, steel tanks and all attachments welded thereto must be postweld heat treated as a unit in compliance with the requirements of AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

* * * * *

■ 97. In § 179.100-12, revise paragraph (c) to read as follows:

§ 179.100-12 Manway nozzle, cover and protective housing.

* * * * *

(c) Except as provided in § 179.103, protective housing of cast, forged, or fabricated approved materials must be bolted to manway cover with not less than 20, 3/4-inch studs. Alternatively, the protective housing may be bolted to a flange connected to the manway reinforcing pad with not less than 20, 3/4-inch studs. The shearing value of the bolts attaching protective housing to manway cover must not exceed 70 percent of the shearing value of bolts attaching manway cover to manway nozzle. Housing must have steel sidewalls not less than 3/4 inch in thickness and must be equipped with a metal cover not less than 1/4 inch in thickness that can be securely closed. Housing cover must have suitable stop to prevent cover striking loading and unloading connections, and be hinged on one side only with approved riveted pin or rod with nuts and cotters. Openings in wall of housing must be equipped with screw plugs or other closures.

■ 98. In § 179.100-18, revise paragraph (c) to read as follows:

§ 179.100-18 Tests of tanks.

* * * * *

(c) Caulking of welded joints to stop leaks developed during the foregoing test is prohibited. Repairs in welded joints shall be made as prescribed in AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

* * * * *

■ 99. In § 179.102-3, add paragraph (c) to read as follows:

§ 179.102-3 Materials poisonous by inhalation.

* * * * *

(c) For tank cars manufactured after [DATE OF EFFECTIVE DATE], tank car heads and shells must be Charpy impact tested in accordance with AAR Specifications for Tank Cars, Chapter 2, section 2.2.1.2 (IBR, see § 171.7 of this subchapter) and meet the requirements of section 2.2.1.2.

■ 100. In § 179.103-5, revise paragraph (b)(1) to read as follows:

§ 179.103-5 Bottom outlets.

* * * * *

(b) * * *

(1) The extreme projection of the bottom outlet equipment may not be more than allowed by Appendix E of the AAR Specifications for Tank Cars (IBR, see § 171.7 of this subchapter). All bottom outlet reducers and closures and their attachments shall be secured to the car by at least 3/8-inch chain, or its equivalent, except that bottom outlet closure plugs may be attached by 1/4-inch chain. When the bottom outlet closure is of the combination cap and valve type, the pipe connection to the valve shall be closed by a plug, cap, or approved quick coupling device. The bottom outlet equipment should include only the valve, reducers, and closures that are necessary for the attachment of unloading fixtures. The permanent attachment of supplementary exterior fittings must be approved.

* * * * *

■ 101. In § 179.200-7, amend the table in paragraph (b) by adding an entry for "ASTM A 537" to read as follows:

§ 179.200-7 Materials.

* * * * *

(b) * * *

Table with 3 columns: Specifications, Minimum tensile strength (p.s.i.) welded condition 1, Minimum elongation in 2 inches (percent) weld metal (longitudinal). Row 1: ASTM A 537, Class 1, 70,000, 23.

* * * * *

■ 102. In § 179.200–10, revise paragraph (a) to read as follows:

§ 179.200–10 Welding.

(a) All joints shall be fusion-welded in compliance with the requirements of AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

* * * * *

■ 103. Revise § 179.200–11 to read as follows:

§ 179.200–11 Postweld heat treatment.

When specified in § 179.201–1, after welding is complete, postweld heat treatment must be in compliance with the requirements of AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

■ 104. In § 179.200–17, revise paragraph (a)(1) to read as follows:

§ 179.200–17 Bottom outlets.

(a) * * *

(1) The extreme projection of the bottom outlet equipment may not be more than that allowed by Appendix E of the AAR Specifications for Tank Cars (IBR, see § 171.7 of this subchapter). All bottom outlet reducers and closures and their attachments shall be secured to the car by at least $\frac{3}{8}$ -inch chain, or its equivalent, except that the bottom outlet closure plugs may be attached by $\frac{1}{4}$ -inch chain. When the bottom outlet closure is of the combination cap and valve type, the pipe connection to the valve shall be closed by a plug, cap, or approved quick coupling device. The bottom outlet equipment should include only the valve, reducers, and closures that are necessary for the attachment of unloading fixtures. The permanent attachment of supplementary exterior fittings shall be approved.

* * * * *

■ 105. In § 179.200–22, revise paragraph (d) to read as follows:

§ 179.200–22 Test of tanks.

* * * * *

(d) Caulking of welded joints to stop leaks developed during the foregoing tests is prohibited. Repairs in welded joints shall be made as prescribed in AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

■ 106. In § 179.220–10, revise paragraph (a) to read as follows:

§ 179.220–10 Welding.

(a) All joints must be fusion welded in compliance with AAR Specifications

for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

* * * * *

■ 107. In § 179.220–11, revise paragraph (b) to read as follows:

§ 179.220–11 Postweld heat treatment.

* * * * *

(b) Postweld heat treatment of the cylindrical portions of the outer shell to which the anchorage or draft sills are attached must comply with AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

* * * * *

■ 108. In § 179.220–15, revise paragraph (b) to read as follows:

§ 179.220–15 Support system for inner container.

* * * * *

(b) The longitudinal acceleration may be reduced to 3G where a cushioning device, which has been tested to demonstrate its ability to limit body forces to 400,000 pounds maximum at a 10 miles per hour impact, is used between the coupler and the tank structure. The support system must be of approved design and the inner container must be thermally isolated from the outer shell to the best practical extent. The inner container and outer shell must be permanently bonded to each other electrically either by the support system used, piping, or a separate electrical connection of approved design.

■ 109. In § 179.220–18, revise paragraph (a)(1) to read as follows:

§ 179.220–18 Bottom outlets.

(a) * * *

(1) The extreme projection of the bottom outlet equipment may not be more than that allowed by Appendix E of the AAR Specifications for Tank Cars (IBR, see § 171.7 of this subchapter). All bottom outlet reducers and closures and their attachments shall be secured to car by at least $\frac{3}{8}$ -inch chain, or its equivalent, except that bottom outlet closure plugs may be attached by $\frac{1}{4}$ -inch chain. When the bottom outlet closure is of the combination cap and valve type, the pipe connection to the valve shall be closed by a plug or cap. The bottom outlet equipment should include only the valve, reducers, and closures that are necessary for the attachment of unloading fixtures. The permanent attachment of supplementary exterior fittings shall be approved.

* * * * *

■ 110. In § 179.300–9, revise paragraph (a) to read as follows:

§ 179.300–9 Welding.

(a) Longitudinal joints must be fusion welded. Head-to-shell joints must be forge welded on class DOT–106A tanks and fusion welded on class DOT–110A tanks. Welding procedures, welders, and fabricators must be in accordance with the requirements of AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

* * * * *

■ 111. Revise § 179.300–10 to read as follows:

§ 179.300–10 Postweld heat treatment.

After welding is complete, steel tanks and all attachments welded thereto, must be postweld heat treated as a unit in compliance with the requirements of AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

■ 112. In § 179.400–5, revise paragraph (d) to read as follows:

§ 179.400–5 Materials.

* * * * *

(d) Impact test values must be equal to or greater than those specified in AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter). The report of impact tests must include the test values and lateral expansion data.

■ 113. In § 179.400–6, revise paragraph (b) to read as follows:

§ 179.400–6 Bursting and buckling pressure.

* * * * *

(b) The outer jacket of the required evacuated insulation system must be designed in accordance with § 179.400–8(d) and in addition must comply with the design loads specified in Section C–II, Chapter 6 of the AAR Specifications for Freight Cars (IBR, see § 171.7 of this subchapter). The designs and calculations must provide for the loadings transferred to the outer jacket through the support system.

■ 114. In § 179.400–11, revise paragraph (c) to read as follows:

§ 179.400–11 Welding.

* * * * *

(c) Each joint must be welded in accordance with the requirements of AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

* * * * *

■ 115. In § 179.400–12, revise paragraph (b) introductory text to read as follows:

§ 179.400–12 Postweld heat treatment.

* * * * *

(b) The cylindrical portion of the outer jacket, with the exception of the circumferential closing seams, must be postweld heat treated as prescribed in AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter). Any item to be welded to this portion of the outer jacket must be attached before postweld heat treatment. Welds securing the following need not be postweld heat treated when it is not practical due to final assembly procedures:

* * * * *

■ 116. In § 179.400–13, revise paragraph (b) to read as follows:

§ 179.400–13 Support system for inner tank.

* * * * *

(b) The support system must be designed to support, without yielding, impact loads producing accelerations of the following magnitudes and directions when the inner tank is fully loaded and the car is equipped with a conventional draft gear:

Longitudinal	7“g”
Transverse	3“g”
Vertical	3“g”

The longitudinal acceleration may be reduced to 3“g” where a cushioning device, which has been tested to demonstrate its ability to limit body forces to 400,000 pounds maximum at 10 miles per hour, is used between the coupler and the tank structure.

* * * * *

■ 117. Revise § 179.400–15 to read as follows:

§ 179.400–15 Radioscopy.

Each longitudinal and circumferential joint of the inner tank, and each longitudinal and circumferential double welded butt joint of the outer jacket, must be examined along its entire length in accordance with the requirements of AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

■ 118. In § 179.400–18, revise paragraph (b) to read as follows:

§ 179.400–18 Test of inner tank.

* * * * *

(b) Caulking of welded joints to stop leaks developed during the test is prohibited. Repairs to welded joints must be made as prescribed in AAR Specifications for Tank Cars, Appendix W (compliance with paragraph 1.2 is not required) (IBR, see § 171.7 of this subchapter).

■ 119. In § 179.400–19, revise paragraph (a)(2) to read as follows:

§ 179.400–19 Valves and gages.

(a) * * *

(2) Packing, if used, must be satisfactory for use in contact with the lading and of materials that will effectively seal the valve stem without causing difficulty of operation.

* * * * *

■ 120. In § 179.500–17, revise paragraph (a)(4) to read as follows:

§ 179.500–17 Marking.

(a) * * *

(4) Name, mark (other than trademark), or initials of company or person for whose use the tank is being made.

* * * * *

■ 121. In § 179.500–18:

■ a. Revise paragraphs (a) and (b)(6); and

■ b. In the form in paragraph (c), revise the sentence under the heading “Steel Tanks”.

The revisions read as follows:

§ 179.500–18 Inspection and reports.

(a) Before a tank car is placed in service, the party assembling the completed car shall furnish to the car owner a report in proper form certifying that tanks and their equipment comply with all the requirements of this specification and including information as to serial numbers, dates of tests, and ownership marks on tanks mounted on car structure.

(b) * * *

(6) Inspector shall stamp his official mark on each accepted tank immediately below serial number, and make certified report (see paragraph (c) of this section) to builder, company, or person for whose use tanks are being made, and to builder of car structure on which tanks are to be mounted.

(c) * * *

Steel Tanks

It is hereby certified that drawings were approved for these tanks by a Design Certifying Engineer under date of ____.

* * * * *

■ 122. In Appendix B to part 179, revise paragraphs 1., 2.a.(1), 2.a.(2), 2.b.(6), 3.a.(1), 3.a.(2), and 3.b.(6) to read as follows:

Appendix B to Part 179—Procedures for Simulated Pool and Torch-Fire Testing

1. This test procedure is designed to measure the thermal effects of new or untried thermal protection systems, and to test for system survivability when exposed to a 100-

minute pool fire and a 30-minute torch fire. Each sample of the thermal resistance material used in the individual tests, performed under the requirement of this Appendix to test the performance of the thermal protection system, shall be identical (within errors of measurement) in thickness dimensions, and thermodynamic and physical properties, including mass density.

2. * * *

a. * * *

(1) The source of the simulated pool fire must be hydrocarbon fuel with a flame temperature of 871 °C plus or minus 55.6 °C (1600 °F plus-or-minus 100 °F), measured throughout the duration of the test at a distance of not more than 15 cm (6 inches) from the test sample surface along the axis of the fire. Calibration tests must be performed with the steel plate in position.

(2) A square bare plate with thermal properties equivalent to the material of construction of the tank car must be used. The plate dimensions must be not less than 30.5 cm by 30.5 cm (one foot by one foot) by nominal 1.6 cm (0.625 inch) thick. The bare plate must be instrumented with not less than nine thermocouples to record the thermal response of the bare plate. The thermocouples must be attached to the surface not exposed to the simulated pool fire, and must be divided into nine equal squares with a thermocouple placed in the center of each square.

* * * * *

b. * * *

(6) A minimum of three consecutive successful simulation fire tests, separate and conducted at different times, must be performed for each thermal protection system.

* * * * *

3. * * *

a. * * *

(1) The source of the simulated torch must be a hydrocarbon fuel with a flame temperature of 1,204 °C plus-or-minus 55.6 °C (2,200 °F plus or minus 100 °F), measured throughout the duration of the test at a distance of not more than 15 cm (6 inches) from the test sample surface, along the axis of the fire. Furthermore, torch velocities must be 64.4 km/h ±16 km/h (40 mph ±10 mph) throughout the duration of the test at a distance of not more than 15 cm (6 inches) from the test sample surface along the axis of the fire. Calibration tests must be performed with the steel plate in position.

(2) A square bare plate with thermal properties equivalent to the material of construction of the tank car must be used. The plate dimensions must be at least 122 cm by 122 cm (four feet by four feet) by nominal 1.6 cm (0.625 inch) thick. The bare plate must be instrumented with not less than nine thermocouples to record the thermal response of the plate. The thermocouples must be attached to the surface not exposed to the simulated torch, and must be divided into nine equal squares with a thermocouple placed in the center of each square.

* * * * *

b. * * *

(6) A minimum of two consecutive successful torch-simulation tests, separate

and conducted at different times, must be performed for each thermal protection system.

PART 180—CONTINUING QUALIFICATION AND MAINTENANCE OF PACKAGINGS

■ 123. The authority citation for part 180 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 124. In § 180.3:

- a. Revise paragraph (b)(3); and
- b. Add paragraphs (c) and (d).

The revision and additions read as follows:

§ 180.3 General requirements.

* * * * *

(b) * * *

(3) Test dates displayed in association with specification, registration, approval, exemption, or special permit markings indicating conformance to a test or retest requirement of this subchapter, an approval issued thereunder, or a special permit issued under subchapter A of this chapter;

* * * * *

(c) No person shall mark or issue a report indicating that a packaging has passed a test or inspection under this subpart, unless the packaging has actually been tested or inspected as required by this subpart.

(d) No person shall falsify a document or marking indicating a packaging as having passed a test or inspection under this subpart.

■ 125. In § 180.403:

- a. Add definitions for “certification plate”, “maintenance”, “objectively reasonable and articulable belief”, and “set pressure” in alphabetical order; and
- b. Revise the definition of “repair”.

The revision and additions read as follows:

§ 180.403 Definitions.

* * * * *

Certification plate means a data plate containing the applicable markings provided in the original specifications for cargo tanks no longer authorized for construction (as identified in § 180.405(c)), and permanently attached to the cargo tank or integral supporting structure by the manufacturer. The markings on this plate are the certification by the manufacturer that the cargo tank or the cargo tank motor vehicle has been designed, constructed, and tested in accordance with the applicable specification.

* * * * *

Maintenance means replacement of components other than welding on the

cargo tank wall, on specification cargo tanks or cargo tank motor vehicles.

* * * * *

Objectively reasonable and articulable belief means a belief based on particularized and identifiable facts that provide an objective basis to believe or suspect that a cargo tank or series of cargo tanks may be in an unsafe operating condition.

* * * * *

Repair means any welding on a cargo tank wall, including replacing 50 percent or less of the combined shell and head material of a cargo tank, done to return a cargo tank or a cargo tank motor vehicle to its original design and construction specification, or to a condition prescribed for a later equivalent specification in effect at the time of the repair. Excluded from this category are the following:

(1) A change to motor vehicle equipment such as lights, truck or tractor power train components, steering and brake systems, and suspension parts, and changes to appurtenances, such as fender attachments, lighting brackets, and ladder brackets;

(2) Replacement of components such as valves, vents, and fittings with a component of a similar design and of the same size; and

(3) Replacement of an appurtenance by welding to a mounting pad.

* * * * *

Set pressure means the pressure of the pressure relief device or system at which it starts to open, allowing discharge.

* * * * *

■ 126. In § 180.405:

- a. Add paragraphs (b)(3);
- b. Revise paragraphs (c)(2);
- c. Add paragraphs (c)(3) and (4);
- d. Revise paragraphs (h)(3), and (j); and
- e. Add paragraph (p).

The revisions and additions read as follows:

§ 180.405 Qualification of cargo tanks.

* * * * *

(b) * * *

(3) *Replacement of missing specification plates.* (i) The replacement of cargo tank and cargo tank motor vehicle specification plates required by this subchapter may be performed by the original manufacturer, or by a Registered Inspector who has been given necessary information by the original cargo tank or cargo tank motor vehicle manufacturer, provided the cargo tank motor vehicle owner has the paperwork documenting the traceability of the specification of the cargo tank or cargo tank motor vehicle.

(ii) If the original manufacturer has been purchased by another entity, and that entity has sufficient paperwork documenting the manufacture of that cargo tank or cargo tank motor vehicle, the entity may apply a replacement specification plate or provide instructions to a Registered Inspector to apply the replacement specification plate.

(iii) If the original manufacturer is no longer in business, or the paperwork documenting the traceability of the specification of the cargo tank or cargo tank motor vehicle is not available, the cargo tank or cargo tank motor vehicle is no longer an authorized specification packaging for hazardous materials transportation. See § 180.405(j).

(iv) The cargo tank motor vehicle owner shall retain, and make available to a representative of the Department upon request, all documentation proving the traceability of the cargo tank manufacturer or cargo tank motor vehicle manufacturer, as applicable, until the cargo tank or cargo tank motor vehicle is permanently rendered no longer capable of retaining lading, and for one year thereafter.

(c) * * *

(2) A cargo tank motor vehicle of a specification listed in paragraph (c)(1) of this section may have its pressure relief devices and outlets modified in accordance with paragraph (h) of this section and § 173.33(d) of this subchapter.

(3) A cargo tank motor vehicle manufactured and certified prior to the dates listed in table 1 or table 2 of this section may be mounted on a different truck chassis provided the mounting and certification is performed in accordance with this subchapter.

* * * * *

(h) * * *

(3) As provided in paragraph (c)(2) of this section, and in § 173.33(d) of this subchapter, the owner of a cargo tank motor vehicle may elect to modify reclosing pressure relief devices to more current cargo tank specifications. However, replacement devices constructed to the requirements of § 178.345–10 of this subchapter must provide the minimum venting capacity required by the original specification to which the cargo tank was designed and constructed.

* * * * *

(j) *Withdrawal of certification.* A specification cargo tank that for any reason no longer meets the applicable specification may not be used to transport hazardous materials unless the cargo tank is repaired and retested in accordance with §§ 180.407 and 180.413

prior to being returned to hazardous materials service. If the cargo tank motor vehicle is not in conformance with the applicable specification requirements, the specification plate must be removed, obliterated, or securely covered. The method of covering must withstand conditions normally incident to transportation. The details of the conditions necessitating withdrawal of the certification must be recorded and signed on the Certificate of Compliance for that cargo tank. The vehicle owner shall retain the Certificate of Compliance for at least one year after withdrawal of the certification.

* * * * *

(p) *Visual Inspection of Remote Device.* At the next external visual inspection after [DATE OF EFFECTIVE DATE], each specification cargo tank motor vehicle equipped with a mechanical means of remote closure shall be inspected to ensure that access or means of manual operation is not obstructed by equipment or appurtenances. The remote closure device may not be in the driver's cab and must be as far forward on the cargo tank as practicable. Any manually operated remote closure device not in compliance with this paragraph must be repaired prior to passing the external visual inspection.

■ 127. In § 180.407, revise paragraphs (a), (b)(1), (b)(3), (b)(5), (c) introductory text, (d), (f) introductory text, (f)(2), (f)(3), (g)(1)(ii), (g)(1)(iii), (g)(1)(viii), (g)(3), (g)(6), (h), (i)(4)(v), (i)(6)(i) and (i)(6)(ii) to read as follows:

§ 180.407 Requirements for test and inspection of specification cargo tanks.

(a) *General.* (1) A cargo tank motor vehicle constructed in accordance with a DOT specification or otherwise required by this subchapter to comply with this subpart, for which a test or inspection specified in this section has become due, may not be filled and offered for transportation or transported until the test or inspection has been successfully completed. This paragraph does not apply to any cargo tank filled prior to the test or inspection due date and offered for transportation or transported after the test or inspection due date (see § 173.33(a)(3) of this subchapter).

(2) Except during a pressure test, a cargo tank may not be subjected to a pressure greater than the design pressure or MAWP marked on the name plate or certification plate.

(3) A person witnessing or performing a test or inspection specified in this section must meet the minimum qualifications prescribed in § 180.409.

(4) Each cargo tank must be evaluated in accordance with the acceptable results of tests and inspections prescribed in § 180.411.

(5) Each cargo tank motor vehicle that has successfully passed a test or inspection specified in this section must be marked in accordance with § 180.415.

(6) A cargo tank motor vehicle that has not been properly inspected or fails a prescribed test or inspection must:

- (i) Be repaired and retested in accordance with § 180.413; or
- (ii) Be removed from hazardous materials service and the specification plate removed, obliterated, or covered in a secure manner. The method of covering must at a minimum withstand conditions normally incident to transportation.

(7) All equipment and instruments required to be used to perform a function under part 180 subpart E must be calibrated in accordance with the manufacturer's instructions. The facility must retain records documenting the type of calibration, date calibrated, and who performed the calibration. The facility must retain a copy of documentation of the two most recent calibrations, which must be made available to a representative of the Department upon request.

(8) The use of video cameras or fiber optics equipment is authorized for any test or inspection, or portion thereof, provided all the required areas and elements can be viewed and evaluated according to this part 180 subpart E. The use of such equipment shall be documented on the report required by § 180.417.

(9) For any test or inspection that requires a cargo tank motor vehicle to be tested at a pressure greater than 50 psig, the hydrostatic method shall be used, except for MC 338 cargo tanks used to transport cryogenic liquids. In all pressure and leakage tests, suitable safeguards must be provided to protect personnel should a system failure occur.

(10) The Registered Inspector shall consult with the owner or motor carrier, as appropriate, to determine if materials corrosive or reactive to the cargo tank or its components were transported in the cargo tank motor vehicle since the last test or inspection was performed. The Registered Inspector shall indicate whether the cargo tank motor vehicle transported a material corrosive or reactive to the cargo tank or its components on the § 180.415 report, and use this information to determine the proper tests and inspections to be conducted on the cargo tank motor vehicle.

(11) For all tests or inspections subject to this subpart, all sources of spark, flame, or glowing heat within the area of enclosure (including any heating system drawing air therefrom) are extinguished, made inoperable, or rendered explosion-proof by a suitable method prior to the tests or inspections being performed.

(b) * * *

(1) The cargo tank shows evidence of dents, cuts, gouges, bulges, corroded or abraded areas, leakage, or any other condition that might render it unsafe for hazardous materials service. At a minimum, any area of a cargo tank showing evidence of dents, cuts, digs, gouges, bulges, or corroded or abraded areas must be thickness tested in accordance with the procedures set forth in paragraphs (i)(2), (i)(3), (i)(5), (i)(6), (i)(9), and (i)(10) of this section; and evaluated in accordance with the criteria prescribed and minimum thickness definition in §§ 178.320 and 180.411 of this subchapter, respectively. Any signs of leakage must be repaired. All repairs must be performed in accordance with § 180.413. The suitability of any repair affecting the structural integrity of the cargo tank must be determined either by the testing required in the applicable manufacturing specification or in paragraph (g)(1)(iv) of this section.

* * * * *

(3) The cargo tank motor vehicle has been out of hazardous materials transportation service for a period of one year or more. For each cargo tank motor vehicle that has been out of hazardous materials transportation service for a period of one year or more, a pressure test in accordance with § 180.407(g) must be conducted prior to further use in hazardous materials transportation.

* * * * *

(5) The Department so requires based on the objectively reasonable and articulable belief that the cargo tank is in an unsafe operating condition.

(c) *Periodic test and inspection.* Each cargo tank motor vehicle subject to this subpart must be tested and inspected as specified in the following table by a Registered Inspector meeting the qualifications in § 180.409. The retest date shall be determined from the specified interval identified in the following table from the most recent inspection completed in accordance with the requirements in part 180 or the cargo tank motor vehicle certification date.

* * * * *

(d) *External visual inspection and testing.* The following applies to the

external visual inspection and testing of cargo tanks:

(1) Where insulation, or coverings such as wrappings and coatings, precludes a complete external visual inspection as required by paragraphs (d)(2) through (d)(6) of this section, the cargo tank also must be given an internal visual inspection in accordance with paragraph (e) of this section. If external visual inspection is precluded because any part of the cargo tank wall is externally lined, coated, or designed to prevent an external visual inspection, those areas of the cargo tank must be internally inspected. If internal visual inspection is precluded because the cargo tank is lined, coated, or designed so as to prevent access for internal inspection, the tank must be hydrostatically or pneumatically tested in accordance with paragraph (g)(1)(iv) of this section. Those items able to be externally inspected must be externally inspected and noted in the inspection report.

(2) The external visual inspection and testing must include as a minimum the following:

(i) The tank shell and heads must be inspected for corroded or abraded areas, dents, distortions, and defects in welds, and evaluated in accordance with § 180.411. During the inspection of the cargo tank shell and heads, all pad attachments on either the cargo tank shell or head shall be inspected for method of attachments and any other conditions that might render the appurtenance as unsafe;

(ii) The piping system, which includes piping, flexible connectors, valves, and gaskets, must be carefully inspected for corroded areas, defects in welds, and other conditions, including leakage, that might render the tank unsafe for transportation service;

(iii) All devices for tightening manhole covers must be operative and there must be no evidence of leakage at manhole covers or gaskets;

(iv) All emergency devices and valves, including self-closing stop valves, excess flow valves, and remote closure devices, including all emergency discharge control systems and delivery hoses required by § 173.315(n), must be inspected for corrosion, distortion, erosion, and any external damage that will prevent safe operation. All emergency closure devices and self-closing stop valves must be operated to demonstrate proper functioning. The distance for testing non-mechanical remote shutoff devices must be in accordance with the original device manufacturer's specification;

(v) Missing bolts, nuts and fusible links or elements must be replaced, and loose bolts and nuts must be tightened;

(vi) All markings on the cargo tank required by parts 172, 178, and 180 of this subchapter must be legible;

(vii) [Reserved]

(viii) All appurtenances and structural attachments on the cargo tank including, but not limited to, suspension system attachments, connecting structures, and those elements of the upper coupler (including the king pin) assembly that can be inspected without dismantling the upper coupler assembly must be inspected for any corrosion or damage that might prevent safe operation;

(ix) For cargo tank motor vehicles transporting lading corrosive to the cargo tank, areas covered by the upper coupler assembly must be inspected at least once in each two-year period for corroded and abraded areas, dents, distortions, defects in welds, and any other condition that might render the tank unsafe for transportation service. The upper coupler assembly must be removed from the cargo tank for this inspection except when the upper coupler allows for a complete inspection of the area of the cargo tank that is directly above the upper coupler, and the inspection is conducted by directly viewing the cargo tank. Directly viewing means the area is inspected without the use of an aid, such as mirrors, cameras, or fiber optics. If the upper coupler is removed from the cargo tank motor vehicle, it must be reattached in accordance with the manufacturer's instructions and § 393.70.

(3) For reclosing pressure relief devices, the following applies:

(i) All reclosing pressure relief devices must be externally inspected for any corrosion or damage that might prevent safe operation.

(ii) All reclosing pressure relief devices on cargo tank motor vehicles carrying lading corrosive to the pressure relief device must be removed from the cargo tank motor vehicle for inspection and bench testing in accordance with paragraph (j) of this section.

(4) Ring stiffeners or appurtenances, installed on cargo tank motor vehicles constructed of mild steel or high-strength, low-alloy steel, that create air cavities adjacent to the tank shell that do not allow for external visual inspection must be thickness tested in accordance with paragraphs (i)(2) and (i)(3) of this section, at least once every two years. At least four symmetrically distributed readings must be taken to establish an average thickness for the ring stiffener or appurtenance. If any

thickness reading is less than the average thickness by more than 10 percent, thickness testing in accordance with paragraphs (i)(2) and (i)(3) of this section must be conducted from the inside of the cargo tank on the area of the tank wall covered by the ring stiffener or appurtenance.

(5) Corroded or abraded areas of the cargo tank wall must be thickness tested in accordance with the procedures set forth in paragraphs (i)(2), (i)(3), (i)(5), (i)(6), (i)(9), and (i)(10) of this section.

(6) The gaskets on any full opening rear head must be:

(i) Visually inspected for cracks or splits caused by weather or wear; and

(ii) Replaced if cuts or cracks that are likely to cause leakage, or are of a depth $\frac{1}{2}$ inch or more, are found.

(7) External ring stiffeners installed on cargo tank motor vehicles must be inspected for corrosion, pitting, abraded areas, or damage, and repaired as appropriate.

(8) Welded repairs on the cargo tank wall must be inspected for leakage and weld defects. The Registered Inspector must verify that the welded repair was done in accordance with § 180.413.

(9) The inspector must record the results of the external visual examination as specified in § 180.417(b).

* * * * *

(f) *Lining inspection.* When lining is required by this subchapter, the integrity of the cargo tank lining must be verified at least once each year as follows:

* * * * *

(2) For linings made of materials other than rubber (elastomeric material), the owner of the cargo tank motor vehicle must obtain documentation from the lining manufacturer or installer that specifies the proper procedure for the lining inspection. This documentation must be provided to the Registered Inspector before inspection.

(3) Degraded or defective areas of the cargo tank lining must be removed and the cargo tank wall below the defect must be inspected. Corroded areas of the tank wall must be thickness tested in accordance with paragraphs (i)(2), (i)(3), (i)(5), (i)(6), (i)(9), and (i)(10) of this section. If the degraded or defective areas of the cargo tank lining are repaired or if the lining is replaced, it must comply with lining manufacturer or installer procedures, subject to the lining requirements of this subchapter.

* * * * *

(g) * * *

(1) * * *

(ii) All self-closing pressure relief devices, including emergency relief

devices and normal vent devices, must be removed from the cargo tank motor vehicle for inspection and bench testing in accordance with paragraph (j) of this section.

(iii) Except for cargo tank motor vehicles carrying lading corrosive to the cargo tank, areas covered by the upper coupler assembly must be inspected for corroded and abraded areas, dents, distortions, defects in welds, and any other condition that might render the tank unsafe for transportation service. The upper coupler assembly must be removed from the cargo tank for this inspection except when the upper coupler allows for a complete inspection of the area of the cargo tank that is directly above the upper coupler, and the inspection is conducted by directly viewing the cargo tank. Directly viewing means the area is inspected without the use of an aid, such as mirrors, cameras, or fiber optics. If the upper coupler is removed from the cargo tank, it must be reattached in accordance with the manufacturer's instructions and § 393.70.

* * * * *

(viii) *Hydrostatic test method.* Each cargo tank must be filled with water or other liquid having similar viscosity, at a temperature not exceeding 100 °F. The cargo tank must then be pressurized as specified in paragraph (g)(1)(iv) of this section. The cargo tank, including its closures, must hold the prescribed test pressure for at least 10 minutes during which time it shall be inspected for leakage, bulging or any other defect.

* * * * *

(3) Each MC 330 and MC 331 cargo tank constructed of quenched and tempered steel in accordance with Part UHT in Section VIII of the ASME Code (IBR, see § 171.7 of this subchapter), or constructed of other than quenched and tempered steel but without postweld heat treatment, and used for the transportation of anhydrous ammonia or any other hazardous materials that may cause corrosion stress cracking, must be internally inspected by the wet fluorescent magnetic particle method immediately prior to and in conjunction with the performance of the pressure test prescribed in this section. Each MC 330 and MC 331 cargo tank constructed of quenched and tempered steel in accordance with Part UHT in Section VIII of the ASME Code and used for the transportation of liquefied petroleum gas must be internally inspected by the wet fluorescent magnetic particle method immediately prior to and in conjunction with the performance of the pressure test prescribed in this section. The wet fluorescent magnetic particle

inspection must be in accordance with Section V of the ASME Code and CGA Technical Bulletin P-26 (formerly TB-2) (IBR, see § 171.7 of this subchapter). This paragraph does not apply to cargo tanks that do not have manholes. (See § 180.417(c) for reporting requirements.)

* * * * *

(6) *Acceptance criteria.* A cargo tank motor vehicle that leaks, fails to retain test pressure, shows distortion, or displays other evidence of weakness that might render the cargo tank motor vehicle unsafe for transportation service may not be returned to service, except as follows: A cargo tank motor vehicle with a heating system that does not hold pressure may remain in service as an unheated cargo tank motor vehicle if:

* * * * *

(h) *Leakage test.* The following requirements apply to cargo tanks requiring a leakage test:

(1) Each cargo tank must be tested for leaks in accordance with paragraph (c) of this section. The leakage test must include all components of the cargo tank wall, and the piping system with all valves and pressure relief devices in place and operative, except that any pressure relief devices set to discharge at less than the leakage test pressure must be removed or rendered inoperative during the test. All internal or external self-closing stop valves must be tested for leak tightness. Each cargo tank of a multi-cargo tank motor vehicle must be tested with adjacent cargo tanks empty and at atmospheric pressure. Test pressure must be maintained for at least five minutes. Cargo tanks in liquefied compressed gas service must be externally inspected for leaks during the leakage test. Suitable safeguards must be provided to protect personnel should a failure occur. Cargo tanks may be leakage tested with hazardous materials contained in the cargo tank during the test. Leakage test pressure must be no less than 80 percent of MAWP marked on the specification plate except as follows:

(i) A cargo tank motor vehicle with an MAWP of 690 kPa (100 psig) or more may be leakage tested at its maximum normal operating pressure provided it is in dedicated service or services.

(ii) A specification MC 330 or MC 331 cargo tank motor vehicle or a non-specification cargo tank motor vehicle authorized under § 173.315(k) of this subchapter in dedicated liquefied petroleum gas service may be leakage tested at not less than 414 kPa (60 psig).

(iii) An operator of a specification MC 330 or MC 331 cargo tank motor vehicle, or a non-specification cargo tank authorized under § 173.315(k) of this

subchapter, equipped with a meter may check leak tightness of the internal self-closing stop valve by conducting a meter creep test. (See Appendix B to this part.)

(iv) A specification MC 330 or MC 331 cargo tank motor vehicle in dedicated service for anhydrous ammonia may be leakage tested at not less than 414 kPa (60 psig).

(v) A non-specification cargo tank required by § 173.8(d) of this subchapter to be leakage tested must be leakage tested at not less than 16.6 kPa (2.4 psig), or as specified in paragraph (h)(2) of this section.

(2) Cargo tank motor vehicles used to transport petroleum distillate fuels that are equipped with vapor collection equipment may be leak tested in accordance with the Environmental Protection Agency's "Method 27—Determination of Vapor Tightness of Gasoline Delivery Tank Using Pressure-Vacuum Test," as set forth in Appendix A to 40 CFR part 60. Test methods and procedures, and maximum allowable pressure and vacuum changes, are in 40 CFR 63.425(e). The hydrostatic test alternative, using liquid in Environmental Protection Agency's "Method 27—Determination of Vapor Tightness of Gasoline Delivery Tank Using Pressure-Vacuum Test," may not be used to satisfy the leak testing requirements of this paragraph. The test must be conducted using air.

(3) A cargo tank motor vehicle that has leaks or fails to retain leakage test pressure may not be returned to service until repaired as required by this subpart.

(4) Registered Inspectors conducting a leakage test on specification MC 330 and MC 331 cargo tank motor vehicles, and non-specification cargo tank motor vehicles authorized under § 173.315(k) of this subchapter, must visually inspect the delivery hose assembly and piping system, including any delivery hose assembly used to meet § 173.315(n), while the assembly is under leakage test pressure utilizing the rejection criteria listed in § 180.416(g). The test pressure of the delivery hose assembly must be at least 80 percent of the MAWP of the cargo tank. Delivery hose assemblies not permanently attached to the cargo tank motor vehicle may be inspected and tested while not attached to the cargo tank motor vehicle. In addition to a written record of the inspection prepared in accordance with § 180.417(b), the Registered Inspector conducting the test must note the hose identification number, the date of the test, and the condition of the hose assembly and piping system tested.

(5) The inspector must record the results of the leakage test as specified in § 180.417(b).

(i) * * *

(4) * * *

(v) Areas around shell reinforcements including around all ring stiffeners and those areas in the bottom half of the cargo tank;

* * * * *

(6) * * *

(i) A Design Certifying Engineer must certify that the cargo tank design and thickness are appropriate for the reduced loading conditions by issuance of a revised manufacturer's certificate. The DCE must provide this revised certificate to the cargo tank motor vehicle owner, and

(ii) The cargo tank motor vehicle's name plate or certification plate must reflect the revised service limits.

* * * * *

■ 128. In § 180.409:

■ a. Revise paragraph (a) introductory text; and

■ b. Add paragraph (a)(4).

The revision and addition read as follows:

§ 180.409 Minimum qualifications for inspectors and testers.

(a) A person performing or witnessing the inspections and tests specified in this subpart must—

* * * * *

(4) Meet the training requirements of part 172 subpart H.

* * * * *

■ 129. In § 180.411:

■ a. Revise paragraphs (b) introductory text, (b)(1), and (g) introductory text; and

■ b. Add paragraph (h).

The revisions and addition read as follows:

§ 180.411 Acceptable results of tests and inspections.

* * * * *

(b) *Dents, cuts, digs, bulges, and gouges.* For evaluation procedures, see CGA C-6 (IBR, see § 171.7 of this subchapter).

(1) For dents or bulges at welds or that include a weld, the maximum allowable depth is 1/2 inch. For dents or bulges away from welds, the maximum allowable depth is 1/10 of the greatest dimension of the dent, but in no case may the depth exceed one inch.

* * * * *

(g) *Pressure test.* Any cargo tank that fails to meet the acceptance criteria found in the individual specification that applies must be properly repaired.

(h) *Conditions requiring removal from service.* (1) If the Registered Inspector

determines that a cargo tank motor vehicle, for any reason, does not meet the applicable design specification, the qualification requirements of § 180.405, or fails any test or inspection required by this subpart, it may not be represented as a DOT specification cargo tank motor vehicle.

(2) The cargo tank motor vehicle shall not be used in specification service until it is in compliance with the specification requirements and has been successfully tested and inspected as required by § 180.407(c) of this subpart.

■ 130. In § 180.413, revise paragraph (b)(6) to read as follows:

§ 180.413 Repair, modification, stretching, rebarrelling, or mounting of specification cargo tanks.

* * * * *

(b) * * *

(6) MC 330 and MC 331 cargo tanks must be repaired in accordance with the repair procedures described in CGA Technical Bulletin P-26 (formerly TB-2) (IBR, see § 171.7 of this subchapter) and the National Board Inspection Code (IBR, see § 171.7 of this subchapter). Each cargo tank having cracks or other defects requiring welded repairs must meet all inspection, test, and heat treatment requirements in § 178.337-16 of this subchapter in effect at the time of the repair, except that postweld heat treatment after minor weld repairs is not required. When a repair is made of defects revealed by the wet fluorescent magnetic particle inspection, including those repaired by grinding, the affected area of the cargo tank must again be examined by the wet fluorescent magnetic particle method after hydrostatic testing to assure that all defects have been removed.

* * * * *

■ 131. In § 180.415, revise paragraph (b) introductory text to read as follows:

§ 180.415 Test and inspection markings.

* * * * *

(b) Each cargo tank must be durably and legibly marked, in English, with the date (month and year), the type of test or inspection performed, and if not already marked on the cargo tank, the registration number, as required by part 107, subpart F, of this chapter, of the person performing the test or inspection, subject to the following provisions:

* * * * *

■ 132. In § 180.416, revise paragraphs (a), (b), (c), (f) introductory text, and (f)(3) to read as follows:

§ 180.416 Discharge system inspection and maintenance program for cargo tanks transporting liquefied compressed gases.

(a) *Applicability.* This section is applicable to an operator using specification MC 330, MC 331, and non-specification cargo tank motor vehicles authorized under § 173.315(k) of this subchapter for transportation of liquefied compressed gases other than carbon dioxide. Paragraphs (b), (c), (d)(1), (d)(5), (e), (f), and (g)(1) of this section, applicable to delivery hose assemblies, apply only to hose assemblies installed or carried on the cargo tank.

(b) *Hose identification.* The operator must assure that each delivery hose assembly is permanently marked with a unique identification number and maximum working pressure.

(c) *Post-delivery hose check.* After each unloading, the operator must visually check that portion of the delivery hose assembly deployed during the unloading using the rejection criteria identified in paragraph (g) of this section.

* * * * *

(f) *New or repaired delivery hose assemblies.* Each operator of a cargo tank motor vehicle must ensure each new and repaired delivery hose assembly is tested at a minimum of 120 percent of the hose maximum working pressure.

* * * * *

(3) The operator must complete a record documenting the test and inspection, including the date, the signature of the inspector, the hose owner, the hose identification number, the date of original delivery hose assembly and test, notes of any defects observed and repairs made, and an indication that the delivery hose assembly passed or failed the tests and inspections. A copy of each test and inspection record must be retained by the operator at its principal place of business or where the vehicle is housed or maintained until the next test of the same type is successfully completed.

* * * * *

■ 133. In § 180.501, revise paragraph (b) to read as follows:

§ 180.501 Applicability

* * * * *

(b) This subpart also establishes the minimum acceptable framework for an owner's qualification and maintenance program for tank cars and components. Owners should follow this subpart in developing their written procedures (work instructions), as required under § 179.7(d), for use by tank car facility employees. The owner's qualification

and maintenance program for each tank car, or a fleet of tank cars, must identify where to inspect, how to inspect, and the acceptance criteria. Alternative inspection and test procedures or intervals based on a damage-tolerance analysis or service reliability assessment must be approved by the Associate Administrator for Railroad Safety in accordance with § 180.509(l). Tank car facilities must incorporate the owner's qualification and maintenance program in their quality assurance program, as required under § 179.7(a)(2), (b)(3), (b)(5), and (d).

■ 134. In § 180.503, revise the definitions of "coating/lining owner", "maintenance", "modification", the first sentence of "qualification", "service equipment", "service equipment owner", and "tank car owner" to read as follows:

§ 180.503 Definitions.

Coating/lining owner means the person responsible for the development or approval, and execution of the qualification and maintenance program for the coating/lining.

Maintenance means performance of functions including repairs, necessary and appropriate to ensure an in-operation tank car's specification until its next qualification.

Modification means any change to a tank car that affects the Design Approval Certificate prescribed in § 179.5 or the certificate of construction for tank cars manufactured prior to [DATE ONE YEAR FROM EFFECTIVE DATE], including an alteration prescribed in § 179.6, or conversion.

Qualification, as relevant to a tank car, means the car and its components conforms to the specification to which it was designed, manufactured, or modified to the requirements of this subpart, to the approved design, and to the owner's acceptance criteria.

Service equipment means pressure or lading retaining equipment including but not limited to:

- (1) Pressure relief devices;
(2) Valves;
(3) Closures;
(4) Fittings;
(5) Manway covers;
(6) Fill-hole covers;
(7) Vents;
(8) Sampling equipment;
(9) Vacuum relief equipment;
(10) Devices used for measuring the amount of lading and/or lading temperature;

- (11) Devices used for flow restriction;
(12) Interior heating systems; or
(13) Other devices used for loading and unloading (e.g., siphon pipe).

Service equipment owner means the person responsible for the development or approval, and execution of the qualification and maintenance program for the service equipment.

Tank car owner means the person responsible for the development or approval, and execution of the qualification and maintenance program for the tank car.

■ 135. In § 180.509, revise paragraphs (i)(1) and (k)(2) to read as follows:

§ 180.509 Requirements for inspection and test of specification tank cars.

(i) At a minimum, the owner of an internal coating or lining applied to protect a tank used to transport a material that is corrosive or reactive to the tank must ensure an inspection adequate enough to detect defects or other conditions that could reduce the design level of reliability and safety of the tank is performed. In addition, the owner of a coating or lining of tank cars used to transport hazardous materials corrosive or reactive to the tank must ensure the lining complies with §§ 173.24(b)(2) and (b)(3) of this subchapter.

(k) Service equipment, including reclosing pressure relief devices and interior heater systems, must conform to the applicable provisions of Appendix D of the AAR Specifications for Tank Cars (IBR, see § 171.7 of this subchapter).

■ 136. In § 180.513, revise paragraph (b) to read as follows:

§ 180.513 Repairs, alterations, conversions, and modifications.

(b) Responsibilities of Tank Car Facility. A tank car facility must obtain the permission of the equipment owner before performing work affecting alteration, conversion, repair, or qualification of the owner's equipment. For the purposes of qualification and maintenance, the tank car facility must use the written instructions furnished by the owner and have written confirmation from the owner allowing the use of written instructions furnished by another. A tank car facility must not use, copy, distribute, forward, or

provide to another person the owner's confidential and proprietary written instructions, procedures, manuals, and records without the owner's permission. A tank car facility must report all work performed to the owner. The tank car facility must also report observed damage, deterioration, failed components, or non-compliant parts to the owner. A tank car facility must incorporate the owner's qualification and maintenance program into their own Quality Assurance Program.

■ 137. In § 180.517:
a. Revise paragraphs (a) and (b)(8); and
b. Add paragraph (b)(9).

The revisions and addition read as follows:

§ 180.517 Reporting and record retention requirements.

(a) Certification and representation. Each owner of a specification tank car must retain the Design Approval Certificate or the certificate of construction (AAR Form 4-2) for a specification tank car manufactured prior to [DATE ONE YEAR FROM EFFECTIVE DATE] and related qualification reports certifying that the manufacture or maintenance of the specification tank car identified in the documents is in accordance with the applicable specification. The qualification reports generated by the tank car facility and the marking of the tank car with the tank specification is the representation that all of the appropriate inspections and tests were successfully performed to qualify the tank for use in accordance with the current Design Approval Certificate or certificate of construction (AAR Form 4-2), as appropriate. These documents must be maintained for the life of the tank car. Each owner of a specification tank car must retain the documents throughout the period of ownership of the specification tank car and for one year thereafter. Upon a change of ownership, the Design Approval Certificate or certificate of construction (AAR Form 4-2), as applicable, and all applicable documents as prescribed in Section 1.3.15 of the AAR Specifications for Tank Cars (IBR, see § 171.7 of this subchapter) must be provided to the new tank car owner. A tank car facility performing work on the car may retain copies of relevant records in accordance with § 179.7(b)(12).

- (b) (8) The unique code (station stencil) identifying the facility; and
(9) Tank car facility registration number(s) (see § 107.905 of this chapter).

■ 138. In Appendix D to part 180, revise the second paragraph to read as follows:

Appendix D to Part 180—Hazardous Materials Corrosive to Tanks or Service Equipment

* * * * *

While every effort was made to identify materials deemed corrosive to the tank or service equipment, owners and operators are cautioned that this list may not be inclusive. Tank car owners and operators are reminded

of their duty to ensure that no in-service tank will deteriorate below the specified minimum thickness requirements in this subchapter. See § 180.509(f)(3). In addition, FRA states a tank car owner must designate an internal coating or lining appropriately based on its knowledge of the chemical and not rely simply on this list. Regarding future thickness tests, this list may also be modified based on an analysis of the test results by the car owner or the Department of Transportation.

* * * * *

Issued in Washington, DC on October 4, 2024, under authority delegated in 49 CFR part 1.97.

William S. Schoonover,
Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

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Part III

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 217

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Port of Alaska Modernization Program Phase 2B: Cargo Terminals Replacement Project in Anchorage, Alaska; Proposed Rule

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 217**

[Docket No. 241018–0276]

RIN 0648–BM30

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Port of Alaska Modernization Program Phase 2B: Cargo Terminals Replacement Project in Anchorage, Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS received a request from the Don Young Port of Alaska (POA) for authorization to take marine mammals incidental to the Cargo Terminals Replacement Project at the existing port facility in Anchorage, Alaska over the course of 5 construction seasons (2026 through 2030). Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is proposing regulations setting forth permissible methods of taking, other means of effecting the least practicable adverse impact on such marine mammal stocks (*i.e.*, mitigation measures), and requirements pertaining to monitoring and reporting such takes and requests comments on the proposed regulations. NMFS will consider public comments prior to making any final decision on the promulgation of the requested MMPA regulations, and NMFS's responses to public comments will be summarized in the final notification of our decision.

DATES: Comments and information must be received no later than November 27, 2024.

ADDRESSES: A plain language summary of this proposed rule is available at <https://www.regulations.gov/docket/NOAA-NMFS-2024-0030>. You may submit comments on this document, identified by NOAA–NMFS–2024–0030, by the following method:

- **Electronic Submission:** Submit all electronic public comments via the Federal e-Rulemaking Portal. Visit <https://www.regulations.gov> and type NOAA–NMFS–2024–0030 in the Search box. Click on the “Comment” icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of

the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on <https://www.regulations.gov> without change. All personal identifying information (*e.g.*, name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/action/incidental-take-authorization-port-alaskas-construction-activities-port-alaska-modernization>. In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Cara Hotchkin, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:**Purpose of Regulatory Action**

These proposed regulations, promulgated under the authority of the MMPA (16 U.S.C. 1361 *et seq.*), would provide a framework for authorizing the take of marine mammals incidental to construction activities associated with the POA's Modernization Program, including impact and vibratory pile driving.

NMFS received an application from the POA requesting 5-year regulations and a letter of authorization issued thereunder to take individuals of seven species, comprising nine stocks of marine mammals by Level A harassment and Level B harassment incidental to the POA's activities. No serious injury or mortality is anticipated or proposed for authorization. Please see Background below for definitions of harassment.

Legal Authority for the Proposed Action

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) directs the Secretary of Commerce to allow, upon request, the incidental, but not intentional taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region for up to 5 years if, after notice and public comment, the agency makes certain findings and promulgates regulations that set forth permissible methods of taking pursuant to that activity and other means of effecting the “least practicable adverse impact” on the affected species or

stocks and their habitat (see the discussion below in the Proposed Mitigation section), as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I provide the legal basis for issuing this proposed rule containing 5-year regulations and for any subsequent Letters of Authorization (LOAs).

Summary of Major Provisions Within the Proposed Rule

Following is a summary of the major provisions of this proposed rule regarding POA's activities. These measures include:

- Prescribing permissible methods of taking of small numbers of marine mammals by Level A harassment and/or Level B harassment incidental to the Cargo Terminals Replacement Project;
- Required monitoring of the construction areas to detect the presence of marine mammals before beginning construction activities;
- Establishment of shutdown zones equivalent to the estimated Level B harassment zone for beluga whales;
- Establishment of shutdown zones equivalent to or greater than the estimated Level A harassment zones for other species;
- Bubble curtains required for all impact and vibratory driving of permanent (72-inch (in) (1.83 meter (m))) piles in more than 3 m of water depth in all months and for vibratory driving of all temporary (24-in (0.61 m) or 36-in (0.91 m)) and permanent (72-in) piles between August and October;
- Soft start for impact pile driving to allow marine mammals the opportunity to leave the area prior to beginning impact pile driving at full power; and
- Submittal of monitoring reports including a summary of marine mammal species and behavioral observations, construction shutdowns or delays, and construction work completed.

Through adaptive management, the proposed regulations would allow NMFS Office of Protected Resources to modify (*e.g.*, remove, revise, or add to) the existing mitigation, monitoring, or reporting measures summarized above and required by the LOA.

Background

The MMPA prohibits the “take” of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of

marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are promulgated or an incidental harassment authorization is issued.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). If such findings are made, NMFS must prescribe the permissible methods of taking and other “means of effecting the least practicable adverse impact” on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as “mitigation”); and requirements pertaining to the monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must evaluate our proposed action’s (*i.e.*, promulgation of regulations and subsequent issuance of a LOA thereunder) and alternatives to that action’s potential impacts on the human environment.

Accordingly, NMFS has prepared an Environmental Assessment (EA) to evaluate the environmental impacts associated with the issuance of the proposed regulations and LOA. NMFS’ EA is available at <https://www.fisheries.noaa.gov/action/incidental-take-authorization-port-alaskas-construction-activities-port-alaska-modernization>. We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on this request.

Summary of Request

On January 3, 2023, NMFS received a request from the POA for regulations and a subsequent LOA to take marine mammals incidental to construction activities related to the POA Modernization Program (PAMP) Phase 2B: Cargo Terminals Replacement (CTR) at the POA in Anchorage, Alaska. NMFS provided comments on the application

on March 3, 2023, April 20, 2023, and May 18, 2023. After POA submitted a revised application on October 13, 2023, and responded to additional questions sent on December 20, 2023, we determined the application was adequate and complete on February 12, 2024.

On March 4, 2024, we published a notice of receipt (NOR) of application in the **Federal Register** (89 FR 15548), requesting comments and information during a 30-day public comment period related to the POA’s request. We received one comment letter from the Center for Biological Diversity. NMFS has reviewed all submitted material and taken the information into consideration during the drafting of this proposed rule.

The POA’s request is for take of seven species of marine mammals by Level B harassment and for a subset of these species, Level A harassment. Neither POA nor NMFS expect serious injury or mortality to result from the specified activities. If promulgated, the regulations would be effective for the first 5 construction seasons (2026–2030).

NMFS previously issued IHAs to the POA for similar work (85 FR 19294, April 6, 2020; 86 FR 50057, September 7, 2021; 89 FR 2832, January 14, 2024). The POA complied with all the requirements (*e.g.*, mitigation, monitoring, and reporting) of the previous IHAs and information regarding their monitoring results may be found in the Effects of the Specified Activity on Marine Mammals and their Habitat and Estimated Take of Marine Mammals sections of this proposed rule and online at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>.

Description of the Specified Activities

Overview

The POA, located on Knik Arm in upper Cook Inlet, provides critical infrastructure for the citizens of Anchorage and a majority of the citizens of Alaska. The POA was constructed primarily in the 1960s and is currently in poor condition and substantially past its initial design life. The existing cargo terminals T1, T2, and T3 are deteriorating and in poor structural condition and present safety and security concerns for human health and the economic stability of the state of Alaska. The PAMP is designed to replace the existing facilities with new infrastructure incorporating modern seismic codes over a 75-year design life.

PAMP Phase 2B includes the demolition and replacement of terminals T1 and T2 and the partial demolition of T3. This phase is expected to take approximately 6 years of in-water work to complete. If promulgated, the regulations would be effective for the first 5 construction seasons (2026–2030).

In-water pile installation will include both temporary (24-in (0.61 m) or 36-in (0.91 m)) and permanent (72-in (1.83 m)) steel pipe piles by impact and vibratory hammers. Removal of temporary piles (24- or 35-in) and existing structures (16-in (0.41 m) to 42-in (1.07 m) steel pipe piles) would be primarily by cutting; dead-pull and vibratory extraction methods may also be used. Existing piles may also be left standing in their current positions. In-water work associated with the project would include installation of approximately 275 permanent piles and 450 temporary piles and vibratory extraction of approximately 46 temporary piles over the 5-year period.

Dates and Duration

The POA anticipates that in-water construction activities associated with this proposed rule would begin on April 1, 2026 and extend through November 30, 2030. In-water pile installation and removal associated with the CTR project is anticipated to take place over approximately 689 hours over approximately 337 nonconsecutive days between the months of April and November over the 5 year period (see table 1 for estimated production rates and durations). While the exact sequence of demolition and construction is uncertain, an estimated schedule is shown in table 2. This schedule is based on best available information and is not intended to be a limitation on the number of pile installation or removal hours that may occur in any given month.

The POA has presented the schedule shown in table 2 using the best available information derived from what is known of the existing Cargo Terminals site and the POA’s experience with similar construction and demolition projects. A typical construction season at the POA extends from approximately mid-April to mid-October (6 months) and may include November. Exact dates of ice-out in the spring and formation of new ice in the fall vary from year to year and cannot be predicted with accuracy. In-water pile installation and removal cannot occur during the winter months when ice is present because of the hazards associated with moving ice floes that change directions four times a day, preventing the use of tugs, barges, workboats, and other vessels. Ice

movement also prevents accurate placement of piles.

While the POA plans to conduct as much work as possible between April and July, when there is lower Cook Inlet beluga whale (CIBW; *Delphinapterus leucas*) abundance (see the Description of Marine Mammals in the Area of Specified Activities section for details on CIBW presence at the POA), front-loading of work is dependent on construction sequencing. Construction

sequencing requires that temporary piles are installed as a template, then larger permanent piles are installed, and then the temporary piles are removed. This required sequence plays out many times, in this order, during the open water construction season. It is not possible to install all of the larger permanent piles during the early season and install temporary piles later in the season; the larger and smaller piles must be alternated. Exact project sequencing

and installation and extraction methods are at the discretion of the construction crew. Construction dates may change because of unexpected project delays, ongoing construction activities in other areas of the POA, timing of ice-out and spring breakup, and other factors. Therefore, the estimated schedule (table 2) reflects a realistic scenario for the proposed project, but conditions on the ground may result in slight changes to this estimated schedule.

TABLE 1—PILE INSTALLATION AND REMOVAL METHODS, ESTIMATED AMOUNTS, AND ESTIMATED DURATIONS FOR YEARS 1–5

Activity type	Pile size and type	Total estimated number of piles	Estimated number of piles in the water ¹		Average vibratory duration per pile (minutes)	Average impact duration per pile (minutes)		Estimated impact strikes per pile	Total duration of removal or installation in water (hours)		Average production rate, piles per day (range)	Estimated number of days over 5 years
			Imp ²	Vib ³		Imp	Vib		Imp	Vib		
Temporary pile installation	24- or 36-in (61- or 91-cm) Steel pipe	565	450	30	225 hours	2–4	144.		
Temporary pile removal	24- or 36-in (61- or 91-cm) Steel pipe	161	46	45	35 hours	2–4	15.		
Permanent pile installation	72-in (182-cm) Steel pipe	310	275	10	86	5,743	440 hours	0.5–3	159.		
Total	1,036	771	700 hours	337 days.		

Note: cm = centimeter(s); 1—Piles installed above the mean lower low water line are considered “in the dry” (i.e., not in-water). It is anticipated that the permanent and temporary piles in the three bents nearest the shore for all five trestles would be installed in the dry at low tide levels. An additional bent would be installed in the dry for the northernmost trestle of T1 and for the three trestles of T2. These piles are not considered to have the potential for impact to marine mammals and are thus excluded from the following analyses.

TABLE 2—ESTIMATED TIMING AND DURATION (IN HOURS PER MONTH) OF PILE INSTALLATION AND REMOVAL ACTIVITIES¹

Activity	Duration (hours of activity by month and year)															
	Apr		May		Jun		Jul		Aug		Sep		Oct		Nov	
	Imp ²	Vib ³	Imp	Vib	Imp	Vib										
Year 1—2026																
24- or 36-in Temporary Pile Installation	2.5	6.0	6.0	6.0	6.0	6.0	6.0	3.0
24- or 36-in Temporary Pile Removal	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
72-in Permanent Pile Installation ⁴	7.2	0.8	15.8	1.8	15.8	1.8	15.8	1.8	12.9	1.5	12.9	1.5	12.9	1.5	12.9	1.5
Year 1 total hours	7.2	4.1	15.8	8.6	15.8	8.6	15.8	8.6	12.9	7.3	11.5	8.3	12.9	8.3	5.3	5.7
Year 2—2027																
24- or 36-in Temporary Pile Installation	3.0	5.0	5.0	5.0	5.0	5.0	5.0	2.5
24- or 36-in Temporary Pile Removal	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
72-in Permanent Pile Installation ⁴	7.2	0.8	12.9	1.5	12.9	1.5	12.9	1.5	12.9	1.5	11.5	1.3	11.5	1.3	11.5	1.3
Year 2 total hours	7.2	4.6	12.9	7.3	12.9	7.3	12.9	7.3	12.9	7.3	11.5	7.1	11.5	4.6	5.7	2.7
Year 3—2028																
24- or 36-in Temporary Pile Installation	6.5	13.0	13.0	13.0	13.0	13.0	13.0	6.5
24- or 36-in Temporary Pile Removal	0.8	2.3	2.3	2.3	2.3	2.3	2.3	0.8
72-in Permanent Pile Installation ⁴	5.7	0.7	5.7	0.7	4.3	0.5	4.3	0.5	4.3	0.5	4.3	0.5	4.3	0.5	4.3	0.5
Year 3 total hours	5.7	7.9	5.7	15.9	4.3	15.9	4.3	15.8	4.3	4.3	15.0	4.3	15.0	4.3	7.8	4.3
Year 4—2029																
24- or 36-in Temporary Pile Installation	2.5	5.5	5.5	6.0	6.0	5.5	5.5	2.5
24- or 36-in Temporary Pile Removal	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
72-in Permanent Pile Installation ⁴	7.2	0.8	12.9	1.5	12.9	1.5	12.9	1.5	12.9	1.5	11.5	1.3	11.5	1.3	11.5	1.3
Year 4 total hours	7.2	4.1	12.9	7.8	12.9	7.8	12.9	8.3	12.9	8.3	11.5	7.6	11.5	4.6	5.7	2.7
Year 5—2030																
24- or 36-in Temporary Pile Installation	2.5	6.0	6.0	6.0	6.0	5.5	5.5	2.5
24- or 36-in Temporary Pile Removal	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
72-in Permanent Pile Installation ⁴	4.3	0.5	12.9	1.5	12.9	1.5	12.9	1.5	11.5	1.3	11.5	1.3	11.5	1.3	11.5	1.3
Year 5 total hours	4.3	3.8	12.9	8.3	12.9	8.3	12.9	8.3	11.5	8.1	11.5	7.6	11.5	7.6	4.3	3.8

¹ Duration estimates assume a single hammer active at any time and therefore likely overestimates of actual time needed due to simultaneous pile installation and removal;

² Impact pile installation;

³ Vibratory pile installation or extraction;

⁴ To account for piles driven in water less than 3m deep, NMFS has estimated approximately 0.5 unattenuated 72-in piles will be driven (approximately 43 minutes of impact driving and 5 minutes of vibratory driving) each month. Numbers may not add exactly due to rounding.

Specific Geographic Region

The specific geographic region for this action encompasses the land occupied by the POA, as well as the shoreline and waters extending from the POA across Knik Arm, northeast towards Wasilla, and southwest towards Fire Island and the Little Susitna River delta (figure 1).

Northern Cook Inlet bifurcates into Knik Arm to the north and Turnagain Arm to the east. Knik Arm is generally considered to begin at Point Woronzof, 7.4 km southwest of the POA. From Point Woronzof, Knik Arm extends about 48 km in a north-northeasterly direction to the mouths of the Matanuska and Knik rivers. At Cairn Point, just northeast of the POA, Knik Arm narrows to about 2.4 km before widening to as much as 8 km at the tidal flats northwest of Eagle Bay at the mouth of Eagle River.

Knik Arm comprises narrow channels flanked by large tidal flats composed of sand, mud, or gravel, depending upon location. Approximately 60 percent of Knik Arm is exposed at Mean Lower Low Water (MLLW). The intertidal (tidally influenced) areas of Knik Arm are mudflats, both vegetated and unvegetated, which consist primarily of fine, silt-sized glacial flour. Freshwater sources often are glacially born waters, which carry high suspended sediment loads as well as a variety of metals such as zinc, barium, mercury, and cadmium. Surface waters in Cook Inlet typically carry high silt and sediment loads, particularly during summer, making Knik Arm an extremely silty, turbid waterbody with low visibility through the water column. The Matanuska and

Knik Rivers contribute the majority of freshwater and suspended sediment into Knik Arm during summer. Smaller rivers and creeks also enter along the sides of Knik Arm (U.S. Department of Transportation and Port of Anchorage, 2008). During winter, sea, beach, and river ice are dominant physical forces within Cook Inlet and Knik Arm. In upper Cook Inlet, sea ice generally forms in October to November and continues to develop through February or March (Moore *et al.*, 2000).

Tides in Cook Inlet are semidiurnal, with two unequal high and low tides per tidal day (tidal day = 24 hours, 50 minutes). Due to Knik Arm's predominantly shallow depths and narrow widths, tides near Anchorage are greater than those in the main body of Cook Inlet. The tides at the POA have a mean range of about 8 m, and the maximum water level has been measured at more than 12.5 m at the Anchorage station (NMFS, 2015). Currents throughout Cook Inlet are strong and tidally periodic, with average velocities ranging from 3 to 6 knots (5.6 to 11.1 kilometers (km)/hour (h)) (Sharma and Burrell, 1970). Maximum current speeds in Knik Arm, observed during spring ebb tide, exceed 7 knots (13 km/h). These tides result in strong currents in alternating directions through Knik Arm and a well-mixed water column. The navigation harbor at the POA is a dredged basin in the natural tidal flat. Sediment loads in upper Cook Inlet can be high; spring thaws occur, and accompanying river discharges introduce considerable amounts of sediment into the system (Ebersole and Raad, 2004). Natural

sedimentation processes act to continuously infill the dredged basin each spring and summer.

The Municipality of Anchorage is located in the lower reaches of Knik Arm of upper Cook Inlet (see figure 2–1 in the POA's application). The POA sits on the industrial waterfront of Anchorage, just south of Cairn Point and north of Ship Creek (lat. 61°15' N, long. 149°52' W; Seward Meridian) (figure 1). The POA's boundaries currently occupy an area of approximately 0.52 km² (figure 2). Other commercial and industrial activities related to secured maritime operations are located near the POA on Alaska Railroad Corporation property immediately south of the POA, on approximately 0.45 km² at a similar elevation. The POA is located north of Ship Creek, an area that experiences concentrated marine mammal activity during seasonal runs of several salmon species. Ship Creek serves as an important recreational fishing resource and is stocked twice each summer. Ship Creek flows into Knik Arm through the Municipality of Anchorage industrial area. Joint Base Elmendorf-Richardson (JBER) is located east of the POA, approximately 30.5 m higher in elevation. The U.S. Army Defense Fuel Support Point-Anchorage site is located east of the POA, south of JBER, and north of Alaska Railroad Corporation property. The perpendicular distance to the west bank directly across Knik Arm from the POA is approximately 4.2 km. The distance from the POA (east side) to nearby Port MacKenzie (west side) is approximately 4.9 km.

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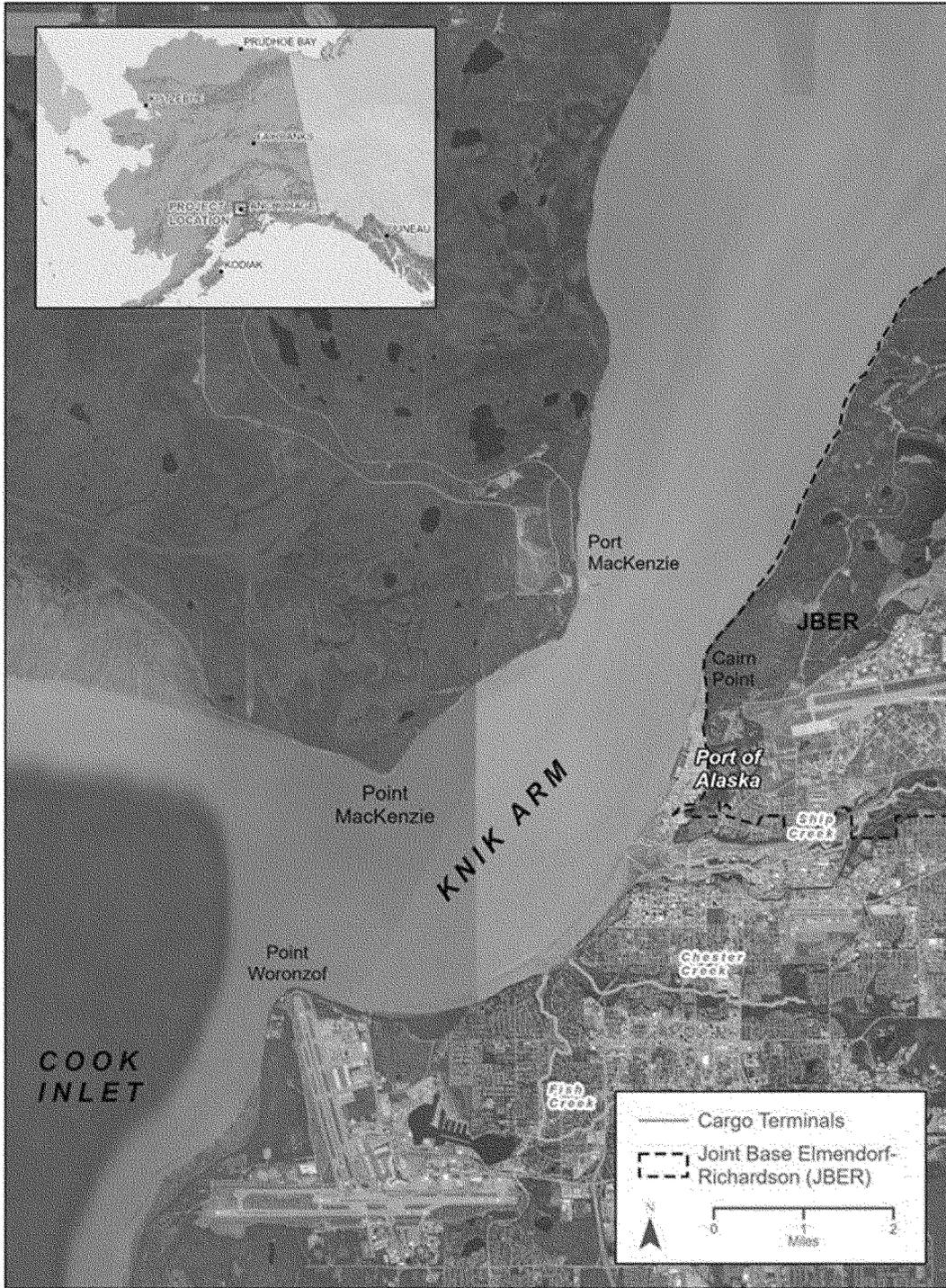


Figure 1 – Overview of POA Location in Knik Arm

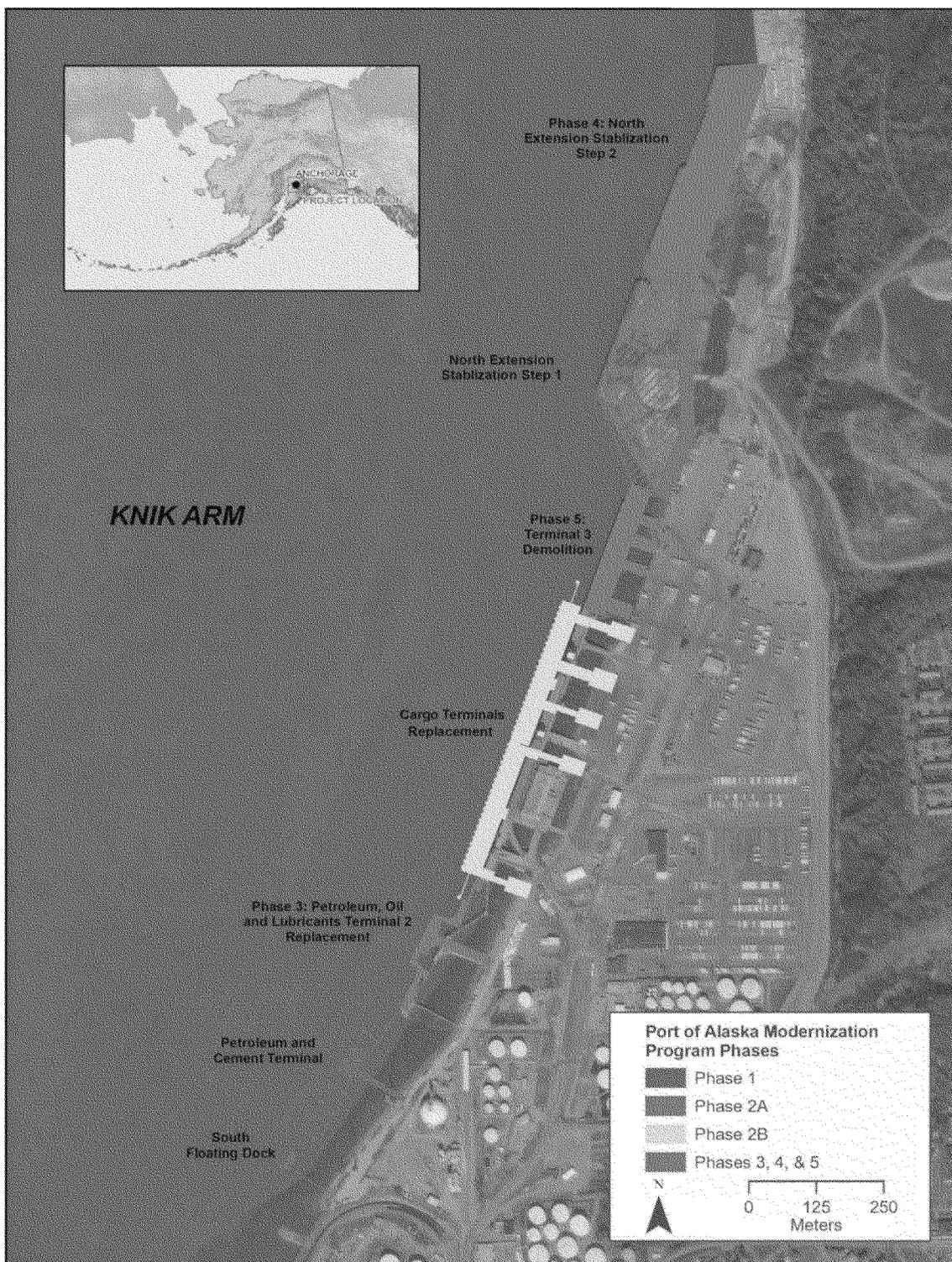


Figure 2 – Overview of Cargo Terminals Location at POA

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Detailed Description of the Specified Activities

As discussed previously, marine-side infrastructure and facilities at the POA are in need of replacement because they

are substantially past their design life and in poor and deteriorating structural condition. Those facilities include three general cargo terminals, two petroleum terminals, a dry barge landing, and an upland sheet-pile-supported storage and

work area. To address deficiencies, the POA is modernizing its marine terminals through the PAMP to enable safe, reliable, and cost-effective Port operations. The PAMP will support infrastructure resilience in the event of

a catastrophic natural disaster over a 75-year design life.

The PAMP is critical to maintaining food and fuel security for the state. At the completion of the PAMP, the POA will have modern, safe, resilient, and efficient facilities through which more than 90 percent of Alaskans will continue to obtain food, supplies, tools, vehicles, and fuel. The PAMP is divided into five separate phases; these phases are designed to include projects that have independent utility yet streamline agency permitting. The projects associated with the PAMP include:

- *Phase 1:* Petroleum and Cement Terminal (PCT Phase 1 and 2) and South Floating Dock (SFD) replacement;
- *Phase 2A:* North Extension Stabilization Phase 1 (NES1);
- *Phase 2B:* CTR;
- *Phase 3:* Petroleum, Oil and Lubricants Terminal 2 Replacement;
- *Phase 4:* North Extension Stabilization part 2; and
- *Phase 5:* Demolition of Terminal 3.

Phase 1 of the PAMP was completed in 2022. NMFS issued IHAs for take incidental to the now completed PCT (Phase 1 and Phase 2; 85 FR 19294, April 6, 2020) and SFD projects (86 FR 50057, September 7, 2021). Phase 2A of the PAMP began in 2023; an IHA was issued for phase one of the NES project (89 FR 2832, January 14, 2024) and in-water construction associated with this project is planned for 2024. The project discussed herein, CTR, is Phase 2B of the PAMP and is proposed to begin onshore preparation in 2025 and in-water construction work in 2026.

The purpose of the CTR project is to replace the existing general cargo docks. It would address deteriorating conditions of the existing cargo facilities; improve operational safety and efficiency; accommodate modern (existing and future) shipping operations; and improve the resiliency of the POA to extreme seismic events, all while sustaining ongoing cargo operations. This project is urgently needed due to severe corrosion of the foundation piles and deteriorating structural conditions at Terminals 1, 2, and 3. The existing terminals are more than 50 years old and suffer from severe damage to the foundation piles caused by corrosion and seismic forces. The piles have exceeded their useful service life, and multiple engineering investigations have highlighted the probability of wharf and trestle structure failure during a future major seismic event. The remaining service life of the cargo terminals is unknown. These facilities must be replaced with new resilient terminals for the Port to continue to meet its critical role serving

Alaska's general cargo needs as well as supporting national defense and military readiness capabilities.

The geographical isolation of Alaska and the POA's role as the containerized logistic hub and distribution center for much of the state make the cargo terminals a critical lifeline for the southcentral region and Alaska. There are no other ports with the cargo capacity, proximity to Alaska's population centers, and intermodal transportation capabilities that can support the logistic missions sustained by the POA, including commerce, national defense, and earthquake resiliency/disaster response and recovery.

CTR Project Activities

The CTR project includes construction of new terminals T1 and T2, which include planned wharves and access trestles. The two new terminals would be located 140 feet (ft) (42.7 meters (m)) seaward of the existing T1, T2, and T3. It is anticipated that this more seaward location of the new terminals will reduce sedimentation, improve room for handling of berthing ships, and allow construction of the new terminals while the existing terminals remain in use. CTR also includes demolition of the existing Petroleum, Oil, and Lubricants Terminal 1 (POL1) and general cargo terminals (T1, T2, and T3).

The southernmost end of the new T1 and T2 would be approximately 1.4 km (0.9 mile (mi)) north of Ship Creek. Construction of the Project will include completion of the following components:

- *Component 1.* Onshore ground improvement shoreline stabilization (2025)
- *Component 2.* Shoreline expansion and protection (2026)
- *Component 3.* General cargo terminals (new Terminals 1 and 2) construction (2026–2031)
- *Component 4.* Demolition of existing terminals (POL1 and general cargo terminals (existing Terminals 1, 2, and 3)) (2026–2031)
- *Component 5.* Onshore utilities and storm drain outfall replacement (2030–2031)

Of these activities, only Components 3 and 4 include construction work that would occur in the water, and therefore, these would be the only components of the project expected to potentially impact marine mammals.

Landside Activities

Landside activities include work which takes place “in the dry,” either above the high tide line or in the

intertidal zone but de-watered. These activities include shoreline stabilization and protection as well as placement of onshore utilities and decking components.

Ground Improvement Shoreline Stabilization—A ground improvement technique, such as deep soil mixing (DSM), or a similar technique would be used to stabilize the shoreline. DSM and similar techniques mechanically mix weak soils with a cement binder causing the soils to behave more like soft rock. This process is used to create foundations for buildings and roads and is used in earthquake-prone areas to prevent soil liquefaction. Soil improvements at trestle abutments, and potentially between the abutments, will mitigate the potential for seismic-induced slope failure that could result in catastrophic structural failure.

The first stage of construction would include installation of soil improvements in the five locations where the access trestles meet the beach to provide geotechnical stability to the embankment. Centered at each of the five trestle abutments, the ground improvement technique would create approximately 200- by 96-ft (61- by 29-m) blocks of treated soil extending from the surface to the top of the clay layer approximately 85-ft (25.9-m) deep (see figure 1–2 of the POA's application). The size of the block is designed to create enough contact area with the clay layer to restrain and significantly reduce the overall ground movements of the liquefiable soils surrounding the trestle abutment. If deemed necessary for geotechnical stability, ground improvements would extend along the embankment in areas between the abutments.

During construction, a temporary soil work pad would be constructed at each of the five trestles to provide a level temporary work surface. The ground improvement panels/columns would extend approximately 100 feet (ft) (30.5-m) seaward and shoreward of the crest of the slope and approximately 30 ft (9-m) to either side of the trestle structure. Temporary armoring will protect the work pad from water forces while in use. After completion of the ground improvement work, the temporary construction work pads will be removed and the foreshore graded and armored.

Shoreline Expansion and Protection—The existing shoreline behind the existing Terminals 1, 2, and 3 is irregular, with two areas where the shoreline is located about 100 ft (30-m) to the east of the typical shoreline (see figure 1–3 of the POA's application). These areas would be excavated to remove deposited silts before the areas

are then filled with more dense, stable materials such as clean gravel and rock. The filled area would provide a consistent shoreline and additional container storage area.

Excavation for the CTR project would be limited to removal of materials that are above the high-water line or below the high-water line in a dewatered state. Sea-based dredging of materials under water will not take place as part of this project.

After ground improvement work and shoreline expansion have been completed, the slope along the shore would be secured with armor stone placed over the clean gravel and rock fill. Placement of armor rock requires good visibility of the shore as each rock is placed carefully to interlock with surrounding armor rock. It is therefore anticipated that placement of most armor rock, filter rock, and granular fill will occur in the dry at low tide levels; however, some placement of armor rock, filter rock, and granular fill may occur in shallow water (*i.e.*, less than 3 m deep). After placement of armor rock, the top of the fill will be paved to match the existing backland pavements.

Onshore utilities and storm drain outfall replacement—The replacement of onshore utilities will involve construction on land and replacement of utilities above the high tide line, on land. Similarly, the storm drain outfall replacement will involve construction on land and replacement of four outfall pipes above the high tide line. No in-water work is proposed as a part of this component.

Ground improvement shoreline stabilization, shoreline expansion and protection, and onshore utilities and storm drain outfall replacement activities would take place on land or in the dry. While a minimal amount of fill and armor rock placement may occur in water, this activity would not be expected to impact marine mammals. Therefore, take of marine mammals related to these activities is not anticipated or proposed to be authorized, and it will not be considered further in this proposed rulemaking.

In-Water Construction

New terminals T1 and T2 would be constructed as seismically resilient adjoining terminals on a continuous berthline with mooring features and appurtenances as required to support safe ship mooring for lift-on/lift-off and

roll-on/roll-off related cargo handling operations. The new T1 wharf would be 870 ft x 120 ft (265- x 37-m) with two 36-ft-wide (11-m) trestles of varying length. The new T2 wharf would be 932 ft x 120 ft (284- x 37-m) with two 259-ft-long x 54-ft-wide (79- x 16.5-m) trestles and one 259-ft-long x 76-ft-wide (79- x 23-m) trestle. Both T1 and T2 would be constructed using 48- and 72-in-diameter (121- and 183-centimeter (cm), respectively) steel piles. The 48-in-diameter piles will be installed in the dry.

Both new terminals would be designed to accommodate lift-on/lift-off container operations serviced by rail-mounted ship-to-shore cranes. Structural, in-deck, and surface features to support operational interface for three 100-gauge rail mounted gantry cranes, and associated appurtenances along with an on-terminal combination stevedore-operations building, would be included on the wharf. Additionally, T2 would be designed to support roll-on/roll-off container operations and other multi-purpose cargo functions. The reinforced concrete deck structure for both new terminals and all new access trestles would be designed to 1,000 pound per square foot load capacity. Construction would also include installation of power, lighting, communications, and signal infrastructure to terminal and onshore electrically powered features; potable water service including ship's water; and fire-flow water for terminal-related operations. The on-terminal stevedore-operations building would also be constructed with a connection to the onshore, existing public utility infrastructure.

In addition to these permanent structures, temporary work including temporary pile installation and removal would be required to support construction. Temporary piles would likely be 36-in-diameter (91-cm) steel; however, 24-in (61-cm) steel piles may be used in place of some of the larger temporary piles. Various work boats and barges would be utilized and would be moored at or in the immediate vicinity of the project, but these vessels are not expected to increase overall noise levels at the POA above existing operational levels. No thrusters or other dynamic positioning methods will be used during pile driving activities.

Construction of each terminal would require installation and removal of temporary steel pipe piles, including

template piles, and installation of permanent steel pipe piles. Pile installation would occur in water depths that range from a few feet or dry (dewatered) conditions nearest the shore to approximately 20 meters (70 ft) at the outer face of the wharves, depending on tidal stage; the mean diurnal tide range at the POA is approximately 8.0 meters (26 ft; NOAA 2015).

Concurrent Activities—In-water construction activities would occur at multiple locations across the project site simultaneously; the POA anticipates that two “spreads” (a construction crew with crane and pile driving hammer) would be on site and working throughout the construction season, with a third “spread” present on some days. Of the two regular spreads, one would be designated for permanent (72-in) piles and one for temporary (24-in or 36-in) piles. Each spread would operate a single hammer at a time (impact or vibratory), with no more than two vibratory hammers simultaneously active in-water at any given time. It is not expected that three piles would be driven concurrently, and this scenario is not addressed further in this analysis. The only combinations of vibratory hammers that could be used simultaneously would be for installation of an attenuated (through use of a bubble curtain; see Proposed Mitigation later in this notice) 72-in pile and an attenuated temporary pile, an attenuated 72-in pile and an unattenuated temporary pile, or two temporary piles. There would be no simultaneous driving of unattenuated 72-in piles in water. Simultaneous use of two hammers would increase production rates.

Duration of active hammer use is anticipated to be brief each day (see table 1), and it is, therefore, anticipated that overlap in use of hammers would be uncommon. Pile installation and removal would occur intermittently over the work period, for durations of minutes to hours at a time. Use of two simultaneous hammers would serve to reduce the overall duration of in-water pile installation and removal during each construction season. One construction crane would likely be based on a floating work barge, and one would likely be based on land or on an access trestle. Table 3 provides a summary of concurrent pile driving scenarios.

TABLE 3—POTENTIAL CONCURRENT DRIVING SCENARIOS THAT COULD OCCUR DURING CTR CONSTRUCTION

Equipment type and quantity	Pile type and size	Construction months
Vibratory × 2	2 x 36-in steel pipe ¹	April–July.
Vibratory, Impact	2 x 72-in steel pipe ² OR 1 x 72-in steel pipe ² (impact) and 1 x 36-in steel pipe (vibratory)	April–November.

¹ POA may elect to use either 36-in or 24-in temporary piles; as 36-in piles are more likely and estimated to have larger ensonified areas, we have used these piles in our analyses of concurrent activities;

² All 72-in piles driven concurrently will be attenuated.

Pile Installation and Removal—

Vibratory and impact hammers would be used for the installation of 72-in (182-cm) permanent piles. Vibratory hammers would be used for installation and removal of 24- (61-cm) and or 36-in (91-cm) temporary piles; however, if obstructions are encountered during installation, impact driving may be necessary. Installation and removal of piles in the dry would be maximized as much as feasible, depending on construction sequencing and tide heights. However, the exact number of piles that may be installed and removed in the dry is unknown (see table 1 for estimates and numbers of piles analyzed for in-water construction activities). Impact and vibratory pile driving activities conducted in the dry are not expected to impact marine mammals and therefore, are not discussed further in this rule.

Pile Cutting—A majority of in-water temporary piles (approximately 90 percent) would be cut off at the mudline and remain in place, removed via direct pulling, or would remain in place intact (without cutting). Temporary piles that conflict with construction or operations or that can be removed in the dry would be removed. Leaving piles in place below the mudline supports stability of the soil. Also, many of the existing T1 and T2 piles are corroded and may break during removal, with the lower part remaining in place. The existing structure is closer to shore than new construction, and many piles can be cut or removed in the dry when their location is dewatered.

The number of piles that would be cut or remain in place would be maximized as feasible; however, the exact number of piles that may be cut or can remain in place is unknown (see table 1 for best estimates of piles to be removed). While the exact method of pile cutting is at the discretion of the construction contractor, any methodology considered for cutting and removing the piles would account for worker safety, constructability, and minimization of potential acoustic impacts that the operation may have on marine mammals. Potential methods of

underwater cutting include ultrathermic cutting, pile clippers or wire-saws.

Underwater ultrathermic cutting is performed by commercial divers using hand-held equipment to cut or melt through ferrous and non-ferrous metals. These systems operate through a torch-like process, initiated by applying a melting amperage to a steel tube packed with alloy steel rods, sometimes mixed with aluminum rods to increase the heat output. In the hands of skilled commercial divers, underwater ultrathermic cutting is reputed to be relatively fast and efficient, cutting through approximately 2 to 4 inches (5 to 10 cm) per minute, depending upon the number of divers deployed. This efficacy may be constrained by the requirement to secure the severed piles from falling into the inlet to prevent an extreme hazard to the diver cutting the piles. Tidally driven currents in Cook Inlet may limit dive times to approximately 2 to 3 hours per high- and low-tide event, depending upon the tide cycle and the ability of divers to efficiently perform the cutting task while holding position during high current periods. This activity is not considered to produce sound.

Pile clipping and underwater sawing generate noise that is typically non-impulsive, low-level, and short duration (typically less than 15 seconds per pile) (NAVFAC SW, 2020). Potential pile cutting methodologies are not anticipated to result in incidental take of marine mammals because they are either above water, do not last for sufficient duration to present the reasonable potential for disruption of behavioral patterns, do not produce sound levels likely to result in marine mammal harassment, or some combination of the above. Impacts on marine mammals from pile cutting are therefore considered *de minimis* and NMFS is not proposing to authorize incidental take from this activity.

Demolition of Existing Terminals—Once the new T1, T2, and petroleum products transfer system are complete and operational, any remaining existing T1, T2, and POL1 platforms, wharves, and trestles would be dismantled (see figure 1–5 of the POA’s application).

Existing and most temporary piles would be cut and removed, removed via vibratory extraction or direct pull, or left in place. The selection of construction equipment by the contractor, including cranes and barges, would determine the plans and sequencing for demolition. Portions of the existing terminals may be used for construction phasing and as support platforms for ongoing new construction, as feasible.

T3 may be partially demolished during Phase 2B construction of T1 and T2, especially where the existing infrastructure may interfere with new construction. Elements of T3 that remain after Phase 2B is complete would remain in place until Phase 5, when they would be removed at that time.

Demolition would take place above the water, and demolished decking, pipes, and other superstructure materials would be contained before they fall into the water following best management practices. Demolished materials would be removed by barge or truck. Because work would take place out of water with best management practices in place to limit any release of material into Cook Inlet, in addition to cutting off or leaving existing piles in place, impacts on marine mammals from demolition of the existing terminals are considered *de minimis* and NMFS is not proposing to authorize incidental take from this activity.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Specified Geographical Region

There are seven species, comprising 9 stocks, of marine mammals that may be found in upper Cook Inlet during the proposed construction and demolition activities. Sections 3 and 4 of the POA’s application and request for regulations summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the

reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>) and more general information about these species (e.g., physical and behavioral descriptions) may be found on NMFS' website (<https://www.fisheries.noaa.gov/find-species>).

Table 4 lists all species or stocks for which take is likely and proposed to be authorized for the specified activities and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the

MMPA as "the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population" (16 U.S.C. 1362(20)). While no serious injury or mortality is anticipated or proposed to be authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of

individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' U.S. Alaska and Pacific SARs (e.g., Carretta, *et al.*, 2023; Young *et al.*, 2023, 2024). Values presented in table 4 are the most recent available at the time of publication (including from the draft 2023 SARs) and are available online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports>. The most recent abundance estimate for CIBWs is available from Goetz *et al.* (2023) and available online at <https://www.fisheries.noaa.gov/feature-story/new-abundance-estimate-endangered-cook-inlet-beluga-whales>.

TABLE 4—SPECIES LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES

Common name	Scientific name	MMPA stock	ESA/ MMPA status; strategic (Y/N) ¹	Stock abundance N _{best} , (CV, N _{min} , most recent abundance survey) ²	PBR	Annual M/SI ³
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Eschrichtiidae: Gray whale	<i>Eschrichtius robustus</i>	Eastern N Pacific	-/-; N	26,960 (0.05, 25,849, 2016).	801	131
Family Balaenopteridae (rorquals): Humpback whale	<i>Megaptera novaeangliae</i>	Hawaii	-/-, N	11,278 (0.56, 7,265, 2020).	127	27.09
		Mexico-North Pacific	T, D, Y	N/A (N/A, N/A, 2006)	UND ⁵	0.57
Order Cetartiodactyla—Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae: Killer whale	<i>Orcinus orca</i>	Eastern North Pacific Alaska Resident.	-/-; N	1,920 (N/A, 1,920, 2019).	19	1.3
		Eastern North Pacific Gulf of Alaska, Aleutian Islands and Bering Sea Transient.	-/-; N	587 (N/A, 587, 2012)	5.9	0.8
Family Monodontidae: Beluga whale	<i>Delphinapterus leucas</i>	Cook Inlet	E/D; Y	331 (0.076, 290, 2022) ⁴	0.53	0
Family Phocoenidae (por- poises): Harbor porpoise	<i>Phocoena phocoena</i>	Gulf of Alaska	-/-; Y	31,046 (0.214, N/A, 1998).	UND ⁵	72
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions): Steller sea lion	<i>Eumetopias jubatus</i>	Western	E/D; Y	49,837 (N/A, 49,837 2022).	299	267
Family Phocidae (earless seals): Harbor seal	<i>Phoca vitulina</i>	Cook Inlet/Sheikof Strait	-/-; N	28,411 (N/A, 26,907, 2018).	807	107

¹ Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

² NMFS marine mammal stock assessment reports online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>. CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable (N.A.).

³ These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range.

⁴ This abundance estimate is from Goetz *et al.* (2023); which was published after the most recent CIBW SAR (Young *et al.*, 2023).

⁵ UND means undetermined.

As indicated above, all seven species (nine managed stocks) in table 4 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur. Minke whales (*Balaenoptera acutorostrata*) and Dall's porpoises (*Phocoenoides dalli*) also occur in Cook Inlet; however, the spatial occurrence of these species is such that take is not likely to occur, and they are not discussed further beyond the explanation provided here. Data from the Alaska Marine Mammal Stranding Network database (NMFS, unpublished data) provide additional support for these determinations. From 2011 to 2020, only one minke whale and one Dall's porpoise were documented as stranded in the portion of Cook Inlet north of Point Possession. Both were dead upon discovery; it is unknown if they were alive upon their entry into upper Cook Inlet or drifted into the area with the tides. With very few exceptions, minke whales and Dall's porpoises do not occur in upper Cook Inlet, and therefore, take of these species is considered unlikely.

In addition to what is included in sections 3 and 4 of the POA's application (<https://www.fisheries.noaa.gov/action/incidental-take-authorization-port-alaska-construction-activities-port-alaska-modernization>), the SARs (<https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>), and NMFS' website, we provide further detail below informing the baseline for species likely to be found in the project area (e.g., information regarding current UMEs and known important habitat areas, such as Biologically Important Areas (BIAs; <https://oceannoise.noaa.gov/biologically-important-areas>) (Van Parijs et al., 2015)).

Gray Whale

Gray whales are infrequent visitors to Cook Inlet but can be seasonally present during spring and fall in the lower inlet (Bureau of Ocean Energy Management (BOEM), 2021). Migrating gray whales pass through the lower inlet during their spring and fall migrations to and from their primary summer feeding areas in the Bering, Chukchi, and Beaufort seas (Swartz, 2018; Silber et al., 2021; BOEM, 2021). There are no BIAs for gray whales in Cook Inlet.

Gray whales are rarely documented in upper Cook Inlet and in the project area. Gray whales were not documented during POA construction or scientific monitoring from 2005 to 2011 or during 2016 (Prevel-Ramos et al., 2006; Markowitz and McGuire, 2007; Cornick and Saxon-Kendall, 2008, 2009; Cornick

et al., 2010, 2011; Integrated Concepts and Research Corporation (ICRC), 2009, 2010, 2011, 2012; Cornick and Pinney, 2011; Cornick and Seagars, 2016); however, one gray whale was observed near Port MacKenzie during 2020 PCT construction (61 North (61N) Environmental, 2021) and a second whale was observed off of Ship Creek during 2021 PCT construction monitoring (61N Environmental, 2022a, Easley-Appleyard and Leonard, 2022). The whale observed in 2020 is believed to be the same whale that later stranded in the Twentymile River, at the eastern end of Turnagain Arm, approximately 80 km southeast of Knik Arm. There was no indication that work at the PCT had any effect on the animal, which was reported to be in "fair to poor" condition during evaluation (see <https://www.fisheries.noaa.gov/feature-story/alaska-gray-whale-ume-update-twentymile-river-whale-likely-one-twelve-dead-gray-whales> for more information). No gray whales were observed during POA's transitional dredging or SFD construction monitoring from May to August, 2022 (61N Environmental, 2022b, 2022c).

Under the MMPA, a UME is defined as "a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response" (16 U.S.C. 1421h(6)). A recently closed UME for gray whales along the West Coast and in Alaska occurred from December 17, 2018 through November 9, 2023. During that time, 146 gray whales stranded off the coast of Alaska. The investigative team concluded that the preliminary cause of the UME was localized ecosystem changes in the whale's Subarctic and Arctic feeding areas that led to changes in food, malnutrition, decreased birth rates, and increased mortality (see <https://www.fisheries.noaa.gov/national/marine-life-distress/2019-2023-gray-whale-unusual-mortality-event-along-west-coast> and for more information). Given the changing environment in the polar regions due to climate change, there is potential for changes to gray whale behavior and distribution in the near future.

Humpback Whale

The 2022 Alaska and Pacific SARs described a revised stock structure for humpback whales, which modifies the previous stocks designated under the MMPA to align more closely with the ESA-designated distinct population segments (DPSS) (Carretta et al., 2023; Young et al., 2023). Specifically, the three previous North Pacific humpback whale stocks (Central and Western

North Pacific stocks and a CA/OR/WA stock) were replaced by five stocks, largely corresponding with the ESA-designated DPSS. These include Western North Pacific and Hawaii stocks and a Central America/Southern Mexico-CA/OR/WA stock (which corresponds with the Central America DPS). The remaining two stocks, corresponding with the Mexico DPS, are the Mainland Mexico-CA/OR/WA and Mexico-North Pacific stocks (Carretta et al., 2023; Young et al., 2023). The former stock is expected to occur along the west coast from California to southern British Columbia, while the latter stock may occur across the Pacific, from northern British Columbia through the Gulf of Alaska and Aleutian Islands/Bering Sea region to Russia.

The Hawaii stock consists of one demographically independent population (DIP) (Hawaii—Southeast Alaska/Northern British Columbia DIP) and the Hawaii—North Pacific unit, which may or may not be composed of multiple DIPs (Wade et al., 2021). The DIP and unit are managed as a single stock at this time, due to the lack of data available to separately assess them and lack of compelling conservation benefit to managing them separately (NMFS, 2019, 2022b, 2023). The DIP is delineated based on two strong lines of evidence: genetics and movement data (Wade et al., 2021). Whales in the Hawaii—Southeast Alaska/Northern British Columbia DIP winter off Hawaii and largely summer in Southeast Alaska and Northern British Columbia (Wade et al., 2021). The group of whales that migrate from Russia, western Alaska (Bering Sea and Aleutian Islands), and central Alaska (Gulf of Alaska excluding Southeast Alaska) to Hawaii have been delineated as the Hawaii-North Pacific unit (Wade et al., 2021). There are a small number of whales that migrate between Hawaii and southern British Columbia/Washington, but current data and analyses do not provide a clear understanding of which unit these whales belong to (Wade et al., 2021; Carretta et al., 2023; Young et al., 2023).

The Mexico-North Pacific stock is likely composed of multiple DIPs, based on movement data (Martien et al., 2021; Wade, 2021; Wade et al., 2021). However, because currently available data and analyses are not sufficient to delineate or assess DIPs within the unit, it was designated as a single stock (NMFS, 2019, 2022c, 2023). Whales in this stock winter off Mexico and the Revillagigedo Archipelago and summer primarily in Alaska waters (Martien et al., 2021; Carretta et al., 2023; Young et al., 2023).

The most comprehensive photo-identification data available suggest that approximately 89 percent of all humpback whales in the Gulf of Alaska are members of the Hawaii stock, 11 percent are from the Mexico-North Pacific stock, and less than 1 percent are from the Western North Pacific stock (Wade, 2021). Members of different stocks are known to intermix in feeding grounds.

On October 9, 2019, NMFS proposed to designate critical habitat for the Western North Pacific, Mexico, and Central America DPSs of humpback whales (84 FR 54354). NMFS issued a final rule on April 21, 2021 to designate critical habitat for ESA-listed humpback whales pursuant to section 4 of the ESA (86 FR 21082). There is no designated critical habitat for humpback whales in or near the Project area (86 FR 21082, April 21, 2021), nor does the project overlap with any known BIAs.

Humpback whales are encountered regularly in lower Cook Inlet and occasionally in mid-Cook Inlet; however, sightings are rare in upper Cook Inlet (e.g., Witteveen *et al.*, 2011). During aerial surveys conducted in summers between 2005 and 2012, Sheldon *et al.* (2013) reported dozens of sightings in lower Cook Inlet, a handful of sightings in the vicinity of Anchor Point and in lower Cook Inlet, and no sightings north of 60° N latitude. NMFS changed to a biennial survey schedule starting in 2014 after analysis showed there would be little reduction in the ability to detect a trend given the current growth rate of the population (Hobbs, 2013). No survey took place in 2020. Instead, consecutive surveys took place in 2021 and 2022 (Shelden *et al.*, 2022). During the 2014–2022 aerial surveys, sightings of humpback whales were recorded in lower Cook Inlet and mid-Cook Inlet, but none were observed in upper Cook Inlet (Shelden *et al.*, 2015b, 2017, 2019, 2022). Vessel-based observers participating in the Apache Corporation's 2014 survey operations recorded three humpback whale sightings near Moose Point in upper Cook Inlet and two sightings near Anchor Point, while aerial and land-based observers recorded no humpback whale sightings, including in the upper inlet (Lomac-MacNair *et al.*, 2014). Observers monitoring waters between Point Campbell and Fire Island during summer and fall 2011 and spring and summer 2012 recorded no humpback whale sightings (Brueggeman *et al.*, 2013). Monitoring of Turnagain Arm during ice-free months between 2006 and 2014 yielded one humpback whale sighting (McGuire, unpublished data,

cited in LGL Alaska Research Associates, Inc., and DOWL, 2015).

There have been few sightings of humpback whales in the vicinity of the proposed project area. Humpback whales were not documented during POA construction or scientific monitoring from 2005 to 2011, in 2016, or during 2020 (Prevel-Ramos *et al.*, 2006; Markowitz and McGuire, 2007; Cornick and Saxon-Kendall, 2008, 2009; Cornick *et al.*, 2010, 2011; ICRC, 2009, 2010, 2011, 2012; Cornick and Pinney, 2011; Cornick and Seagars, 2016; 61N Environmental, 2021). Observers monitoring the Ship Creek Small Boat Launch from August 23 to September 11, 2017 recorded two sightings, each of a single humpback whale, which was presumed to be the same individual (POA, 2017). One other humpback whale sighting has been recorded for the immediate vicinity of the project area. This event involved a stranded whale that was sighted near a number of locations in upper Cook Inlet before washing ashore at Kincaid Park in 2017; it is unclear as to whether the humpback whale was alive or deceased upon entering Cook Inlet waters. Another juvenile humpback stranded in Turnagain Arm in April 2019 near mile 86 of the Seward Highway. One additional humpback whale was observed in July during 2022 transitional dredging monitoring (61N Environmental, 2022c). No humpback whales were observed during the 2020 to 2021 PCT construction monitoring, the NMFS marine mammal monitoring, or the 2022 SFD construction monitoring from April to June (61N Environmental, 2021, 2022a, 2022b, 2022c; Easley-Appleyard and Leonard, 2022).

Killer Whale

Killer whales are rare in Cook Inlet, and there are no known BIAs for this species in Cook Inlet. Most sightings of killer whales in the area are in lower Cook Inlet (Shelden *et al.*, 2013). The infrequent sightings of killer whales that are reported in upper Cook Inlet tend to occur when their primary prey (anadromous fish for resident killer whales and beluga whales for transient killer whales) are also in the area (Shelden *et al.*, 2003). During CIBW aerial surveys between 1993 and 2012, killer whales were sighted in lower Cook Inlet 17 times, with a total of 70 animals (Shelden *et al.*, 2013); no killer whales were observed in upper Cook Inlet during this time. Surveys over 20 years by Sheldon *et al.* (2003) documented an increase in CIBW sightings and strandings in upper Cook Inlet beginning in the early 1990s.

Several of these sightings and strandings reported evidence of killer whale predation on CIBWs. The pod sizes of killer whales preying on CIBWs ranged from one to six individuals (Shelden *et al.*, 2003). Passive acoustic monitoring efforts throughout Cook Inlet documented killer whales at the Beluga River, Kenai River, and Homer Spit, although they were not encountered within Knik Arm (Castellote *et al.*, 2016). These detections were likely resident killer whales. Transient killer whales likely have not been acoustically detected due to their propensity to move quietly through waters to track prey (Small, 2010; Lammers *et al.*, 2013).

Few killer whales, if any, are expected to approach or be in the vicinity of the proposed project area. No killer whales were spotted in the vicinity of the POA during surveys by Funk *et al.* (2005), Ireland *et al.* (2005), or Brueggeman *et al.* (2007, 2008a, 2008b). Killer whales have also not been documented during any POA construction or scientific monitoring from 2005 to 2011, in 2016, or in 2020 (Prevel-Ramos *et al.*, 2006; Markowitz and McGuire, 2007; Cornick and Saxon-Kendall, 2008; ICRC, 2009, 2010, 2011, 2012; Cornick *et al.*, 2010, 2011; Cornick and Pinney, 2011; Cornick and Seagars, 2016; 61N Environmental, 2021). Two killer whales, one male and one juvenile of unknown sex, were sighted offshore of Point Woronzof in September 2021 during PCT Phase 2 construction monitoring (61N Environmental, 2022a). The pair of killer whales moved up Knik Arm, reversed direction near Cairn Point, and moved southwest out of Knik Arm toward the open water of Upper Cook Inlet. No killer whales were sighted during the 2021 NMFS marine mammal monitoring or the 2022 transitional dredging and SFD construction monitoring that occurred between May and June 2022 (61N Environmental, 2022b, 2022c; Easley-Appleyard and Leonard, 2022).

Beluga Whale

Five stocks of beluga whales are recognized in Alaska: the Beaufort Sea stock, eastern Chukchi Sea stock, eastern Bering Sea stock, Bristol Bay stock, and Cook Inlet stock (Young *et al.*, 2023). The Cook Inlet stock is geographically and genetically isolated from the other stocks (O'Corry-Crowe *et al.*, 1997; Laidre *et al.*, 2000) and resides year-round in Cook Inlet (Laidre *et al.*, 2000; Castellote *et al.*, 2020). Only the CIBW stock inhabits the proposed project area. CIBWs were designated as a DPS and listed as endangered under the ESA in October 2008 (73 FR 62919, October 10, 2008).

On June 15, 2023, NMFS released an updated abundance estimate for CIBWs (Goetz *et al.*, 2023) that incorporates aerial survey data from June 2021 and 2022, which represents an update from the most recent SAR (Young *et al.*, 2023) and suggest that the CIBW population is stable or may be slightly increasing. The methodology in the 2023 report is the same as that used for NMFS's SARs (Young *et al.* 2023) and incorporates the same time-series of data from previous years. The only change was the inclusion of more recent data from 2021 and 2022 surveys; the 2021 data collection efforts were delayed from 2020 due to COVID-19. Goetz *et al.* (2023) estimated that the population size is currently between 290 and 386, with a median best estimate of 331. We have determined that Goetz *et al.* (2023) represents the most recent and best available science.

Goetz *et al.* (2023) also present an analysis of population trends for the most recent 10-year period (2012–2022). The addition of data from the 2021 and 2022 survey years in the analysis resulted in a 65.1 percent probability that the CIBW population is now increasing at 0.9 percent per year (95 percent prediction interval of – 3 to 5.7 percent). This increase drops slightly to 0.2 percent per year (95 percent prediction interval of – 1.8 to 2.6 percent) with a 60 percent probability that the CIBW population is increasing more than 1 percent per year when data from 2021, which had limited survey coverage due to poor weather, are excluded from the analysis. Median group size estimates in 2021 and 2022 were 34 and 15, respectively (Goetz *et al.*, 2023). NMFS has determined that the carrying capacity of Cook Inlet is 1,300 CIBWs (65 FR 34590, May 31, 2000) based on historical CIBW abundance estimated by Calkins (1989). Additional information may be found in NMFS' 2023 report on the abundance and trend of CIBWs in Cook Inlet in June 2021 and June 2022, available online at <https://www.fisheries.noaa.gov/resource/document/abundance-and-trend-belugas-delphinapterus-leucas-cook-inlet-alaska-june-2021-and>.

Live stranding events of CIBWs have been regularly observed in upper Cook Inlet. This can occur when an individual or group of individuals strands as the tide recedes. Most live strandings have occurred in Knik Arm and Turnagain Arm, which are shallow and have large tidal ranges, strong currents, and extensive mudflats. Most whales involved in a live stranding event survive, although some associated deaths may not be observed if the

whales die later from live-stranding-related injuries (Vos and Shelden, 2005; Burek-Huntington *et al.*, 2015). Between 2014 and 2018, there were reports of approximately 79 CIBWs involved in 3 known live stranding events plus 1 suspected live stranding event with two associated deaths reported (NMFS, 2016b; NMFS, unpublished data; Muto *et al.*, 2020). In 2014, necropsy results from two whales found in Turnagain Arm suggested that a live stranding event contributed to their deaths as both had aspirated mud and water. No live stranding events were reported prior to the discovery of these dead whales suggesting that not all live stranding events are observed.

Another source of CIBW mortality in Cook Inlet is predation by transient-type (mammal-eating) killer whales (NMFS, 2016b; Shelden *et al.*, 2003). No human-caused mortality or serious injury of CIBWs through interactions with commercial, recreational, and subsistence fisheries or because of other human-caused events (*e.g.*, entanglement in marine debris, ship strikes) has been recently documented, and subsistence harvesting of CIBWs has not occurred since 2008 (NMFS, 2008b).

Recovery Plan. The Final Recovery Plan for CIBW was published in the **Federal Register** on January 5, 2017 (82 FR 1325), available online at <https://www.fisheries.noaa.gov/resource/document/recovery-plan-cook-inlet-beluga-whale-delphinapterus-leucas>.

In its Recovery Plan (82 FR 1325, January 5, 2017), NMFS identified several potential threats to CIBWs, including: (1) high concern: catastrophic events (*e.g.*, natural disasters, spills, mass strandings), cumulative effects of multiple stressors, and noise; (2) medium concern: disease agents (*e.g.*, pathogens, parasites, and harmful algal blooms), habitat loss or degradation, reduction in prey, and prohibited take (*e.g.*, entanglements, strikes, poaching or intentional harassment, and close approaches by private vessels); and (3) low concern: pollution, predation, and subsistence harvest. The recovery plan did not treat climate change as a distinct threat but rather as a consideration in the threats of high and medium concern. Other potential threats most likely to result in direct human-caused mortality or serious injury of this stock include vessel strikes.

Critical Habitat. On April 11, 2011, NMFS designated two areas of critical habitat for CIBW (76 FR 20179). The designation includes 7,800 km² of marine and estuarine habitat within Cook Inlet, encompassing approximately 1,909 km² in Area 1 and

5,891 km² in Area 2 (see figure 1 in 76 FR 20179). Area 1 of the CIBW critical habitat encompasses all marine waters of Cook Inlet north of a line connecting Point Possession (lat. 61.04° N, long. 150.37° W) and the mouth of Three Mile Creek (lat. 61.08.55° N, long. 151.04.40° W), including waters of the Susitna, Little Susitna, and Chickaloon Rivers below mean higher high water. From spring through fall, Area 1 critical habitat has the highest concentration of CIBWs due to its important foraging and calving habitat. Area 2 critical habitat has a lower concentration of CIBWs in spring and summer but is used by CIBWs in fall and winter. Critical habitat does not include two areas of military usage: the Eagle River Flats Range on Fort Richardson and military lands of JBER between Mean Higher High Water and MHW. Additionally, the POA, adjacent navigation channel, and turning basin (approximately 6.84 km²) were excluded from the critical habitat designation due to national security reasons (76 FR 20180, April 11, 2011). The POA exclusion area is within Area 1, however, marine mammal monitoring results from the POA suggest that this exclusion area is not a particularly important feeding or calving area. CIBWs have been occasionally documented to forage around Ship Creek (south of the POA) but are typically transiting through the area to other, potentially richer, foraging areas to the north (*e.g.*, Six Mile Creek, Eagle River, Eklutna River) (*e.g.*, 61N Environmental, 2021, 2022a, 2022b, 2022c, Easley-Appleyard and Leonard, 2022). These locations contain predictable salmon runs, an important food source for CIBWs, and the timing of these runs has been correlated with CIBW movements into the upper reaches of Knik Arm (Ezer *et al.*, 2013). More information on CIBW critical habitat can be found at <https://www.fisheries.noaa.gov/action/critical-habitat-cook-inlet-beluga-whale>.

The designation identified the following Primary Constituent Elements (PCE), essential features important to the conservation of the CIBW:

- (1) Intertidal and subtidal waters of Cook Inlet with depths of less than 9 m (MLLW) and within 8 km of high- and medium-flow anadromous fish streams;
- (2) Primary prey species, including four of the five species of Pacific salmon (chum (*Oncorhynchus keta*), sockeye (*Oncorhynchus nerka*), Chinook (*Oncorhynchus tshawytscha*), and coho (*Oncorhynchus kisutch*)), Pacific eulachon (*Thaleichthys pacificus*), Pacific cod (*Gadus macrocephalus*), walleye pollock (*Gadus chalcogrammus*), saffron cod (*Eleginus*

gracilis), and yellowfin sole (*Limanda aspera*);

(3) The absence of toxins or other agents of a type or amount harmful to CIBWs;

(4) Unrestricted passage within or between the critical habitat areas; and

(5) The absence of in-water noise at levels resulting in the abandonment of habitat by CIBWs.

The area around the POA, while exempted from the Critical Habitat designation due to national security issues, does contain the requisite bathymetric features in the first PCE, as well as the presence of primary prey species. However, given the industrialized nature of the POA and the historical use of the site from the early 1900s, the other physical features are more difficult to confirm. Sediment contamination was examined during a 2008 U.S. Army Corps of Engineers dredging project near the Port, and contaminant levels of volatile and semi-volatile organic compounds, total recoverable petroleum hydrocarbons, PCBs, pesticides, cadmium, mercury, selenium, silver, arsenic, barium, chromium, and lead were found to be suitable for in-water discharge (USACE 2008). Ambient and background noise levels at the POA have been measured and are addressed quantitatively later in this document; briefly, noise levels are elevated due to both anthropogenic activities (*i.e.*, commercial shipping, dredging, and construction) and normal environmental factors (*e.g.*, high current velocity, ice movement, seismic activity). While neither contaminants nor noise have been shown to approach the “harmful” and “habitat abandonment” thresholds described in the PCEs, the concentration of both stressors is highest closer to the POA facilities, within the exemption area, ultimately degrading the habitat at POA relative to the surrounding areas. In total, the exempted area surrounding the POA represents approximately 0.35 percent of the designated Critical Habitat Area 1.

Biologically Important Areas. Wild *et al.* (2023) delineated portions of Cook Inlet, including near the proposed project area, as a BIA for the small and resident population of CIBWs based on scoring methods outlined by Harrison *et al.* (2023) (see <https://ocean.noaa.gov/biologically-important-areas> for more information). The BIA is used

year-round by CIBWs for feeding and breeding, and there are limits on food supply such as salmon runs and seasonal movement of other fish species (Wild *et al.*, 2023). The boundary of the CIBW BIA is consistent with NMFS’ critical habitat designation and does not include the aforementioned exclusion areas (*e.g.*, the POA and surrounding waters) (Wild *et al.*, 2023).

Foraging Ecology. CIBWs feed on a wide variety of prey species, particularly those that are seasonally abundant. From late spring through summer, most CIBW stomachs sampled contained salmon, which corresponded to the timing of fish runs in the area. Anadromous smolt and adult fish aggregate at river mouths and adjacent intertidal mudflats (Calkins, 1989). All five Pacific salmon species (*i.e.*, Chinook, pink (*Oncorhynchus gorbusha*), coho, sockeye, and chum) spawn in rivers throughout Cook Inlet (Moulton, 1997; Moore *et al.*, 2000). Overall, Pacific salmon represent the highest percent frequency of occurrence of prey species in CIBW stomachs. This suggests that their spring feeding in upper Cook Inlet, principally on fat-rich fish, such as salmon and eulachon, is important to the energetics of these animals (NMFS, 2016b).

The nutritional quality of Chinook salmon in particular is unparalleled, with an energy content four times greater than that of a Coho salmon. It is suggested the decline of the Chinook salmon population has left a nutritional void in the diet of the CIBWs that no other prey species can fill in terms of quality or quantity (Norman *et al.*, 2020, 2022).

In fall, as anadromous fish runs begin to decline, CIBWs consume fish species (cod and bottom fish) found in nearshore bays and estuaries. Stomach samples from CIBWs are not available for winter (December through March), although dive data from CIBWs tagged with satellite transmitters suggest that they feed in deeper waters during winter (Hobbs *et al.*, 2005), possibly on such prey species as flatfish, cod, sculpin, and pollock.

Fish runs in the Anchorage and Matanuska-Susitna area include Chinook (May–August), sockeye (June–September), coho (July–September), pin (July–August), and chum (July–September) salmon, as well as dolly

warden, rainbow and lake trout, northern pike, burbot, grayling, smelt, and whitefish. In proximity to the POA, anadromous fish runs occur at Ship Creek, which is heavily used by recreational anglers. On June 26, 2024, the Alaska Department of Fish and Game (ADF&G) issued an emergency closure of recreational fishing on Ship Creek until July 13, 2024, and limited Chinook catching to catch-and-release for the remainder of the season due to low returns of Chinook in the creek. ADF&G anticipates a poor return of this species throughout Knik Arm for 2024, in keeping with a trend of declining Chinook Runs throughout Cook Inlet since 2008 (ADF&G 2019). The Gulf of Alaska Chinook salmon is currently under review for listing under the ESA (89 FR 45815, May 24, 2024).

Distribution in Cook Inlet. The CIBW stock remains within Cook Inlet throughout the year, showing only small seasonal shifts in distribution (Goetz *et al.*, 2012a; Lammers *et al.*, 2013; Castallotte *et al.*, 2015; Shelden *et al.*, 2015a, 2018; Lowery *et al.*, 2019). During spring and summer, CIBWs generally aggregate near the warmer waters of river mouths where prey availability is high and predator occurrence is low (Moore *et al.*, 2000; Shelden and Wade, 2019; McGuire *et al.*, 2020). In particular, CIBW groups are seen in the Susitna River Delta approximately 36 km (23 mi) to the west of the POA across the mouth of Knik arm in Upper Cook Inlet, the Beluga River (approximately 55 km (34 mi) west) and along the shore to the Little Susitna River (21 km (13 mi) west), within all of Knik Arm, and along the shores of Chickaloon Bay to the south of Anchorage, across Turnagain Arm (figure 3). Small groups were recorded farther south in Kachemak Bay, Redoubt Bay (Big River), and Trading Bay (McArthur River) prior to 1996 but rarely thereafter. Since the mid-1990s, most CIBWs (96 to 100 percent) aggregate in shallow areas near river mouths in upper Cook Inlet, and they are only occasionally sighted in the central or southern portions of Cook Inlet during summer (Hobbs *et al.*, 2008). Almost the entire population can be found in northern Cook Inlet from late spring through the summer and into the fall (Muto *et al.*, 2020).

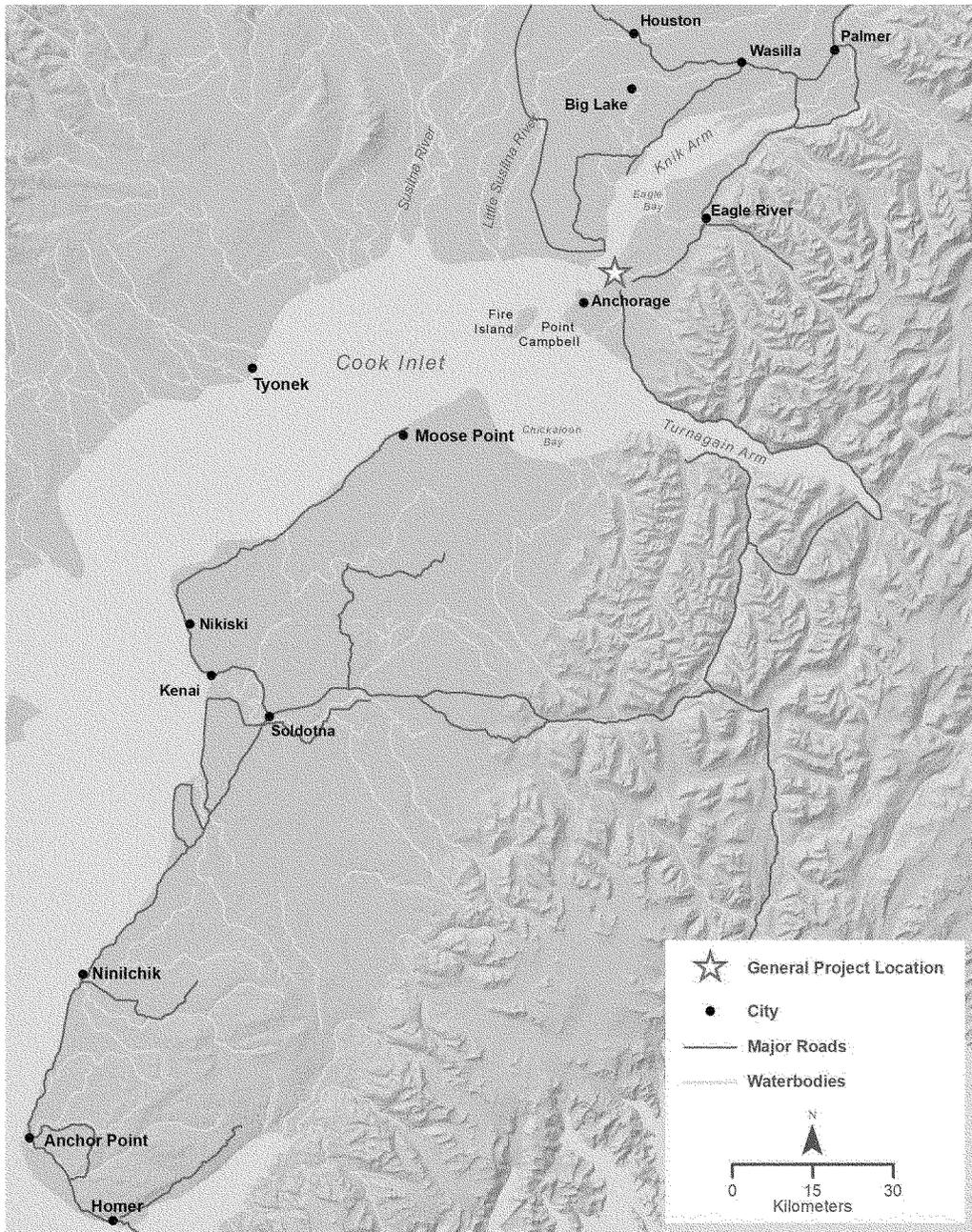


Figure 3 – Overview of Cook Inlet Geography.

Data from tagged whales (14 tags deployed July 2000 through March 2003) show that CIBWs use upper Cook Inlet intensively between summer and late autumn (Hobbs *et al.*, 2005). CIBWs tagged with satellite transmitters continue to use Knik Arm, Turnagain Arm, and Chickaloon Bay as late as October, but some range into lower Cook Inlet to Chinitna Bay, Tuxedni Bay, and Trading Bay (McArthur River) in fall (Hobbs *et al.*, 2005, 2012). From September through November, CIBWs

move between Knik Arm, Turnagain Arm, and Chickaloon Bay (Hobbs *et al.*, 2005; Goetz *et al.*, 2012b). By December, CIBWs are distributed throughout the upper to mid-inlet. From January into March, they move as far south as Kalgin Island and slightly beyond in central offshore waters. CIBWs make occasional excursions into Knik Arm and Turnagain Arm in February and March in spite of ice cover (Hobbs *et al.*, 2005). Although tagged CIBWs move widely around Cook Inlet throughout the year,

there is no indication of seasonal migration in and out of Cook Inlet (Hobbs *et al.*, 2005). Data from NMFS aerial surveys, opportunistic sighting reports, and corrected satellite-tagged CIBWs confirm that they are more widely dispersed throughout Cook Inlet during winter (November–April), with animals found between Kalgin Island and Point Possession. Generally fewer observations of CIBWs are reported from the Anchorage and Knik Arm area from November through April as documented

in the designation of Critical Habitat (76 FR 20179, April 11, 2011; Rugh *et al.*, 2000, 2004).

The NMFS Marine Mammal Lab has conducted long-term passive acoustic monitoring demonstrating seasonal shifts in CIBW concentrations throughout Cook Inlet. Castellote *et al.* (2015) conducted long-term acoustic monitoring at 13 locations throughout Cook Inlet between 2008 and 2015: North Eagle Bay, Eagle River Mouth, South Eagle Bay, Six Mile, Point MacKenzie, Cairn Point, Fire Island, Little Susitna, Beluga River, Trading Bay, Kenai River, Tuxedni Bay, and Homer Spit; the former 6 stations being located within Knik Arm. In general, the observed seasonal distribution is in accordance with descriptions based on aerial surveys and satellite telemetry: CIBW detections are higher in the upper inlet during summer, peaking at Little Susitna, Beluga River, and Eagle Bay, followed by fewer detections at those locations during winter. Higher detections in winter at Trading Bay, Kenai River, and Tuxedni Bay suggest a broader CIBW distribution in the lower inlet during winter, particularly in Tuxedni Bay in the months of September through March (Castellote *et al.*, 2015, 2018, 2024; Castellote *et al.* 2024).

Goetz *et al.* (2012b) modeled habitat preferences using NMFS' 1994–2008 June abundance survey data. In large areas, such as the Susitna Delta (Beluga to Little Susitna Rivers) and Knik Arm, there was a high probability that CIBWs were in larger groups. CIBW presence and acoustic foraging behavior also increased closer to rivers with Chinook salmon runs, such as the Susitna River (*e.g.*, Castellote *et al.*, 2021). Movement has been correlated with the peak discharge of seven major rivers emptying into Cook Inlet. Boat-based surveys from 2005 to the present (McGuire and Stephens, 2017) and results from passive acoustic monitoring across the entire inlet (Castellote *et al.*, 2015) also support seasonal patterns observed with other methods. Based on long-term passive acoustic monitoring, seasonally, foraging behavior was more prevalent during summer, particularly at upper inlet rivers, than during winter. Foraging index was highest at Little Susitna, with a peak in July-August and a secondary peak in May, followed by Beluga River and then Eagle Bay; monthly variation in the foraging index indicates CIBWs shift their foraging behavior among these three locations from April through September.

CIBWs are believed to mostly calve in the summer and concurrently breed between late spring and early summer

(NMFS, 2016b), primarily in upper Cook Inlet. McGuire *et al.* (2020) documented three suspected calving events between July and September with no neonates observed during surveys conducted from April to June. The first neonates encountered during each field season from 2005 through 2015 were always seen in the Susitna River Delta in July. Important calving grounds are thought to be located near the river mouths of upper Cook Inlet—both potential births documented in July were at the Susitna River Delta; the third was in Turnagain Arm in September (McGuire *et al.*, 2020). The photographic identification team's documentation of the dates of the first neonate of each year indicate that calving begins in mid-late July/early August, generally coinciding with the observed timing of annual maximum group size. Probable mating behavior of CIBWs was observed during all months of the aerial surveys (McGuire *et al.*, 2020). Young CIBWs are nursed for 2 years and may continue to associate with their mothers for a considerable time thereafter (Colbeck *et al.*, 2013). Demographic rates were modeled for this population, indicating that low survival of non-breeding (*i.e.*, subadult, male, and non-breeding adult female) CIBWs and general low reproductive rates are likely contributing to the non-recovery of the population (Himes Boor *et al.*, 2022).

Presence in Project Area. Knik Arm is one of three areas in upper Cook Inlet where CIBWs are concentrated during spring, summer, and early fall. Most CIBWs observed in or near the POA are transiting between upper Knik Arm and other portions of Cook Inlet, and the POA itself is not considered high-quality foraging habitat. CIBWs tend to follow their anadromous prey and travel in and out of Knik Arm with the tides. The predictive habitat model derived by Goetz *et al.* (2012a) indicated that the highest predicted densities of CIBWs are in Knik Arm near the mouth of the Susitna River and in Chickaloon Bay. The model suggests that the density of CIBWs ranges from 0 to 1.12 whales per km² in Cook Inlet but is lower at the mouth of Knik Arm, near the POA, ranging between approximately 0.013 and 0.062 whales per km². The distribution presented by Goetz *et al.* (2012a) is generally consistent with CIBW distribution documented in upper Cook Inlet throughout ice-free months (NMFS, 2016b).

Several marine mammal monitoring programs and studies have been conducted at or near the POA during the last 17 years. These studies offer some of the best available information on the presence of CIBWs in the proposed

project area. Studies that occurred prior to 2020 are summarized in Section 4.5.5 of the POA's application. More recent programs, which most accurately portray current information regarding CIBW presence in the proposed project area, are summarized here.

PCT Construction Monitoring (2020–2021). A marine mammal monitoring program was implemented during construction of the PCT in 2020 (Phase 1) and 2021 (Phase 2), as required by the NMFS IHAs (85 FR 19294, April 6, 2020). PCT Phase 1 construction included impact installation of 48-in (122-cm) attenuated piles; impact installation of 36-in (91-cm) and 48-in (122-cm) unattenuated piles; vibratory installation of 24-in (61-cm), 36-in (91-cm), and 48-in (122 cm) attenuated and unattenuated piles; and vibratory installation of an unattenuated 72-in (183-cm) casing for a confined bubble curtain across 95 days. PCT Phase 2 construction included vibratory installation of 36-in (91-cm) attenuated piles and impact and vibratory installation of 144-in (366-cm) attenuated breasting and mooring dolphins across 38 days. Marine mammal monitoring in 2020 occurred during 128 non-consecutive days with a total of 1,238.7 hours of monitoring from April 27 to November 24, 2020 (61N Environmental, 2021). Marine mammal monitoring in 2021 occurred during 74 non-consecutive days with a total of 734.9 hours of monitoring from April 26 to June 24 and September 7 to 29, 2021 (61N Environmental, 2022a). A total of 1,504 individual CIBWs across 377 groups were sighted during PCT construction monitoring. Sixty-five and 67 percent of CIBW observations occurred on non-pile driving days or before pile driving occurred on a given day during PCT Phase 1 and PCT Phase 2 construction, respectively.

The monitoring effort and data collection were conducted before, during, and after pile driving activities from four locations as stipulated by the PCT IHAs (85 FR 19294, April 6, 2020): (1) the Anchorage Public Boat Dock by Ship Creek, (2) the Anchorage Downtown Viewpoint near Point Woronzof, (3) the PCT construction site, and (4) the North End (North Extension) at the north end of the POA, near Cairn Point. Marine mammal sighting data from April to September both before, during, and after pile driving indicate that CIBWs swam near the POA and lingered there for periods of time ranging from a few minutes to a few hours. CIBWs were most often seen traveling at a slow or moderate pace, either from the north near Cairn Point or from the south or milling at the

mouth of Ship Creek. Groups of CIBWs were also observed swimming north and south in front of the PCT construction and did not appear to exhibit avoidance behaviors either before, during, or after pile driving activities (61N Environmental, 2021, 2022a). CIBW sightings in June were concentrated on the west side of Knik Arm from the Little Susitna River Delta to Port MacKenzie. From July through September, CIBWs were most often seen milling and traveling on the east side of Knik Arm from Point Woronzof to Cairn Point (61N Environmental, 2021, 2022a).

SFD Construction Monitoring and Transitional Dredging (2022). In 2022, a marine mammal monitoring program almost identical to that used during PCT construction was implemented during construction of the SFD, as required by the NMFS IHA (86 FR 50057, September 7, 2021). SFD construction included the vibratory installation of ten 36-in (91-cm) attenuated plumb piles and two unattenuated battered piles (61N Environmental, 2022b). Marine mammal monitoring was conducted during 13 non-consecutive days with a total of 108.2 hours of monitoring observation from May 20 through June 11, 2022 (61N Environmental, 2022b). Forty-one individual CIBWs across 9 groups were sighted (61N Environmental, 2022b). One group was observed on a day with no pile-driving, three groups were seen on days before pile driving activities started, and five groups were seen during vibratory pile driving activities (61N Environmental, 2022b).

During SFD construction, the position of the Ship Creek monitoring station was adjusted to allow monitoring of a portion of the shoreline north of Cairn Point that could not be seen by the station at the northern end of the POA (61N Environmental, 2022b). Eleven protected species observers (PSOs) worked from four monitoring stations located along a 9-km (6-mi) stretch of coastline surrounding the POA. The monitoring effort and data collection were conducted at the following four locations: (1) Point Woronzof approximately 6.5 km (4 mi) southwest of the SFD, (2) the promontory near the boat launch at Ship Creek, (3) the SFD project site, and (4) the northern end of the POA (61N Environmental, 2022b).

Ninety groups comprised of 529 CIBWs were also sighted during the transitional dredging monitoring that occurred from May 3 to 15, 2022 and June 27 to August 24, 2022 (61N Environmental, 2022b). Of the nine groups of CIBWs sighted during SFD construction, traveling was recorded as the primary behavior for each group

(61N Environmental, 2022b). CIBWs traveled and milled between the SFD construction area, Ship Creek, and areas to the south of the POA for more than an hour at a time, delaying some construction activities.

Harbor Porpoise

Harbor porpoises occur throughout Cook Inlet with passive acoustic detections being more prevalent in lower Cook Inlet. Although harbor porpoises have been frequently observed during aerial surveys in Cook Inlet (Shelden *et al.*, 2014), most sightings are of single animals and are concentrated at Chinitna and Tuxedni bays on the west side of lower Cook Inlet (Rugh *et al.*, 2005). The occurrence of larger numbers of porpoise in the lower Cook Inlet may be driven by greater availability of preferred prey and possibly less competition with CIBWs as CIBWs move into upper inlet waters to forage on Pacific salmon during the summer months (Shelden *et al.*, 2014). There are no known BIAs for harbor porpoise in Cook Inlet.

An increase in harbor porpoise sightings in upper Cook Inlet has been observed over recent decades (*e.g.*, 61N Environmental, 2021, 2022a; Shelden *et al.*, 2014). Small numbers of harbor porpoises have been consistently reported in upper Cook Inlet between April and October (Prevel-Ramos *et al.*, 2008). The overall increase in the number of harbor porpoise sightings in upper Cook Inlet is unknown, although it may be an artifact from increased studies and marine mammal monitoring programs in upper Cook Inlet. It is also possible that the apparent contraction in the CIBW's range has opened up previously occupied CIBW range to harbor porpoises (Shelden *et al.*, 2014).

Harbor porpoises have been observed within Knik Arm during monitoring efforts from 2005 to 2016. Between April 27 and November 24, 2020, 18 harbor porpoises were observed near the POA during the PCT Phase 1 construction monitoring (61N Environmental, 2021). Twenty-seven harbor porpoises were observed near the POA during the PCT Phase 2 construction monitoring conducted between April 26 and September 29, 2021 (61N Environmental, 2022a). During NMFS marine mammal monitoring conducted in 2021, one harbor porpoise was observed in August and six harbor porpoises were observed in October (Easley-Appleyard and Leonard, 2022). During 2022, five harbor porpoises were sighted during transitional dredging monitoring (61N Environmental, 2022c). No harbor porpoises were sighted at the POA

during the 2022 SFD construction monitoring that occurred between May and June 2022 (61N Environmental, 2022b).

Steller Sea Lion

Two DPSs of Steller sea lion occur in Alaska: the western DPS and the eastern DPS. The western DPS includes animals that occur west of Cape Suckling, Alaska and therefore, includes individuals within the Project area. The western DPS was listed under the ESA as threatened in 1990 (55 FR 49204, November 26, 1990), and its continued population decline resulted in a change in listing status to endangered in 1997 (62 FR 24345, May 5, 1997). Since 2000, studies indicate that the population east of Samalga Pass (*i.e.*, east of the Aleutian Islands) has increased and is potentially stable (Young *et al.*, 2023).

NMFS designated critical habitat for Steller sea lions on August 27, 1993 (58 FR 45269). The critical habitat designation for the Western DPS of was determined to include a 37-km (20-nautical mile) buffer around all major haul-outs and rookeries, and associated terrestrial, atmospheric, and aquatic zones, plus three large offshore foraging areas, none of which occurs in the project area. There are no known BIAs for Steller sea lions in Cook Inlet.

Within Cook Inlet, Steller sea lions primarily inhabit lower Cook Inlet. However, they occasionally venture to upper Cook Inlet and Knik Arm and may be attracted to salmon runs in the region. Steller sea lions have not been documented in upper Cook Inlet during CIBW aerial surveys conducted annually in June from 1994 through 2012 and in 2014 (Shelden *et al.*, 2013, 2015b, 2017; Shelden and Wade, 2019); however, there has been an increase in individual Steller sea lion sightings near the POA in recent years.

Steller sea lions were observed near the POA in 2009, 2016, and 2019 through 2022 (ICRC, 2009; Cornick and Seagars, 2016; POA, 2019; 61N Environmental, 2021, 2022a, 2022b, 2022c). In 2009, there were three Steller sea lion sightings that were believed to be the same individual (ICRC, 2009). In 2016, Steller sea lions were observed on 2 separate days. On May 2, 2016, one individual was sighted, while on May 25, 2016, there were five Steller Sea lion sightings within a 50-minute period, and these sightings occurred in areas relatively close to one another (Cornick and Seagars, 2016). Given the proximity in time and space, it is believed these five sightings were of the same individual sea lion. In 2019, one Steller sea lion was observed in June at the POA during transitional dredging (POA,

2019). There were six sightings of individual Steller sea lions near the POA during PCT Phase 1 construction monitoring (61N Environmental, 2021). At least two of these sightings may have been re-sights on the same individual. An additional seven unidentified pinnipeds were observed that could have been Steller sea lions or harbor seals (61N Environmental, 2021). In 2021, there were a total of eight sightings of individual Steller sea lions observed near the POA during PCT Phase 2 construction monitoring (61N Environmental, 2022a). During NMFS marine mammal monitoring, one Steller sea lion was observed in August 2021 in the middle of the inlet (Easley-Appleyard and Leonard, 2022). In 2022, there were three Steller sea lion sightings during the transitional dredging monitoring and three during SFD construction monitoring (61N Environmental, 2022b, 2022c). All sightings occurred during summer, when the sea lions were likely attracted to ongoing salmon runs. Sea lion observations near the POA may be increasing due to more consistent observation effort or due to increased presence; observations continue to be occasional.

Harbor Seal

Harbor seals inhabit the coastal and estuarine waters of Cook Inlet and are observed in both upper and lower Cook Inlet throughout most of the year (Boveng *et al.*, 2012; Shelden *et al.*, 2013), though there are no known BIAs for this species in this area. Recent research on satellite-tagged harbor seals observed several movement patterns within Cook Inlet (Boveng *et al.*, 2012), including a strong seasonal pattern of more coastal and restricted spatial use during the spring and summer (breeding, pupping, molting) and more wide-ranging movements within and outside of Cook Inlet during the winter months, with some seals ranging as far as Shumagin Islands. During summer months, movements and distribution were mostly confined to the west side of Cook Inlet and Kachemak Bay, and seals captured in lower Cook Inlet generally exhibited site fidelity by remaining south of the Forelands in lower Cook Inlet after release (Boveng *et al.*, 2012). In the fall, a portion of the harbor seals appeared to move out of Cook Inlet and into Shelikof Strait, northern Kodiak Island, and coastal habitats of the Alaska Peninsula. The western coast of Cook Inlet had higher usage by harbor seals than eastern coast habitats, and seals captured in lower Cook Inlet generally exhibited site fidelity by remaining south of the

Forelands in lower Cook Inlet after release (south of Nikiski; Boveng *et al.*, 2012).

The presence of harbor seals in upper Cook Inlet is seasonal. Harbor seals are commonly observed along the Susitna River and other tributaries within upper Cook Inlet during eulachon and salmon migrations (NMFS, 2003). The major haulout sites for harbor seals are in lower Cook Inlet; however, there are a few haulout sites in upper Cook Inlet, including near the Little and Big Susitna rivers, Beluga River, Theodore River, and Ivan River (Barbara Mahoney, personal communication, November 16, 2020; Montgomery *et al.*, 2007). During CIBW aerial surveys of upper Cook Inlet from 1993 to 2012, harbor seals were observed 24 to 96 km south-southwest of Anchorage at the Chickaloon, Little Susitna, Susitna, Ivan, McArthur, and Beluga rivers (Shelden *et al.*, 2013). Harbor seals have been observed in Knik Arm and in the vicinity of the POA (Shelden *et al.*, 2013), but they are not known to haul out within the proposed project area.

Harbor seals were observed during construction monitoring at the POA from 2005 through 2011 and in 2016, in groups of one to seven individuals (Prevel-Ramos *et al.*, 2006; Markowitz and McGuire, 2007; Cornick and Saxon-Kendall, 2008, 2009; Cornick *et al.*, 2010, 2011; Cornick and Seagars, 2016). Harbor seals were also observed near the POA during construction monitoring for PCT Phase 1 in 2020 and PCT Phase 2 in 2021, NMFS marine mammal monitoring in 2021, and transitional dredging monitoring and SFD construction monitoring in 2022 (61N Environmental, 2021, 2022a, 2022b, 2022c, Easley-Appleyard and Leonard, 2022). During the 2020 PCT Phase 1 and 2021 PCT Phase 2 construction monitoring, harbor seals were regularly observed in the vicinity of the POA with frequent observations near the mouth of Ship Creek, located approximately 1,500 m southeast of the CTR location. Harbor seals were observed almost daily during 2020 PCT Phase 1 construction, with 54 individuals documented in July, 66 documented in August, and 44 sighted in September (61N Environmental, 2021). During the 2021 PCT Phase 2 construction, harbor seals were observed with the highest numbers of sightings in June (87 individuals) and in September (124 individuals) (61 N Environmental, 2022a). Over the 13 days of SFD construction monitoring in May and June 2022, 27 harbor seals were observed (61N Environmental, 2022b). Seventy-two groups of 75 total harbor seals (3 groups of 2 individuals) were observed during transitional

dredging monitoring in 2022 (61N Environmental, 2022c). Sighting rates of harbor seals have been highly variable and may have increased since 2005. It is unknown whether any potential increase was due to local population increases or habituation to ongoing construction activities. It is possible that increased sighting rates are correlated with more intensive monitoring efforts in 2020 and 2021, when the POA used 11 PSOs spread among four monitoring stations.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.*, Richardson *et al.*, 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, *etc.*). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.*, low-frequency cetaceans). Subsequently, NMFS (2018, 2024) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained.

On May 3, 2024, NMFS published and solicited public comment on its draft Updated Technical Guidance (89 FR 36762), which includes updated hearing ranges and names for the marine mammal hearing groups and is intended to replace the 2018 Technical Guidance once finalized. The public comment period ended on June 17th, 2024. Because NMFS may finalize the Guidance prior to taking a final agency action on this proposed rulemaking, we considered both the 2018 and 2024 Technical Guidance in our effects and estimated take analysis below. Marine mammal hearing groups and their associated hearing ranges from NMFS (2018) and NMFS (2024) are provided in tables 5 and 6. In the draft Updated

Technical Guidance, mid-frequency cetaceans have been re-classified as high-frequency cetaceans, and high-

frequency cetaceans have been updated to very-high-frequency (VHF) cetaceans. Additionally, the draft Updated

Technical Guidance includes in-air data for phocid (PA) and otariid (OA) pinnipeds.

TABLE 5—MARINE MAMMAL HEARING GROUPS [NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, <i>Kogia</i> , river dolphins, Cephalorhynchid, <i>Lagenorhynchus cruciger</i> & <i>L. australis</i>).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (i.e., all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.* 2007) and PW pinniped (approximation).

TABLE 6—MARINE MAMMAL HEARING GROUPS [NMFS 2024]

Hearing group	Generalized hearing range *
Underwater:	
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 36 kHz.
High-frequency (HF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
Very High-frequency (VHF) cetaceans (true porpoises, <i>Kogia</i> , river dolphins, Cephalorhynchid, <i>Lagenorhynchus cruciger</i> & <i>L. australis</i>).	200 Hz to 165 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	40 Hz to 90 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 68 kHz.
In-air:	
Phocid pinnipeds (PA) (true seals)	42 Hz to 52 kHz.
Otariid pinnipeds (OA) (sea lions and fur seals)	90 Hz to 40 kHz.

* Represents the generalized hearing range for the entire group as a composite (i.e., all species within the group), where individual species' hearing ranges may not be as broad. Generalized hearing range chosen based on ~65 dB threshold from composite audiogram, previous analysis in NMFS 2018, and/or data from Southall *et al.* 2007; Southall *et al.* 2019. Additionally, animals are able to detect very loud sounds above and below that "generalized" hearing range

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018, 2024) for a review of available information.

Potential Effects of the Specified Activity on Marine Mammals and Their Habitat

This section provides a discussion of the ways in which components of the specified activity may impact marine mammals and their habitat. The Estimated Take of Marine Mammals section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take of Marine Mammals section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and whether those impacts are reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Acoustic effects on marine mammals during the specified activities are expected to potentially occur from vibratory pile installation and removal and impact pile installation. The effects of underwater noise from the POA's proposed activities have the potential to result in Level B harassment of marine mammals in the project area and, for some species as a result of certain activities, Level A harassment.

Background on Sound

This section contains a brief technical background on sound, on the characteristics of certain sound types and on metrics used relevant to the specified activity and to a discussion of the potential effects of the specified activities on marine mammals found later in this document. For general information on sound and its interaction with the marine environment, please see: Erbe and Thomas (2022); Au and Hastings (2008); Richardson *et al.* (1995); Urick (1983); as well as the Discovery of Sound in the Sea website at <https://dosits.org/>.

Sound is a vibration that travels as an acoustic wave through a medium such as a gas, liquid or solid. Sound waves alternately compress and decompress the medium as the wave travels. In water, sound waves radiate in a manner similar to ripples on the surface of a pond and may be either directed in a beam (narrow beam or directional sources) or sound may radiate in all directions (omnidirectional sources), as is the case for sound produced by the construction activities considered here. The compressions and decompressions associated with sound waves are detected as changes in pressure by marine mammals and human-made sound receptors such as hydrophones. Sound travels more efficiently in water than almost any other form of energy, making the use of sound as a primary sensory modality ideal for inhabitants of the aquatic environment. In seawater, sound travels at roughly 1,500 meters per second (m/s). In air, sound waves travel much more slowly at about 340 m/s. However, the speed of sound in water can vary by a small amount based on characteristics of the

transmission medium such as temperature and salinity.

The basic characteristics of a sound wave are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in hertz (Hz) or cycles per second. Wavelength is the distance between two peaks or corresponding points of a sound wave (length of one cycle). Higher frequency sounds have shorter wavelengths than lower frequency sounds, and typically attenuate (decrease) more rapidly with distance. The amplitude of a sound pressure wave is related to the subjective "loudness" of a sound and is typically expressed in dB, which are a relative unit of measurement that is used to express the ratio of one value of a power or pressure to another. A sound pressure level (SPL) in dB is described as the ratio between a measured pressure and a reference pressure, and is a logarithmic unit that accounts for large variations in amplitude; therefore, a relatively small change in dB corresponds to large changes in sound pressure. For example, a 10-dB increase is a ten-fold increase in acoustic power. A 20-dB increase is then a 100-fold increase in power and a 30-dB increase is a 1,000-fold increase in power. However, a ten-fold increase in acoustic power does not mean that the sound is perceived as being 10 times louder due to the anatomy of mammalian ears. A 10-dB increase in sound is perceived as a doubling of loudness to the human ear, and marine mammal studies of loudness perception are ongoing (Houser *et al.* 2017).

The dB is a relative unit comparing two pressures; therefore, a reference pressure must always be indicated. For underwater sound, this is 1 microPascal (μPa). For in-air sound, the reference pressure is 20 microPascal (μPa). The amplitude of a sound can be presented in various ways; however, NMFS typically considers three metrics: sound exposure level (SEL), root-mean-square (RMS) SPL, and peak SPL (defined below). The source level represents the SPL referenced at a standard distance from the source, typically 1 m (Richardson *et al.*, 1995; American National Standards Institute (ANSI, 2013), while the received level is the SPL at the receiver's position. For pile driving activities, the SPL is typically referenced at 10 m.

SEL (represented as dB referenced to 1 micropascal squared second (re 1 $\mu\text{Pa}^2\text{-s}$)) represents the total energy in a stated frequency band over a stated time interval or event, and considers both intensity and duration of exposure. The

per-pulse SEL (*e.g.*, single strike or single shot SEL) is calculated over the time window containing the entire pulse (*i.e.*, 100 percent of the acoustic energy). SEL can also be a cumulative metric; it can be accumulated over a single pulse (for pile driving this is the same as single-strike SEL, above; SEL_{ss}), or calculated over periods containing multiple pulses (SEL_{cum}). Cumulative SEL (SEL_{cum}) represents the total energy accumulated by a receiver over a defined time window or during an event. The SEL metric is useful because it allows sound exposures of different durations to be related to one another in terms of total acoustic energy. The duration of a sound event and the number of pulses, however, should be specified as there is no accepted standard duration over which the summation of energy is measured.

RMS SPL is equal to 10 times the logarithm (base 10) of the ratio of the mean-square sound pressure to the specified reference value, and given in units of dB (International Organization for Standardization (ISO), 2017). RMS is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1983). RMS accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak SPL. For impulsive sounds, RMS is calculated by the portion of the waveform containing 90 percent of the sound energy from the impulsive event (Madsen, 2005).

Peak SPL (also referred to as zero-to-peak sound pressure or 0-pk) is the maximum instantaneous sound pressure measurable in the water, which can arise from a positive or negative sound pressure, during a specified time, for a specific frequency range at a specified distance from the source, and is represented in the same units as the RMS sound pressure (ISO, 2017). Along with SEL, this metric is used in evaluating the potential for permanent threshold shift (PTS) and temporary threshold shift (TTS) associated with impulsive sound sources.

Sounds are also characterized by their temporal components. Continuous sounds are those whose sound pressure level remains above that of the ambient or background sound with negligibly small fluctuations in level (ANSI, 2005) while intermittent sounds are defined as

sounds with interrupted levels of low or no sound (National Institute for Occupational Safety and Health (NIOSH), 1998). A key distinction between continuous and intermittent sound sources is that intermittent sounds have a more regular (predictable) pattern of bursts of sounds and silent periods (*i.e.*, duty cycle), which continuous sounds do not.

Sounds may be either impulsive or non-impulsive (defined below). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to noise-induced hearing loss (*e.g.*, Ward, 1997 in Southall *et al.*, 2007). Please see NMFS (2018) and Southall *et al.* (2007, 2019) for an in-depth discussion of these concepts.

Impulsive sound sources (*e.g.*, explosions, gunshots, sonic booms, seismic airgun shots, impact pile driving) produce signals that are brief (typically considered to be less than 1 second), broadband, atonal transients (ANSI, 1986, 2005; NIOSH, 1998) and occur either as isolated events or repeated in some succession. Impulsive sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features. Impulsive sounds are intermittent in nature. The duration of such sounds, as received at a distance, can be greatly extended in a highly reverberant environment.

Non-impulsive sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or non-continuous (*i.e.*, intermittent) (ANSI, 1995; NIOSH, 1998). Some of these non-impulsive sounds can be transient signals of short duration but without the essential properties of impulses (*e.g.*, rapid rise time). Examples of non-impulsive sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems.

Even in the absence of sound from the specified activity, the underwater environment is characterized by sounds from both natural and anthropogenic sound sources. Ambient sound is defined as a composite of naturally-occurring (*i.e.*, non-anthropogenic) sound from many sources both near and far (ANSI, 1995). Background sound is similar but includes all sounds, including anthropogenic sounds minus

the sound produced by the proposed activities (NMFS, 2012, 2016a). The sound level of a region is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (e.g., wind and waves, earthquakes, ice, atmospheric sound), biological (e.g., sounds produced by marine mammals, fish, and invertebrates), and anthropogenic (e.g., vessels, dredging, construction) sound. A number of sources contribute to background and ambient sound, including wind and waves, which are a main source of naturally occurring ambient sound for frequencies between 200 Hz and 50 kilohertz (kHz) (Mitson, 1995). In general, background and ambient sound levels tend to increase with increasing wind speed and wave height. Precipitation can become an important component of total sound at frequencies above 500 Hz, and possibly down to 100 Hz during quiet times. Marine mammals can contribute significantly to background and ambient sound levels, as can some fish and snapping shrimp. The frequency band for biological contributions is from approximately 12 Hz to over 100 kHz. Sources of background sound related to human activity include transportation (surface vessels), dredging and construction, oil and gas drilling and production, geophysical surveys, sonar, and explosions. Vessel noise typically dominates the total background sound for frequencies between 20 and 300 Hz. In general, the frequencies of many anthropogenic sounds, particularly those produced by construction activities, are below 1 kHz (Richardson *et al.*, 1995). When sounds at frequencies greater than 1 kHz are produced, they generally attenuate relatively rapidly (Richardson *et al.*, 1995), particularly above 20 kHz due to propagation losses and absorption (Urlick, 1983).

Transmission loss (*TL*) defines the degree to which underwater sound has spread in space and lost energy after having moved through the environment and reached a receiver. It is defined by the ISO as the reduction in a specified level between two specified points that are within an underwater acoustic field (ISO, 2017). Careful consideration of transmission loss and appropriate propagation modeling is a crucial step in determining the impacts of underwater sound, as it helps to define the ranges (isopleths) to which impacts are expected and depends significantly on local environmental parameters such as seabed type, water depth (bathymetry), and the local speed of

sound. Geometric spreading laws are powerful tools which provide a simple means of estimating *TL*, based on the shape of the sound wave front in the water column. For a sound source that is equally loud in all directions and in deep water, the sound field takes the form of a sphere, as the sound extends in every direction uniformly. In this case, the intensity of the sound is spread across the surface of the sphere, and thus we can relate intensity loss to the square of the range (as $\text{area} = 4 \cdot \pi \cdot r^2$). This can be expressed logarithmically, where $TL = 20 \cdot \text{Log}_{10}(\text{range})$. This situation is known as spherical spreading. In shallow water, the sea surface and seafloor will bound the shape of the sound wave, leading to a more cylindrical shape, as the top and bottom of the sphere is truncated by the largely reflective boundaries. This situation is termed cylindrical spreading, and is given by $TL = 10 \cdot \text{Log}_{10}(\text{range})$ (Urlick, 1983). An intermediate scenario may be defined by the equation $TL = 15 \cdot \text{Log}_{10}(\text{range})$, and is referred to as practical spreading. Though these geometric spreading scenarios do not capture many often important details (scattering, absorption, *etc.*), they offer a reasonable and simple approximation of how sound decreases in intensity as it is transmitted. In the absence of measured data indicating the level of transmission loss at a given site for a specific activity, NMFS recommends practical spreading (*i.e.*, $TL = 15 \cdot \text{Log}_{10}(\text{range})$) to model acoustic propagation for construction activities in most nearshore environments.

The sum of the various natural and anthropogenic sound sources at any given location and time depends not only on the source levels, but also on the propagation of sound through the environment. Sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, background and ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10 to 20 dB from day to day (Richardson *et al.*, 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

Background underwater noise levels in the CTR Project area are both variable and relatively high, primarily because of extreme tidal activity, elevated sediment

loads in the water column, periodic high winds, the seasonal presence of ice, and anthropogenic activities. Sources of anthropogenic noise in the CTR Project area consist of dredging operations, boats, ships, oil and gas operations, construction noise, and aircraft overflights from JBER and Ted Stevens International Airport, all of which contribute to high underwater noise levels in upper Cook Inlet (e.g., Blackwell and Greene, 2002; (Knik Arm Bridge and Toll Authority (KABATA), 2011; Castellote *et al.*, 2018).

Background sound levels were measured at the POA during the PAMP 2016 Test Pile Program (TPP) in the absence of pile driving at two locations during a 3-day break in pile installation. Median background noise levels, measured at a location just offshore of the POA SFD and at a second location about 1 km offshore, were 117 and 122.2 dB RMS, respectively (Austin *et al.*, 2016). NMFS considers the median sound levels to be most appropriate when considering background noise levels for purposes of evaluating the potential impacts of the proposed project on marine mammals (NMFS, 2012). By using the median value, which is the 50th percentile of the measurements, for background noise levels, one will be able to eliminate the few transient loud identifiable events that do not represent the true ambient condition of the area. This is relevant because during 2 of the 4 days (50 percent) when background measurement data were being collected, the USACE was dredging Terminal 3 (located just north of the Ambient-Offshore hydrophone) for 24 hours per day with two 1-hour breaks for crew change. On the last 2 days of data collection, no dredging occurred. Therefore, the median provides a better representation of background noise levels when the CTR project would be occurring. During the measurements, some typical sound signals were noted, such as noise from current flow and the passage of vessels.

With regard to spatial considerations of the measurements, the offshore location is most applicable to assessing background sound during the CTR project (NMFS, 2012). The median background noise level measured at the offshore hydrophone was 122.2 dB RMS. The measurement location closer to the POA was quieter, with a median of 117 dB; however, that hydrophone was placed very close to a dock. During PCT acoustic monitoring, noise levels in Knik Arm absent pile driving were also collected (Illingworth & Rodkin (I&R), 2021a, 2022b)); however, the PCT IHAs did not require background noise

measurements to be collected in adherence with NMFS (2012) methodological recommendations. Despite this, the noise levels measured during the PCT project were not significantly different from 122.2 dB (I&R, 2021a, 2022b). If additional background data are collected in the future in this region, NMFS may re-evaluate the data to appropriately characterize background sound levels in Knik Arm.

Description of Sound Sources for the Specified Activities

In-water construction activities associated with the project that have the potential to incidentally take marine mammals through exposure to sound would include impact pile installation and vibratory pile installation and removal. Impact hammers typically operate by repeatedly dropping and/or pushing a heavy piston onto a pile to drive the pile into the substrate. Sound generated by impact hammers is impulsive, characterized by rapid rise times and high peak levels, a potentially injurious combination (Hastings and Popper, 2005). Vibratory hammers install piles by vibrating them and allowing the weight of the hammer to push them into the sediment. Vibratory hammers typically produce less sound (*i.e.*, lower levels) than impact hammers. Peak SPLs may be 180 dB or greater but are generally 10 to 20 dB lower than SPLs generated during impact pile driving of the same-sized pile (Oestman *et al.*, 2009; California Department of Transportation (CALTRANS), 2015, 2020). Sounds produced by vibratory hammers are non-impulsive; the rise time is slower, reducing the probability and severity of injury, and the sound energy is distributed over a greater amount of time (Nedwell and Edwards, 2002; Carlson *et al.*, 2005).

The likely or possible impacts of the POA's proposed activities on marine mammals could involve both non-acoustic and acoustic stressors. Potential non-acoustic stressors could result from the physical presence of the equipment and personnel; however, given there are no known pinniped haul-out sites in the vicinity of the CTR project site, visual and other non-acoustic stressors would be limited, and any impacts to marine mammals are expected to primarily be acoustic in nature.

Acoustic Impacts

The introduction of anthropogenic noise into the aquatic environment from pile driving is the primary means by which marine mammals may be

harassed from the POA's specified activity. In general, animals exposed to natural or anthropogenic sound may experience physical and psychological effects, ranging in magnitude from none to severe (Southall *et al.*, 2007, 2019). Exposure to pile driving noise has the potential to result in auditory threshold shifts and behavioral reactions (*e.g.*, avoidance, temporary cessation of foraging and vocalizing, changes in dive behavior). Exposure to anthropogenic noise can also lead to non-observable physiological responses, such as an increase in stress hormones. Additional noise in a marine mammal's habitat can mask acoustic cues used by marine mammals to carry out daily functions, such as communication and predator and prey detection. The effects of pile driving noise on marine mammals are dependent on several factors, including, but not limited to, sound type (*e.g.*, impulsive vs. non-impulsive), the species, age and sex class (*e.g.*, adult male vs. mom with calf), duration of exposure, the distance between the pile and the animal, received levels, behavior at time of exposure, and previous history with exposure (Wartzok *et al.*, 2004; Southall *et al.*, 2007). Here, we discuss physical auditory effects (threshold shifts) followed by behavioral effects and potential impacts on habitat.

NMFS defines a noise-induced threshold shift (TS) as a change, usually an increase, in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). The amount of threshold shift is customarily expressed in dB. A TS can be permanent or temporary. As described in NMFS (2018, 2024) there are numerous factors to consider when examining the consequence of TS, including, but not limited to, the signal temporal pattern (*e.g.*, impulsive or non-impulsive), likelihood an individual would be exposed for a long enough duration or to a high enough level to induce a TS, the magnitude of the TS, time to recovery (seconds to minutes or hours to days), the frequency range of the exposure (*i.e.*, spectral content), the hearing frequency range of the exposed species relative to the signal's frequency spectrum (*i.e.*, how animal uses sound within the frequency band of the signal; *e.g.*, Kastelein *et al.*, 2014), and the overlap between the animal and the source (*e.g.*, spatial, temporal, and spectral).

Auditory Injury and Permanent Threshold Shift (PTS). NMFS defines auditory injury as "damage to the inner ear that can result in destruction of

tissue . . . which may or may not result in PTS" (NMFS, 2024). NMFS defines PTS as a permanent, irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2024). PTS does not generally affect more than a limited frequency range, and an animal that has incurred PTS has incurred some level of hearing loss at the relevant frequencies; typically, animals with PTS are not functionally deaf (Au and Hastings, 2008; Finneran, 2016). Available data from humans and other terrestrial mammals indicate that a 40-dB threshold shift approximates PTS onset (see Ward *et al.*, 1958, 1959, 1960; Kryter *et al.*, 1966; Miller, 1974; Ahroon *et al.*, 1996; Henderson *et al.*, 2008). PTS levels for marine mammals are estimates, as with the exception of a single study unintentionally inducing PTS in a harbor seal (Kastak *et al.*, 2008), there are no empirical data measuring PTS in marine mammals largely due to the fact that, for various ethical reasons, experiments involving anthropogenic noise exposure at levels inducing PTS are not typically pursued or authorized (NMFS, 2018).

Temporary Threshold Shift (TTS). A temporary, reversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). Based on data from marine mammal TTS measurements (see Southall *et al.*, 2007, 2019), a TTS of 6 dB is considered the minimum threshold shift clearly larger than any day-to-day or session-to-session variation in a subject's normal hearing ability (Finneran *et al.*, 2000, 2002; Schlundt *et al.*, 2000). As described in Finneran (2015), marine mammal studies have shown the amount of TTS increases with SEL_{cum} in an accelerating fashion: at low exposures with lower SEL_{cum}, the amount of TTS is typically small and the growth curves have shallow slopes. At exposures with higher SEL_{cum}, the growth curves become steeper and approach linear relationships with the noise SEL.

Depending on the degree (elevation of threshold in dB), duration (*i.e.*, recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during

a time when the animal is traveling through the open ocean, where ambient noise is lower and there are not as many competing sounds present.

Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts. We note that reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.*, 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

Many studies have examined noise-induced hearing loss in marine mammals (see Finneran (2015) and Southall *et al.* (2019) for summaries). TTS is the mildest form of hearing impairment that can occur during exposure to sound (Kryter, 2013). While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends. For cetaceans, published data on the onset of TTS are limited to captive bottlenose dolphin (*Tursiops truncatus*), beluga whale, harbor porpoise, and Yangtze finless porpoise (*Neophocoena asiaeorientalis*) (Southall *et al.*, 2019). For pinnipeds in water, measurements of TTS are limited to harbor seals, elephant seals (*Mirounga angustirostris*), bearded seals (*Erignathus barbatus*) and California sea lions (*Zalophus californianus*) (Kastak *et al.*, 1999, 2007; Kastelein *et al.*, 2019b, 2019c, 2021, 2022a, 2022b; Reichmuth *et al.*, 2019; Sills *et al.*, 2020). TTS was not observed in spotted (*Phoca largha*) and ringed (*Pusa hispida*) seals exposed to single airgun impulse sounds at levels matching previous predictions of TTS onset (Reichmuth *et al.*, 2016). These studies examine hearing thresholds measured in marine mammals before and after exposure to intense or long-duration sound exposures. The difference between the pre-exposure and post-exposure thresholds can be used to determine the amount of threshold shift at various post-exposure times.

The amount and onset of TTS depends on the exposure frequency. Sounds at low frequencies, well below the region of best sensitivity for a species or hearing group, are less hazardous than those at higher frequencies, near the region of best sensitivity (Finneran and Schlundt,

2013). At low frequencies, onset-TTS exposure levels are higher compared to those in the region of best sensitivity (*i.e.*, a low frequency noise would need to be louder to cause TTS onset when TTS exposure level is higher), as shown for harbor porpoises and harbor seals (Kastelein *et al.*, 2019a, 2019c). Note that in general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran, 2015). In addition, TTS can accumulate across multiple exposures, but the resulting TTS will be less than the TTS from a single, continuous exposure with the same SEL (Mooney *et al.*, 2009; Finneran *et al.*, 2010; Kastelein *et al.*, 2014, 2015). This means that TTS predictions based on the total, cumulative SEL will overestimate the amount of TTS from intermittent exposures, such as sonars and impulsive sources. Nachtigall *et al.* (2018) describe measurements of hearing sensitivity of multiple odontocete species (bottlenose dolphin, harbor porpoise, beluga, and false killer whale (*Pseudorca crassidens*)) when a relatively loud sound was preceded by a warning sound. These captive animals were shown to reduce hearing sensitivity when warned of an impending intense sound. Based on these experimental observations of captive animals, the authors suggest that wild animals may dampen their hearing during prolonged exposures or if conditioned to anticipate intense sounds. Another study showed that echolocating animals (including odontocetes) might have anatomical specializations that might allow for conditioned hearing reduction and filtering of low-frequency ambient noise, including increased stiffness and control of middle ear structures and placement of inner ear structures (Ketten *et al.*, 2021). Data available on noise-induced hearing loss for mysticetes are currently lacking (NMFS, 2018). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, and there is no PTS data for cetaceans. However, such relationships are assumed to be similar to those in humans and other terrestrial mammals. PTS typically occurs at exposure levels at least several dB above that inducing mild TTS (*e.g.*, a 40-dB threshold shift approximates PTS onset (Kryter *et al.*, 1966; Miller, 1974), while a 6-dB threshold shift approximates TTS onset (Southall *et al.*, 2007, 2019). Based on data from terrestrial mammals, a

precautionary assumption is that the PTS thresholds for impulsive sounds (such as impact pile driving pulses as received close to the source) are at least 6 dB higher than the TTS threshold on a peak-pressure basis, and PTS cumulative sound exposure level thresholds are 15 to 20 dB higher than TTS cumulative sound exposure level thresholds (Southall *et al.*, 2007, 2019). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.

Behavioral Harassment. Exposure to noise also has the potential to behaviorally disturb marine mammals to a level that rises to the definition of harassment under the MMPA. Generally speaking, NMFS considers a behavioral disturbance that rises to the level of harassment under the MMPA a non-minor response—in other words, not every response qualifies as behavioral disturbance, and for responses that do, those of a higher level, or accrued across a longer duration, have the potential to affect foraging, reproduction, or survival. Behavioral disturbance may include a variety of effects, including subtle changes in behavior (*e.g.*, minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses may include changing durations of surfacing and dives; changing direction and/or speed; reducing/increasing vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); eliciting a visible startle response or aggressive behavior (such as tail/fin slapping or jaw clapping); avoidance of areas where sound sources are located. Pinnipeds may increase their haul out time, possibly to avoid in-water disturbance (Thorson and Reyff, 2006).

Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.*, species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.*, Richardson *et al.*, 1995; Wartzok *et al.*, 2004; Southall *et al.*, 2007, 2019; Weilgart, 2007; Archer *et al.*, 2010; Erbe *et al.*, 2019). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.*, 2012), and can

vary depending on characteristics associated with the sound source (e.g., whether it is moving or stationary, number of sources, distance from the source). In general, pinnipeds seem more tolerant of, or at least habituate more quickly to, potentially disturbing underwater sound than do cetaceans and generally seem to be less responsive to exposure to industrial sound than most cetaceans. Please see appendices B and C of Southall *et al.* (2007) and Gomez *et al.* (2016) for reviews of studies involving marine mammal behavioral responses to sound.

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.*, 2004). Animals are most likely to habituate to sounds that are predictable and unvarying. It is important to note that habituation is appropriately considered as a "progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial," rather than as, more generally, moderation in response to human disturbance (Bejder *et al.*, 2009). The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure.

As noted above, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.*, 1995; Wartzok *et al.*, 2004; National Research Council (NRC), 2005). Controlled experiments with captive marine mammals have showed pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.*, 1997; Finneran *et al.*, 2003). Observed responses of wild marine mammals to loud pulsed sound sources (e.g., seismic airguns) have been varied but often consist of avoidance behavior or other behavioral changes (Richardson *et al.*, 1995; Morton and Symonds, 2002; Nowacek *et al.*, 2007).

Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal (e.g., Erbe *et al.*, 2019). If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an

important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (e.g., Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005). However, there are broad categories of potential response, which we describe in greater detail here, that include alteration of dive behavior, alteration of foraging behavior, effects to breathing, interference with or alteration of vocalization, avoidance, and flight.

Changes in dive behavior can vary widely and may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (e.g., Frankel and Clark, 2000; Costa *et al.*, 2003; Ng and Leung, 2003; Nowacek *et al.*, 2004; Goldbogen *et al.*, 2013a, 2013b, Blair *et al.*, 2016). Variations in dive behavior may reflect interruptions in biologically significant activities (e.g., foraging) or they may be of little biological significance. The impact of an alteration to dive behavior resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure and the type and magnitude of the response.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (e.g., bubble nets or sediment plumes) or changes in dive behavior. However, acoustic and movement bio-logging tools have been used in some cases, to infer responses of feeding to anthropogenic noise. For example, Blair *et al.* (2016) reported significant effects on humpback whale foraging behavior in Stellwagen Bank in response to ship noise including slower descent rates, and fewer side-rolling events per dive with increasing ship noise. In addition, Wisniewska *et al.* (2018) reported that tagged harbor porpoises demonstrated fewer prey capture attempts when encountering occasional high-noise levels resulting from vessel noise as well as more vigorous fluking, interrupted foraging, and cessation of echolocation signals observed in response to some high-noise vessel passes.

In response to playbacks of vibratory pile driving sounds, captive bottlenose dolphins showed changes in target detection and number of clicks used for a trained echolocation task (Branstetter *et al.* 2018). Similarly, harbor porpoises trained to collect fish during playback of impact pile driving sounds also showed potential changes in behavior and task success, though individual differences were prevalent (Kastelein *et al.* 2019d). As for other types of behavioral

response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (e.g., Croll *et al.*, 2001; Nowacek *et al.*, 2004; Madsen *et al.*, 2006; Yazvenko *et al.*, 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationships among prey availability, foraging effort and success, and the life history stage(s) of the animal.

Variations in respiration naturally vary with different behaviors and alterations to breathing rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Various studies have shown that respiration rates may either be unaffected or could increase, depending on the species and signal characteristics, again highlighting the importance in understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure (e.g., Kastelein *et al.*, 2001, 2005, 2006; Gailey *et al.*, 2007). For example, harbor porpoise' respiration rate increased in response to pile driving sounds at and above a received broadband SPL of 136 dB (zero-peak SPL: 151 dB re 1 μ Pa; SEL of a single strike: 127 dB re 1 μ Pa²-s) (Kastelein *et al.*, 2013).

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors, and is one of the most obvious manifestations of disturbance in marine mammals (Richardson *et al.*, 1995). For example, gray whales are known to change direction—deflecting from customary migratory paths—in order to avoid noise from seismic surveys (Malme *et al.*, 1984). In response to construction noise from offshore wind farms, harbor porpoises and harbor seals have demonstrated avoidance on the scale of hours to weeks (Brandt *et al.*, 2018; Russell *et al.*, 2016). Avoidance may be short-term, with animals returning to the area once the noise has ceased (e.g., Bowles *et al.*, 1994; Goold, 1996; Stone *et al.*, 2000; Morton and Symonds, 2002; Gailey *et al.*, 2007). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of

the affected species in the affected region if habituation to the presence of the sound does not occur (*e.g.*, Blackwell *et al.*, 2004; Bejder *et al.*, 2006; Teilmann *et al.*, 2006).

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (*e.g.*, directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996; Bowers *et al.*, 2018). The result of a flight response could range from brief, temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, marine mammal strandings (England *et al.*, 2001). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford and Reeves, 2008), and whether individuals are solitary or in groups may influence the response.

Behavioral disturbance can also impact marine mammals in more subtle ways. Increased vigilance may result in costs related to diversion of focus and attention (*i.e.*, when a response consists of increased vigilance, it may come at the cost of decreased attention to other critical behaviors such as foraging or resting). These effects have generally not been demonstrated for marine mammals, but studies involving fishes and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (*e.g.*, Beauchamp and Livoreil, 1997; Fritz *et al.*, 2002; Purser and Radford, 2011). In addition, chronic disturbance can cause population declines through reduction of fitness (*e.g.*, decline in body condition) and subsequent reduction in reproductive success, survival, or both (*e.g.*, Harrington and Veitch, 1992; Daan *et al.*, 1996; Bradshaw *et al.*, 1998). However, Ridgway *et al.* (2006) reported that increased vigilance in bottlenose dolphins exposed to sound over a 5-day period did not cause any sleep deprivation or stress effects.

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hour cycle). Disruption of such functions resulting from reactions to stressors such as sound exposure are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.*, 2007). Consequently, a behavioral response lasting less than 1 day and not recurring

on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.*, 2007). Note that there is a difference between multi-day substantive (*i.e.*, meaningful) behavioral reactions and multi-day anthropogenic activities. For example, just because an activity lasts for multiple days does not necessarily mean that individual animals are either exposed to activity-related stressors for multiple days or, further, exposed in a manner resulting in sustained multi-day substantive behavioral responses.

Behavioral Reactions Observed at the POA. Specific to recent construction at the POA, behavioral reactions to pile driving have not been reported in non-CIBW species. During POA's PCT construction, 81 harbor seals were observed within estimated Level B harassment zones associated with vibratory and impact installation and removal of 36-in (61-cm) and 144-in (366-cm) piles, and 5 harbor seals were observed within estimated Level A harassment zones during the installation of 144-in (366-cm) piles. No observable behavioral reactions were observed in any of these seals (61N Environmental, 2021, 2022a). One harbor porpoise was observed within the estimated Level B harassment zone during vibratory driving of a 36-in (61-cm) pile in May 2021. The animal was traveling at a moderate pace. No observable reactions to pile driving were noted by the PSOs. Another harbor porpoise near the border of (and may have been within) the estimated Level B harassment zone during the impact installation of 36-in (61-cm) piles in June 2021, but PSOs did not record any behavioral responses of this individual to the pile driving activities. Similarly 13 harbor seals observed within estimated Level B harassment zones associated with pile driving 36-in (61-cm) piles during POA's SFD construction did not exhibit observable behavioral reactions (61N Environmental, 2022b).

Specific to CIBWs, several years of marine mammal monitoring data demonstrate behavioral responses to pile driving at the POA. Previous pile driving activities at the POA include the installation and removal of sheet piles, the vibratory and impact installation of 24-in (61-cm), 36-in (91-cm), 48-in (122-cm), and 144-in (366-cm) pipe piles, and the vibratory installation of 72-in (182-cm) air bubble casings.

Kendall and Cornick (2015) provide a comprehensive overview of 4 years of scientific marine mammal monitoring conducted before (2005–2006) and during the POA's MTRP (2008–2009). These were observations made by

biologists at Alaska Pacific University, funded by the POA and other groups but independent of the POA's required monitoring for pile driving activities (*i.e.*, not construction based PSOs). The authors investigated CIBW behavior before and during pile driving activity at the POA. Sighting rates, mean sighting duration, behavior, mean group size, group composition, and group formation were compared between the two periods. A total of about 2,329 hours of sampling effort was completed across 349 days from 2005 to 2009. Overall, 687 whales in 177 groups were documented during the 69 days that whales were sighted. A total of 353 and 1,663 hours of pile driving took place in 2008 and 2009, respectively. There was no relationship between monthly CIBW sighting rates and monthly pile driving rates ($r = 0.19$, $p = 0.37$). Sighting rates before ($n = 12$; 0.06 ± 0.01) and during ($n = 13$; 0.01 ± 0.03) pile driving were not significantly different. However, sighting duration of CIBWs decreased significantly during pile driving (39 ± 6 min before and 18 ± 3 min during). There were also significant differences in behavior before versus during pile driving. CIBWs primarily traveled through the study area both before and during pile driving; however, traveling increased relative to other behaviors during pile driving. Documentation of milling was observed on 21 occasions during pile driving. Mean group size decreased during pile driving; however, this difference was not statistically significant. In addition, group composition was significantly different before and during pile driving, with more white (*i.e.*, likely older) animals being present during pile driving (Kendall and Cornick, 2015). CIBWs were primarily observed densely packed before and during pile driving; however, the number of densely packed groups increased by approximately 67 percent during pile driving. There were also significant increases in the number of dispersed groups (approximately 81 percent) and lone white whales (approximately 60 percent) present during pile driving than before pile driving (Kendall and Cornick, 2015).

During PCT and SFD construction monitoring, behaviors of CIBWs groups were compared by month and by construction activity (61N Environmental, 2021, 2022a, 2022b). Little variability was evident in the behaviors recorded from month to month or among sightings that coincided with in-water pile installation and removal and those that did not (61N Environmental, 2021, 2022a). Definitive behavioral reactions to in-water pile

driving or avoidance behaviors were not documented; however, potential reactions (where a group reversed its trajectory shortly after the start of in-water pile driving occurred; a group reversed its trajectory as it got closer to the sound source during active in-water pile driving; or upon an initial sighting, a group was already moving away from in-water pile driving, raising the possibility that it had been moving towards, but was only sighted after they turned away) and instances where CIBWs moved toward active in-water pile driving were recorded. During these instances, impact driving appeared to cause potential behavioral reactions more readily than vibratory hammering (61N Environmental, 2021, 2022a, 2022b). One minor difference documented during PCT construction was a slightly higher incidence of milling behavior and diving during the periods of no pile driving and slightly higher rates of traveling behavior during periods when potential CIBW behavioral reactions to pile driving, as described above, were recorded (61N Environmental, 2021, 2022a). Note, narratives of each CIBW reaction can be found in the appendices of the POA's final monitoring reports (61N Environmental, 2021, 2022a, 2022b).

Acoustically, Saxon-Kendall *et al.* (2013) recorded echolocation clicks (which can be indicative of feeding behavior) during the MTR Project at the POA both while pile driving was occurring and when it was not. This indicates that while feeding is not a predominant behavior that PSOs visually observed in CIBWs sighted near the POA (61N Environmental, 2021, 2022a, 2022b, 2022c; Easley-Appleyard and Leonard, 2022) CIBWs can and still exhibit feeding behaviors during pile driving activities. In addition, Castellote *et al.* (2020) found low echolocation detection rates in lower Knik Arm (*i.e.*, Six Mile, Port MacKenzie, and Cairn Point) and suggested that CIBWs moved through that area relatively quickly when entering or exiting the Arm. No whistles or noisy vocalizations were recorded during the MTRP construction activities; however, it is possible that persistent noise associated with construction activity at the MTR project masked beluga vocalizations and or that CIBWs did not use these communicative signals when they were near the MTR Project (Saxon-Kendall *et al.*, 2013).

Recently, McHuron *et al.* (2023) developed a model to predict general patterns related to the movement and foraging decisions of pregnant CIBWs in Cook Inlet. They found that the effects of disturbance from human activities, such as pile driving activities occurring

at the POA assuming no mitigation measures, are inextricably linked with prey availability. If prey are abundant during the summer and early fall and prey during winter is above some critical threshold, pregnant CIBWs can likely cope with intermittent disruptions, such as those produced by pile driving at the POA (McHuron *et al.*, 2023). However, they stress that more information needs to be acquired regarding CIBW prey and CIBW body condition, specifically in their critical habitat, to better understand possible behavioral responses to disturbance.

Stress responses. An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.*, Selye, 1950; Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.*, Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.*, 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and "distress" is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficient to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.*, Holberton *et al.*, 1996; Hood *et al.*, 1998; Jessop *et al.*, 2003; Krausman *et al.*, 2004; Lankford *et al.*, 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000; Romano *et al.*, 2002b) and, more rarely, studied in wild populations (*e.g.*, Romano *et al.*, 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. In addition, Lemos *et al.* (2022) observed a correlation between higher levels of fecal glucocorticoid metabolite concentrations (indicative of a stress response) and vessel traffic in gray whales. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as "distress." In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2005), however distress is an unlikely result of this project based on observations of marine mammals during previous, similar construction projects.

Norman (2011) reviewed environmental and anthropogenic stressors for CIBWs. Lyamin *et al.* (2011) determined that the heart rate of a beluga whale increases in response to noise, depending on the frequency and intensity. Acceleration of heart rate in the beluga whale is the first component of the "acoustic startle response." Romano *et al.* (2004) demonstrated that captive beluga whales exposed to high-level impulsive sounds (*i.e.*, seismic airgun and/or single pure tones up to 201 dB RMS) resembling sonar pings showed increased stress hormone levels of norepinephrine, epinephrine, and dopamine when TTS was reached. Thomas *et al.* (1990) exposed beluga whales to playbacks of an oil-drilling platform in operation ("Sedco 708," 40 Hz–20 kHz; source level 153 dB). Ambient SPL at ambient conditions in the pool before playbacks was 106 dB and 134 to 137 dB RMS during playbacks at the monitoring hydrophone across the pool. All cell and platelet counts and 21 different blood chemicals, including epinephrine and norepinephrine, were within normal

limits throughout baseline and playback periods, and stress response hormone levels did not increase immediately after playbacks. The difference between the Romano *et al.* (2004) and Thomas *et al.* (1990) studies could be the differences in the type of sound (seismic airgun and/or tone versus oil drilling), the intensity and duration of the sound, the individual's response, and the surrounding circumstances of the individual's environment. The construction sounds in the Thomas *et al.* (1990) study would be more similar to those of pile installation than those in the study investigating stress response to water guns and pure tones. Therefore, no more than short-term, low-level hormonal stress responses, if any, of beluga whales or other marine mammals are expected as a result of exposure to in-water pile installation and removal during the CTR project.

Auditory Masking. Since many marine mammals rely on sound to find prey, moderate social interactions, and facilitate mating (Tyack, 2008), noise from anthropogenic sound sources can interfere with these functions but only if the noise spectrum overlaps with the hearing sensitivity of the receiving marine mammal (Southall *et al.*, 2007; Clark *et al.*, 2009; Hatch *et al.*, 2012). Chronic exposure to excessive, though not high-intensity, noise could cause masking at particular frequencies for marine mammals that utilize sound for vital biological functions (Clark *et al.*, 2009). Acoustic masking is when other noises such as from human sources interfere with an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.*, those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.*, 1995; Erbe *et al.*, 2016). Therefore, under certain circumstances, marine mammals whose acoustical sensors or environment are being severely masked could also be impaired from maximizing their performance fitness in survival and reproduction. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.*, signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.*, sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions (Hotchkinn and Parks, 2013).

Marine mammals vocalize for different purposes and across multiple

modes, such as whistling, echolocation click production, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result from a need to compete with an increase in background noise or may reflect increased vigilance or a startle response. For example, in the presence of potentially masking signals, humpback whales and killer whales have been observed to increase the length of their songs (Miller *et al.*, 2000; Frstrup *et al.*, 2003) or vocalizations (Foote *et al.*, 2004), respectively, while North Atlantic right whales (*Eubalaena glacialis*) have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.*, 2007). Fin whales have also been documented lowering the bandwidth, peak frequency, and center frequency of their vocalizations under increased levels of background noise from large vessels (Castellote *et al.*, 2012). Other alterations to communication signals have also been observed. For example, gray whales, in response to playback experiments exposing them to vessel noise, have been observed increasing their vocalization rate and producing louder signals at times of increased outboard engine noise (Dahlheim and Castellote, 2016). Alternatively, animals may cease sound production during production of aversive signals (Bowles *et al.*, 1994).

Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (masking) sound is human-made, it may be considered harassment when disrupting or altering critical behaviors. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs during the sound exposure. Because masking (without resulting in TS) is not associated with abnormal physiological function, it is not considered a physiological effect but rather, a potential behavioral effect (though not necessarily one that would be associated with harassment).

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of

communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (*e.g.*, Clark *et al.*, 2009) and may result in energetic or other costs as animals change their vocalization behavior (*e.g.*, Miller *et al.*, 2000; Foote *et al.*, 2004; Parks *et al.*, 2007; Di Iorio and Clark, 2010; Holt *et al.*, 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.*, 1995), through amplitude modulation of the signal, or through other compensatory behaviors (Hotchkinn and Parks, 2013). Masking can be tested directly in captive species (*e.g.*, Erbe, 2008), but in wild populations, it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (*e.g.*, Branstetter *et al.*, 2013).

Marine mammals at or near the proposed CTR project site may be exposed to anthropogenic noise, which may be a source of masking. Vocalization changes may result from a need to compete with an increase in background noise and include increasing the source level, modifying the frequency, increasing the call repetition rate of vocalizations, or ceasing to vocalize in the presence of increased noise (Hotchkinn and Parks, 2013). For example, in response to loud noise, beluga whales may shift the frequency of their echolocation clicks and communication signals, reduce their overall calling rates, and/or increase the emission of certain call signals to prevent masking by anthropogenic noise (Lessage *et al.*, 1999; Tyack, 2000; Eickmeier and Vallarta, 2022).

Masking occurs in the frequency band or bands that animals utilize and is more likely to occur in the presence of broadband, relatively continuous noise sources such as vibratory pile driving. Energy distribution of pile driving covers a broad frequency spectrum, and sound from pile driving would be within the audible range of pinnipeds and cetaceans present in the proposed action area. While some construction during the POA's activities may mask some acoustic signals that are relevant to the daily behavior of marine mammals, the short-term duration and limited areas affected make it very unlikely that the fitness of individual marine mammals would be impacted.

Airborne Acoustic Effects. Pinnipeds that occur near the project site could be exposed to airborne sounds associated with construction activities that have

the potential to cause behavioral harassment, depending on their distance from these activities. Airborne noise would primarily be an issue for pinnipeds that are swimming or hauled out near the project site within the range of noise levels elevated above airborne acoustic harassment criteria. Although pinnipeds are known to haul-out regularly on man-made objects, we believe that incidents of take resulting solely from airborne sound are unlikely given there are no known pinniped haulout or pupping sites within the vicinity of the proposed project area; the nearest known pinniped haulout is located a minimum of 24 km south-southwest of Anchorage for harbor seals. Cetaceans are not expected to be exposed to airborne sounds that would result in harassment as defined under the MMPA.

We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with their heads above water. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled-out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations or cause them to temporarily abandon the area and move further from the source. However, these animals would previously have been 'taken' because of exposure to underwater sound above the behavioral harassment thresholds, which are in all cases larger than those associated with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here.

Potential Effects on Marine Mammal Habitat

The proposed project would occur mostly within the same footprint as existing marine infrastructure; the new T1 and T2 would extend approximately 140 ft (47-m) seaward of the existing terminals. The nearshore and intertidal habitat where the proposed project will occur is an area of relatively high marine vessel traffic. Temporary, intermittent habitat alteration may result from increased noise levels during the proposed construction activities. Noise from impact and vibratory pile driving may extend across Knik Arm, and affect areas outside of the area around POA excluded from

designated CIBW Critical Habitat. However, increased noise levels will only be present during construction activities and will cease when pile driving ends. Pile driving is not expected on all days during the construction season (April–November) and is not expected at all during the months of December–March. Noise exposure is, therefore, expected to be temporary and intermittent with long periods of typical background noise levels on a daily and seasonal scale. Effects to CIBW critical habitat are, therefore, considered to be non-significant. Effects on prey species will be limited in time and space. The long-term impact on marine mammal habitat associated with CTR would be a small permanent decrease in low-quality potential habitat because of the expanded footprint of the new cargo terminals T1 and T2. Installation and removal of in-water piles would be temporary and intermittent, and the increased footprint of the facilities would destroy only a small amount of low-quality habitat, which currently experiences high levels of anthropogenic activity.

Water quality—Temporary and localized reduction in water quality would occur as a result of in-water construction activities. Most of this effect would occur during the installation and removal of piles when bottom sediments are disturbed. The installation and removal of piles would disturb bottom sediments and may cause a temporary increase in suspended sediment in the project area. During pile removal, sediment attached to the pile moves vertically through the water column until gravitational forces cause it to slough off under its own weight. The small resulting sediment plume is expected to settle out of the water column within a few hours. Studies of the effects of turbid water on fish (marine mammal prey) suggest that concentrations of suspended sediment can reach thousands of milligrams per liter before an acute toxic reaction is expected (Burton, 1993).

Effects to turbidity and sedimentation are expected to be short-term, minor, and localized. Since the currents are so strong in the area, following the completion of sediment-disturbing activities, suspended sediments in the water column should dissipate and quickly return to background levels in all construction scenarios. Turbidity within the water column has the potential to reduce the level of oxygen in the water and irritate the gills of prey fish species in the proposed project area. However, turbidity plumes associated with the project would be

temporary and localized, and fish in the proposed project area would be able to move away from and avoid the areas where plumes may occur. Thus, it is expected that the impacts on prey fish species from turbidity and therefore, on marine mammals, would be minimal and temporary. In general, the area likely impacted by the proposed construction activities is relatively small compared to the available marine mammal habitat in Knik Arm, and does not include any areas of particular importance.

Potential Effects on Prey. Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (e.g., crustaceans, cephalopods, fishes, zooplankton). Marine mammal prey varies by species, season, and location and, for some, is not well documented. Studies regarding the effects of noise on known marine mammal prey are described here.

Fishes utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (e.g., Zelick *et al.*, 1999; Fay, 2009). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.*, 2008). The potential effects of noise on fishes depends on the overlapping frequency range, distance from the sound source, water depth of exposure, and species-specific hearing sensitivity, anatomy, and physiology. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality.

Fish react to sounds that are especially high amplitude and/or intermittent at low frequencies. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to noise depends on the physiological state of the fish, past exposures, motivation (e.g., feeding, spawning, migration), and other environmental factors. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fishes (e.g. Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Several studies have demonstrated that impulsive sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (e.g., Fewtrell

and McCauley, 2012; Pearson *et al.*, 1992; Skalski *et al.*, 1992; Santulli *et al.*, 1999; Paxton *et al.*, 2017). However, some studies have shown no or slight reaction to impulse sounds (*e.g.*, Peña *et al.*, 2013; Wardle *et al.*, 2001; Jorgenson and Gyselman, 2009; Cott *et al.*, 2012). More commonly, though, the impacts of noise on fishes are temporary.

During the POA's MTRP, the effects of impact and vibratory installation of 30-in (76-cm) steel sheet piles at the POA on 133 caged juvenile coho salmon in Knik Arm were studied (Hart Crowser Incorporated *et al.*, 2009; Houghton *et al.*, 2010). Acute or delayed mortalities or behavioral abnormalities were not observed in any of the coho salmon. Furthermore, results indicated that the pile driving had no adverse effect on feeding ability or the ability of the fish to respond normally to threatening stimuli (Hart Crowser Incorporated *et al.*, 2009; Houghton *et al.*, 2010).

SPLs of sufficient strength have been known to cause injury to fishes and fish mortality (summarized in Popper *et al.*, 2014). However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012b) showed that a TTS of 4 to 6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long. Injury caused by barotrauma can range from slight to severe, can cause death, and is most likely for fish with swim bladders. Barotrauma injuries have been documented during controlled exposure to impact pile driving (Halvorsen *et al.*, 2012a; Casper *et al.*, 2013, 2017).

Fish populations in the proposed project area that serve as marine mammal prey could be temporarily affected by noise from pile installation and removal. The frequency range in which fishes generally perceive underwater sounds is 50 to 2,000 Hz, with peak sensitivities below 800 Hz (Popper and Hastings, 2009). Fish behavior or distribution may change, especially with strong and/or intermittent sounds that could harm fishes. High underwater SPLs have been documented to alter behavior, cause hearing loss, and injure or kill individual fish by causing serious internal injury (Hastings and Popper, 2005).

Essential Fish Habitat (EFH) has been designated in the estuarine and marine waters in the vicinity of the proposed project area for all five species of salmon (*i.e.*, chum salmon, pink salmon, coho salmon, sockeye salmon, and

Chinook salmon; North Pacific Fishery Management Council (NPFMC), 2020, 2021), which are common prey of marine mammals, as well as for other species. (NPFMC, 2020). However, there are no designated habitat areas of particular concern in the vicinity of the Port, and therefore, adverse effects on EFH in this area are not expected.

The greatest potential impact to fishes during construction would occur during impact pile installation. Impact piling would occur over 1 to 3 hours on any given day across the construction season, with significant breaks between piles due to repositioning of the crane, installation and removal of temporary piles, and other construction sequencing. Additionally, impact driving of 72-in permanent piles would be mitigated with the use of a bubble curtain (see Proposed Mitigation section for full details) in all months of construction for piles driven in water greater than 3-m deep. Unattenuated impact driving in shallow water would be minimized as much as feasible by timing installation to occur during periods of low tide, when the pilings are out of water ("in the dry"). In-water construction activities would only occur during daylight hours, allowing fish to forage and transit the project area in the evening. Vibratory pile driving would possibly elicit behavioral reactions from fishes, such as temporary avoidance of the area, but is unlikely to cause injuries to fishes or have persistent effects on local fish populations. Construction also would have minimal permanent and temporary impacts on benthic invertebrate species, a marine mammal prey source. In addition, it should be noted that the area in question is low-quality habitat since it is already highly developed and experiences a high level of anthropogenic noise from normal operations and other vessel traffic at the POA. In general, any negative impacts on marine mammal prey species are expected to be minor and temporary.

In-Water Construction Effects on Potential Foraging Habitat

The CTR project area is not considered to be high-quality habitat for marine mammals or marine mammal prey, such as fish, and it is anticipated that the long-term impact on marine mammals associated with CTR would be a small permanent decrease in low-quality potential habitat because of the expanded footprint of the new cargo terminals T1 and T2. The CTR project is not expected to result in any habitat related effects that could cause significant negative consequences for individual marine mammals or their populations since installation and

removal of in-water piles would be temporary and intermittent and the increased footprint of the facilities would destroy only a small amount of low-quality habitat, which currently experiences high levels of anthropogenic activity. Therefore, impacts of the project are not likely to have adverse effects on marine mammal foraging habitat in the proposed project area.

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes proposed for authorization through promulgation of regulations and issuance of a LOA, which will inform NMFS' consideration of "small numbers," the negligible impact determinations, and impacts on subsistence uses.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines "harassment" as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would primarily be by Level B harassment, as use of the acoustic sources (*i.e.*, vibratory and impact pile driving) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for high frequency cetaceans and phocids because predicted auditory injury zones are larger than for mid-frequency cetaceans and otariids. Auditory injury is unlikely to occur for mysticetes, mid-frequency cetaceans, and otariids due to measures described in the Proposed Mitigation section. The proposed mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable. As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below, we describe how the proposed take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent

hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (e.g., previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimates.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably likely to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (e.g., frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (e.g., bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage,

depth) and can be difficult to predict (e.g., Southall *et al.*, 2007, 2021; Ellison *et al.*, 2012). Based on the best scientific information available and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB re 1 μPa for continuous (e.g., vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 μPa for non-explosive impulsive (e.g., seismic airguns) or intermittent (e.g., scientific sonar) sources. Generally speaking, Level B harassment estimates based on these behavioral harassment thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

The POA’s proposed activity includes the use of continuous (vibratory pile

driving) and intermittent (impact pile driving) noise sources, and therefore, the RMS SPL thresholds of 120 and 160 dB re 1 μPa are applicable.

Level A harassment. NMFS’ Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0; NMFS, 2018) and the draft Updated Technical Guidance (NMFS, 2024) identify dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). This proposed rule estimates Level A harassment using the existing Technical Guidance (NMFS, 2018) as well as the draft Updated Technical Guidance (NMFS, 2024) because at the time of the final agency decision on this request for incidental take, it’s possible NMFS may have made a final agency decision on the draft Guidance.

These thresholds are provided in the tables below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS’ 2018 Technical Guidance and NMFS’ 2024 draft Updated Technical Guidance, both of which may be accessed at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance>.

The POA’s proposed activity includes the use of impulsive (impact pile driving) and non-impulsive (vibratory driving) sources.

TABLE 7—NMFS’ 2018 THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT (PTS)

Hearing group	PTS onset acoustic thresholds* (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	Cell 1: $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	Cell 2: $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	Cell 3: $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	Cell 4: $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	Cell 5: $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	Cell 6: $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW)(Underwater)	Cell 7: $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	Cell 8: $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW)(Underwater)	Cell 9: $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	Cell 10: $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 μPa, and cumulative sound exposure level (L_E) has a reference value of 1μPa²s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI, 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for NMFS’ 2018 Technical Guidance. Hence, the subscript “flat” is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (i.e., varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

TABLE 8—NMFS’ 2024 THRESHOLDS IDENTIFYING THE ONSET OF AUDITORY INJURY (AUD INJ)

Hearing group	AUD INJ acoustic thresholds* (received level)	
	Impulsive	Non-impulsive
Underwater:		
Low-Frequency (LF) Cetaceans	Cell 1: $L_{p,0-pk,flat}$: 222 dB; $L_{E,p,LF,24h}$: 183 dB	Cell 2: $L_{E,p,LF,24h}$: 197 dB.
High-Frequency (HF) Cetaceans	Cell 3: $L_{p,0-pk,flat}$: 230 dB; $L_{E,p,HF,24h}$: 193 dB	Cell 4: $L_{E,p,HF,24h}$: 201 dB.
Very High-Frequency (VHF) Cetaceans	Cell 5: $L_{p,0-pk,flat}$: 202 dB; $L_{E,p,VHF,24h}$: 159 dB	Cell 6: $L_{E,p,VHF,24h}$: 181 dB.
Phocid Pinnipeds (PW) (Underwater)	Cell 7: $L_{p,0-pk,flat}$: 223 dB; $L_{E,p,PW,24h}$: 183 dB	Cell 8: $L_{E,p,PW,24h}$: 195 dB.
Otariid Pinnipeds (OW) (Underwater)	Cell 9: $L_{p,0-pk,flat}$: 230 dB; $L_{E,p,OW,24h}$: 185 dB	Cell 10: $L_{E,p,OW,24h}$: 199 dB.
In-air:		
Phocid Pinnipeds (PA) (In-Air)	Cell 11: $L_{p,0-pk,flat}$: 162 dB; $L_{E,p,PA,24h}$: 140 dB	Cell 12: $L_{E,p,PA,24h}$: 154 dB.
Otariid Pinnipeds (OA) (In-Air)	Cell 13: $L_{p,0-pk,flat}$: 177 dB; $L_{E,p,OA,24h}$: 163 dB	Cell 14: $L_{E,p,OA,24h}$: 177 dB.

*Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating AUD INJ onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 μ Pa, and cumulative sound exposure level (L_E) has a reference value of 1 μ Pa²s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI, 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for NMFS’ 2018 Technical Guidance. Hence, the subscript “flat” is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.*, varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the proposed project. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.*, impact pile removal and vibratory pile installation and removal). Calculation of the area ensonified by the proposed action is dependent on the background sound levels at the project site, the source levels of the proposed activities, and the estimated transmission loss coefficients for the proposed activities at the site. These factors are addressed in order, below.

Background Sound Levels at the Port of Alaska—As noted in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section of this proposed rule, the POA is an industrial facility in a location with high levels of commercial vessel traffic, port operations (including dredging), and extreme tidal flow. Previous measurements of background noise at the POA have recorded a background SPL of 122.2 dB RMS (Austin *et al.*, 2016). NMFS concurs that this SPL reasonably represents background noise near the proposed project area, and therefore, we have used 122.2 dB RMS as the threshold for Level B harassment (instead of 120 dB RMS).

Sound Source Levels of Proposed Activities—The intensity of pile driving sounds is greatly influenced by factors such as the type of piles (material and diameter), hammer type, and the physical environment (*e.g.*, sediment type) in which the activity takes place. In order to calculate the distances to the Level A harassment and the Level B harassment sound thresholds for the methods and piles being used in this project, we used acoustic monitoring data from sound source verification studies (both at the POA and elsewhere) to develop proxy source levels for the various pile types, sizes and methods (tables 9 and 10).

The POA collected sound measurements during pile installation and removal for 3 seasons (Austin *et al.* 2016; Illingworth & Rodkin [I&R] 2021a, 2021b); a summary of these data and findings can be found in appendix A of the POA’s application.

Vibratory Driving—NMFS concurs that the source levels proposed by the POA for vibratory installation and removal of all pile types are appropriate to use for calculating harassment isopleths for the POA’s proposed CTR activities (tables 9 and 10). The proposed sound levels for vibratory removal are based on an analysis done for the POA’s NES1 IHA (89 FR 2832, January 14, 2024) and are partially based on sound source verification data measured at the POA during the PCT project (Illingworth and Rodkin, 2021a). Interestingly, the analyzed RMS SPL for the unattenuated vibratory removal of 24-in (61-cm) piles was much louder than the unattenuated vibratory removal

of 36-in piles (91-cm), and even louder than the unattenuated vibratory installation of 24-in piles. Illingworth and Rodkin (2023) suggest that at least for data recorded at the POA, the higher 24-in (61-cm) removal levels are likely due to the piles being removed at rates of 1,600 to 1,700 revolutions per minute (rpm), while 36-in (91-cm) piles, which are significantly heavier than 24-in (61-cm) piles, were removed at a rate of 1,900 rpm. The slower rates combined with the lighter piles would cause the hammer to easily “jerk” or excite the 24-in (61-cm) piles as they were extracted, resulting in a louder rattling sound and louder sound levels. This did not occur for the 36-in (91-cm) piles, which were considerably heavier due to increased diameter, longer length, and greater thickness.

The TPP found that for vibratory installation of 48-in piles, an air bubble curtain provided about a 9-dB reduction at 10 meters. An 8-dB reduction at close-in positions was estimated for vibratory pile driving that occurred during the PCT project in 2021 (I&R 2021b). The PCT 2020 measurements indicated 2 to 8 dB reduction for the 48-in piles at 10 meters, but no apparent broadband reduction was found in the far-field at about 2,800 meters (I&R 2021a). Far-field sound levels were characterized by very low frequency sound at or below 100 Hz, causing broadband measurements to remain above the ambient RMS level at approximately 2.8km from the source. However, levels at frequencies above 100 Hz were effectively reduced by the bubble curtain system. Because CIBW

are most sensitive to frequencies over 100 Hz, NMFS considers the use of bubble curtains during vibratory driving to be an effective and important mitigation measure for CIBW.

Based on the aforementioned measurements conducted at POA, for vibratory driving during the CTR Project, it is assumed that a well-designed and robust bubble curtain system will achieve a mean reduction of 7 dB at the source and will also reduce sound levels at frequencies over 100 Hz at longer ranges. The POA proposes to use a bubble curtain when water depth is greater than 3 meters during vibratory installation of all permanent (72-in) piles and during vibratory driving of temporary (24-in or 36-in) piles during the months of August through October when CIBWs are most likely to be present.

Impact Driving—NMFS concurs that the source levels proposed by the POA for impact installation of all pile types are appropriate to use for calculating harassment isopleths for the POA's proposed CTR activities (tables 9 and 10). Impact driving of temporary piles (24-in and 36-in piles) is not currently proposed; however, in the unlikely event that vibratory driving is insufficient to stabilize a temporary pile, impact driving may be necessary. Sound source verification studies at the POA during the PCT project did not measure unattenuated impact driving of 24-in or 36-in piles; therefore, proxy sound levels from Navy (2015) are proposed.

The TPP measured reductions of 9 to 12 dB for a 48-in pile installed with an impact hammer using a confined air bubble curtain. The PCT 2020 measurements (I&R 2021a) found reductions of about 10 dB when comparing the attenuated conditions that occurred with that project to unattenuated conditions for the TPP. The TPP did not report the reduction in sound levels in the acoustic far field; however, the computed distances to 125 dB RMS isopleths were essentially reduced by half with the bubble curtain (from 1,291 to 698 meters).

It is currently unclear whether the POA's proposed bubble curtain system for the CTR project will be confined or unconfined; confined systems are typically more effective, especially in sites like Knik Arm, with high current velocity. Therefore, for impact pile installation for the CTR Project, it is assumed that a well-designed and robust bubble curtain system will achieve a mean reduction of 7 dB from the source. The POA proposes to use a bubble curtain system on all permanent

piles in all months, which will be installed with both vibratory and impact hammers. The bubble curtain by necessity will be installed around each permanent pile as it is moved into position, and therefore, the bubble curtain will be available as a mitigation measure to reduce sound levels throughout each driving event for permanent 72-in piles when water depth is greater than 3 meters. To account for piles driven in water less than 3m deep, NMFS has estimated approximately 0.5 unattenuated 72-in piles will be driven (approximately 43 minutes of impact driving and 5 minutes of vibratory driving) each month.

Concurrent activities—The POA proposes to concurrently operate up to two hammers to install or extract piles at different parts of the project site, in order to reduce the need for pile driving during months of high beluga presence. When two noise sources have overlapping sound fields, the sources are considered additive and combined using the rules of dB addition. For addition of two simultaneous sources, the difference between the two sound source levels is calculated, and if that difference is between 0 and 1 dB, 3 dB are added to the higher sound source levels; if the difference is between 2 and 3 dB, 2 dB are added to the highest sound source levels; if the difference is between 4 and 9 dB, 1 dB is added to the highest sound source levels; and with differences of 10 or more dB, there is no addition. For two simultaneous sources of different type (*i.e.*, impact and vibratory driving), there is no sound source addition.

Possible concurrent scenarios are shown in table 3; the predicted source values and transmission loss coefficients for these combinations are shown in table 11.

Transmission Loss. For all piles driven with an active bubble curtain ("attenuated" impact and vibratory driving), and for unattenuated impact installation, the POA proposed to use 15 as the *TL* coefficient, meaning they assume practical spreading loss (*i.e.*, the POA assumes $TL = 15 * \text{Log}_{10}(\text{range})$); NMFS concurs with this value and has assumed practical spreading loss for all (attenuated impact and vibratory) driving and unattenuated impact driving.

The *TL* coefficient that the POA proposed for unattenuated vibratory installation and removal of piles is 16.5 (*i.e.*, $TL = 16.5 * \text{Log}_{10}(\text{range})$). This value is an average of measurements obtained from two 48-in (122-cm) piles installed

via an unattenuated vibratory hammer in 2016 (Austin *et al.*, 2016). To assess the appropriateness of this *TL* coefficient to be used for the proposed project, NMFS examined and analyzed additional *TL* measurements recorded at the POA. This includes a *TL* coefficient of 22 (deep hydrophone measurement) from the 2004 unattenuated vibratory installation of one 36-in (91-cm) pile at Port MacKenzie, across Knik Arm from the POA (Blackwell, 2004), as well as *TL* coefficients ranging from 10.3 to 18.2 from the unattenuated vibratory removal of 24-in (61 cm) and 36-in (91-cm) piles and the unattenuated vibratory installation of one 48-in (122-cm) pile at the POA in 2021 (I&R 2021, 2023). To account for statistical interdependence due to temporal correlations and equipment issues across projects, values were averaged first within each individual project, and then across projects. The mean and median value of the measured *TL* coefficients for unattenuated vibratory piles in Knik Arm by project are equal to 18.9 and 16.5, respectively. NMFS proposes to use the project median *TL* coefficient of 16.5 during unattenuated vibratory installation and removal of all piles during the CTR project. This value is representative of all unattenuated vibratory measurements in the Knik Arm, *i.e.*, including data from POA and Port MacKenzie. Further, 16.5 is the mean of the 2016 measurements, which were made closer to the CTR proposed project area than other measurements and were composed of measurements from multiple directions (both north and south/southwest).

In certain scenarios, the POA may perform concurrent vibratory driving of two piles. The POA proposed, and NMFS concurs, that in the event that both piles are unattenuated, the *TL* coefficient would be 16.5; if both piles are attenuated, the *TL* coefficient would be 15. In the event that one pile is attenuated and one is unattenuated, the POA proposed a *TL* coefficient of 15.75 to be used in the acoustic modeling. NMFS evaluated the contributions of one attenuated and one unattenuated vibratory-driven pile to the sound field (assuming a 7-dB reduction in source level due to the bubble curtain for the attenuated source), and determined that the unattenuated source would likely dominate the received sound field. Therefore, the POA's proposed *TL* coefficient is conservative, and NMFS concurs with this value.

TABLE 9—SUMMARY OF UNATTENUATED IN-WATER PILE DRIVING PROXY LEVELS
[at 10 m]

Vibratory hammer					
Method and pile type	dB rms		TL coefficient	Data source for source levels	
24-in steel installation	161		16.5	U.S. Navy 2015. NMFS average 2023; see 89 FR 2832. U.S. Navy 2015. NMFS average 2023; see 89 FR 2832. I&R 2003, unpublished data for Castrol Oil berthing dolphin in Richmond, CA.	
24-in steel removal	169				
36-in steel installation	166				
36-in steel removal	159				
72-in steel	171				
Impact hammer					
	dB rms	dB SEL	dB peak	TL coefficient	Data source for source levels
24-in steel	193	181	210	15.0	U.S. Navy 2015. U.S. Navy 2015. I&R model. Estimate based on interpolation of data for piles 24 to 144 inches in diameter.
36-in steel	193	184	211		
72-in steel	203	191	217		

TABLE 10—SUMMARY OF ATTENUATED IN-WATER PILE DRIVING PROXY LEVELS
[at 10 m]

Vibratory hammer					
Method and pile type	dB rms		TL coefficient	Reference for proxy levels	
24-in steel installation	158.5		15.0	I&R 2021a (measured). I&R 2021a (measured). I&R 2021a, 2021b (measured). I&R 2021a (measured). Assumed 7-dB reduction supported by I&R 2021a.	
24-in steel removal	157				
36-in steel installation	160.5				
36-in steel removal	154				
72-in steel	164				
Impact hammer					
	dB rms	dB SEL	dB peak	TL coefficient	Reference for proxy levels
24-in steel	186	174	203	15.0	Assumed 7-dB reduction supported by I&R 2021a. Assumed 7-dB reduction supported by I&R 2021a. Assumed 7-dB reduction supported by Caltrans Compendium (2020).
36-in steel	186	177	204		
72-in steel	196	184	210		

TABLE 11—SOURCE VALUES FOR POTENTIAL CONCURRENT DRIVING SCENARIOS¹

Activity	Method	Pile type/size ²	Attenuated or unattenuated	Proxy source value			TL coefficient	# Piles per day ³
				dB RMS	dB SEL	dB peak		
Concurrent Driving (2 sources)	Vibratory/Vibratory	36-in and 36-in	Attenuated/Attenuated	163.5	15	8
			Attenuated/Unattenuated	169	15.75	8
			Unattenuated/Unattenuated	171	16.5	8
			Unattenuated/Attenuated	166	15	7
	Vibratory/Impact ¹	36-in and 72-in	Attenuated/Attenuated	169	15.75	7
			Attenuated/Unattenuated	160.5/196	—/210	15/15	8
			Unattenuated/Attenuated	166/196	—/184	16.5/15	8
			Unattenuated/Unattenuated	—/210	7

¹ Concurrent vibratory and impact driving source values and TL coefficients are the same as for the piles driven individually (shown in tables 7 and 8), with no adjustments for concurrent driving. The Level A harassment isopleths would be determined by the calculated impact pile driving isopleths, and Level B harassment isopleth would be generated by vibratory pile driving.

² POA may elect to use either 36-in or 24-in temporary piles; as 36-in piles are more likely and estimated to have larger ensouffled areas, we have used these piles in our analyses of concurrent activities.

³ Piles per day were calculated as the maximum daily number of each type of pile (24-in and 36-in = 4 piles per hammer per day; 72-in piles = 3 piles per day) with complete overlap for 45 minutes of driving with the largest possible combined source value, a scenario that would over-estimate duration of noise production given the estimated time required to drive 72-in piles with a vibratory hammer (10 minutes).

Estimated Harassment Isoleths. All estimated Level B harassment isopleths are reported in tables 15 and 16. At POA, Level B harassment isopleths from the proposed project will be limited in some cases to less than the estimated value by the coastline along Knik Arm along and across from the project site. The maximum predicted isopleth distance for a single pile is 9,069 m during vibratory installation of unattenuated 72-in (182-cm) steel pipe piles. For concurrent driving the maximum isopleth distance is 9,363 m during vibratory driving of two unattenuated 24- or 36-in piles or during vibratory driving of one attenuated (24-, 36-, or 72-in) and one

unattenuated (24- or 36-in) pile (tables 15 and 16).

The ensonified area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some

degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources, such as pile driving, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur auditory injury. Inputs used in the optional User Spreadsheet tool and the resulting estimated isopleths are reported in tables 12 through 14, below.

TABLE 12—NMFS USER SPREADSHEET INPUTS FOR 72-IN PERMANENT PILES

	Impact pile driving		Vibratory pile driving	
	Attenuated	Unattenuated ¹	Attenuated	Unattenuated ¹
Spreadsheet tab used	(E.1) Impact pile driving		(A.1) Non-Impul, Stat, Cont.	
Source Level	184 dB SEL	191 dB SEL	164 dB RMS	171 dB RMS
Transmission Loss Coefficient	15	15	15	16.5
Weighting Factor Adjustment (kHz)	2		2.5	
Time to install single pile (minutes)	—		10	
Number of strikes per pile	5,743		—	
Piles per day	1—3	1	3	
Distance of sound pressure level measurement (m)	10			

¹ To account for piles driven in water less than 3m deep, NMFS has estimated approximately 0.5 unattenuated 72-in piles will be driven (approximately 43 minutes of impact driving and 5 minutes of vibratory driving) each month.

TABLE 13—NMFS USER SPREADSHEET INPUTS FOR TEMPORARY (24- OR 36-IN) PILES

	Vibratory pile driving							
	24-in (61-cm) steel pipe				36-in (91-cm) steel pipe			
	Installation		Removal		Installation		Removal	
	Atten.	Unatten.	Atten.	Unatten.	Atten.	Unatten.	Atten.	Unatten.
Spreadsheet Tab Used	(A.1) Non-Impul, Stat, Cont.							
Source Level (dB RMS)	158.5	161	157	169	160.5	166	154	159
Transmission Loss Coefficient	15	16.5	15	16.5	15	16.5	15	16.5
Weighting Factor Adjustment (kHz)	2.5							
Time to install or remove single pile (minutes)	30		45		30		45	
Number of strikes per pile	—							
Piles per day	4							
Distance of sound pressure level measurement (m)	10							
	Impact Pile Driving							
	24-in (61-cm) steel pipe				36-in (91-cm) steel pipe			
	Attenuated		Unattenuated		Attenuated		Unattenuated	
Spreadsheet Tab Used	(E.1) Impact pile driving							
Source Level (dB RMS)	174 dB SEL		181 dB SEL		177 dB SEL		184 dB SEL	
Transmission Loss Coefficient	15							
Weighting Factor Adjustment (kHz)	2							
Time to install or remove single pile (minutes)	—							

TABLE 13—NMFS USER SPREADSHEET INPUTS FOR TEMPORARY (24- OR 36-in) PILES—Continued

	Vibratory pile driving							
	24-in (61-cm) steel pipe				36-in (91-cm) steel pipe			
	Installation		Removal		Installation		Removal	
	Atten.	Unatten.	Atten.	Unatten.	Atten.	Unatten.	Atten.	Unatten.
Number of strikes per pile					1,000			
Piles per day					1			
Distance of sound pressure level measurement (m)					10			

TABLE 14—NMFS USER SPREADSHEET INPUTS FOR CONCURRENT VIBRATORY DRIVING

	24- or 36-in AND 24-in or 36-in			24- or 36-in AND 72-in	
	Attenuated/attenuated	Attenuated/unattenuated	Unattenuated/unattenuated	Attenuated/attenuated	Unattenuated/attenuated
Spreadsheet Tab Used	(A.1) Non-Impul, Stat, Cont.				
Source Level (dB RMS)	163.5	170	172	166	170
Transmission Loss Coefficient	15	15.75	16.5	15	15.75
Weighting Factor Adjustment (kHz)	2.5				
Time to install or remove a single pile (minutes)	45				
Number of strikes per pile	—				
Piles per day	8			7	
Distance of sound pressure level measurement (m)	10				

TABLE 15—CALCULATED DISTANCE OF LEVEL A (BASED ON NMFS’ 2018 TECHNICAL GUIDANCE) AND LEVEL B HARASSMENT ISOPLETHS BY PILE TYPE AND PILE DRIVING METHOD

Activity	Pile type/size	Attenuated or unattenuated	Level A harassment distance (m)					Level B harassment distance (m) all hearing groups ¹	
			LF	MF	HF	PW	OW		
Impact	24-in (61-cm)	Unattenuated	735	27	876	394	29	1,585	
		Attenuated	251	9	299	135	10	541	
	36-in (91-cm)	Unattenuated	1,165	42	1,387	624	46	1,585	
		Attenuated	398	15	474	213	16	541	
	72-in (182-cm)	Unattenuated	10,936	389	13,026	5,853	427	7,356	
		Attenuated (1 pile per day) ...	3,734	133	4,448	1,999	146	2,512	
Attenuated (2 piles per day) ...		5,928	211	7,061	3,173	231		
Vibratory Installation	24-in (61-cm)	Attenuated (3 piles per day) ...	7,767	277	9,252	4,157	303	
		Unattenuated	11	2	16	7	1	2,247	
	36-in (91-cm)	Attenuated	8	1	11	5	1	2,630	
		Unattenuated	22	3	31	14	2	4,514	
	72-in (182-cm)	Attenuated	11	1	15	7	1	3,575	
		Unattenuated	19	3	27	12	2	9,069	
Vibratory Removal	24-in (61-cm)	Attenuated	7	1	11	5	1	6,119	
		Unattenuated	42	4.6	60	27	2.4	6,861	
	36-in (91-cm)	Attenuated	16	1.7	23	11	1	2,583	
		Unattenuated	11	2	15	7	1	1,699	
	Concurrent Vibratory	36-in AND 36-in	Attenuated	5	1	8	3	1	1,318
			Attenuated/Attenuated	33	2.9	49	20	1.4	5,667
Concurrent Vibratory/Impact	36-in AND 72-in	Attenuated/Unattenuated	81	8.0	118	51	4.0	9,363	
		Unattenuated/Unattenuated ..	98	11	139	62	5.5	9,069	
	36-in AND 72-in	Attenuated/Attenuated	45	3.9	66	27	1.9	8,318	
		Unattenuated/Attenuated	75	7.4	108	47	3.7	9,363	
	36-in AND 72-in	Attenuated/Attenuated (1 pile per day) ..	3,734	133	4,448	1,999	146	3,575	
		Attenuated/Attenuated (2 piles per day) ..	5,928	211	7,061	3,173	231	
Attenuated/Attenuated (3 piles per day) ..		7,767	277	9,252	4,157	303		
Unattenuated/Attenuated (1 pile per day) ..		3,734	133	4,448	1,999	146	4,514		
36-in AND 72-in	Unattenuated/Unattenuated (2 piles per day) ..	5,928	211	7,061	3,173	231		
	Unattenuated/Attenuated (3 piles per day) ..	7,767	277	9,252	4,157	303		

¹ Distances to thresholds are as modeled; however, interaction with shorelines would truncate zones. See figures 6–1 through 6–10 in the POA’s application for further details.

TABLE 16—CALCULATED DISTANCE AND AREAS OF LEVEL A (BASED ON NMFS’ PROPOSED 2024 UPDATE TO THE 2018 TECHNICAL GUIDANCE) AND LEVEL B HARASSMENT ISOPLETHS BY PILE TYPE AND PILE DRIVING METHOD

Activity	Pile type/size	Attenuated or unattenuated	Level A harassment distance (m)					Level B harassment distance (m) all hearing groups ¹	
			LF	HF	VHF	PW	OW		
Impact	24-in (61-cm)	Unattenuated	732	94	1,133	651	243	1,585	
		Attenuated	250	32	387	222	83	541	
	36-in (91-cm)	Unattenuated	1,160	148	1,796	1,031	385	1,585	
		Attenuated	397	51	613	352	132	541	
	72-in (182-cm)	Unattenuated	10,896	1,390	16,861	9,679	3,608	7,356	
		Attenuated (1 pile per day)	3,720	474.7	5,757	3,305	1,232	2,512	
Attenuated (2 piles per day)		5,906	753.5	9,139	5,246	1,956			
Vibratory Installation	24-in (61-cm)	Unattenuated	14.1	5.9	11.8	17.8	6.6	2,247	
		Attenuated	10	3.8	8.1	12.8	4.3	2,630	
	36-in (91-cm)	Unattenuated	28.4	11.9	23.6	35.7	13.3	4,514	
		Attenuated	13.6	5.2	11.1	17.5	5.9	3,575	
	72-in (182-cm)	Unattenuated	24.6	10.3	20.5	31	11.5	9,069	
		Attenuated	9.2	3.5	7.5	11.9	4	6,119	
Vibratory Removal	24-in (61-cm)	Unattenuated	55.2	23.1	45.9	69.5	25.8	6,861	
		Attenuated	10.4	4	8.5	13.4	4.5	2,583	
	36-in (91-cm)	Unattenuated	13.7	5.7	11.4	17.2	6.4	1,699	
		Attenuated	6.6	2.5	5.4	8.4	2.8	1,318	
Concurrent Vibratory/Vibratory.	36-in AND 36-in	Unattenuated/Unattenuated	44.7	17.2	36.5	57.5	19.4	5,667	
		Attenuated/Attenuated	107.6	43.3	88.8	136.9	48.5	9,363	
	36-in AND 72-in	Unattenuated/Unattenuated	127.7	53.5	106.3	160.7	59.7	9,069	
		Attenuated/Attenuated	60	23.1	49	77.3	26	8,318	
	Concurrent Vibratory/Impact	36-in AND 72-in	Unattenuated/Attenuated	98.9	39.8	81.6	125.8	44.6	9,363
			Attenuated/Attenuated (1 pile per day).	3,720	474.7	5,757	3,305	1,232	3,575
36-in AND 72-in		Attenuated/Attenuated (2 piles per day).	5,906	753.5	9,139	5,246	1,956		
		Attenuated/Attenuated (3 piles per day).	7,739	987.4	11,976	6,875	2,563		
36-in AND 72-in	Unattenuated/Attenuated (1 pile per day).	3,720	474.7	5,757	3,305	1,232	4,514		
	Unattenuated/Attenuated (2 piles per day).	5,906	753.5	9,139	5,246	1,956			
	Unattenuated/Attenuated (3 piles per day).	7,739	987.4	11,976	6,875	2,563			

¹ Distances to thresholds are as modeled; however, interaction with shorelines would truncate zones. See figures 6–1 through 6–10 in the POA’s application for further details.

Marine Mammal Occurrence

In this section, we provide information about the occurrence of marine mammals, including density or other relevant information, which will inform the take calculations. Available information regarding marine mammal occurrence and abundance in the vicinity of the POA includes monitoring data from the PCT and SFD projects. These programs produced a unique and comprehensive data set of marine mammal sightings and for CIBWs, locations and movements near the POA (61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022). This is the most current data set available for Knik Arm. During the PCT and SFD projects, the POA’s marine mammal monitoring programs included 11 PSOs working from four elevated, specially designed monitoring stations located along a 9-km stretch of coastline surrounding the POA. The number of days data was collected varied among

years and projects, with 128 days during PCT Phase 1 in 2020, 74 days during PCT Phase 2 in 2021, and 13 days during SFD in 2022 (see table 6–15 in the POA’s application for additional information regarding CIBW monitoring data). PSOs during these projects used 25-power “big-eye” and hand-held binoculars to detect and identify marine mammals and theodolites to track movements of CIBW groups over time and collect location data while they remained in view.

These POA monitoring programs were supplemented in 2021 with a NMFS-funded visual marine mammal monitoring project that collected data during non-pile driving days during PCT Phase 2 (Easley-Appleyard and Leonard, 2022). NMFS replicated the POA monitoring efforts, as feasible, including use of 2 of the POA’s monitoring platforms, equipment (Big Eye binoculars, theodolite, 7x50 reticle binoculars), data collection software, monitoring and data collection protocol,

and observers; however, the NMFS-funded program utilized only 4 PSOs and 2 observation stations along with shorter (4- to 8-hour) observation periods compared to PCT or SFD data collection, which included 11 PSOs, 4 observation stations, and most observation days lasting close to 10 hours. Despite the differences in effort, the NMFS dataset fills in gaps during the 2021 season and is thus valuable in this analysis. NMFS’ PSOs monitored for 231.6 hours on 47 non-consecutive days in July, August, September, and October.

Density data are not available for any of the relevant species in this area; therefore, we have used reasonable yearly, monthly, or hourly occurrence estimates based on the previous POA monitoring datasets for all species. Table 17 shows the estimated occurrence rates for non-CIBW species at the POA; descriptions are provided in the text below.

TABLE 17—ESTIMATED OCCURRENCE FOR NON-CIBW SPECIES AT THE POA

Species	Timeframe	Estimated occurrence rates	Estimated annual occurrence	Estimated 5-year occurrence
Gray whale	Yearly	6/year	6	30
Humpback whale		4/year	4	20
Killer whale		6/year	6	30
Steller sea lion		9/year	9	45
Harbor porpoise	Hourly	0.15/hour	1,314	6,570
Harbor seal		1/hour	8,760	43,800

Gray Whale

Sightings of gray whales in the proposed project area are rare. Few, if any, gray whales are expected to approach the proposed project area. However, based on three separate sightings of single gray whales near the POA in 2020 and 2021 (61N Environmental, 2021, 2022a; Easley-Appleyard and Leonard, 2022), the POA anticipates that up to six individuals could occur within estimated harassment zones each year during CTR project activities.

Humpback Whale

Sightings of humpback whales in the proposed project area are rare, and few, if any, humpback whales are expected to approach the proposed project area. However, there have been a few observations of humpback whales near the POA. Based on the two sightings in 2017 of what was likely a single individual at the Anchorage Public Boat Dock at Ship Creek (ABR, Inc., 2017) south of the Project area, the POA requested authorization of six takes of humpback whales per year of the CTR project. However, given the maximum number of humpback whales observed within a single construction season was two (in 2017), NMFS instead anticipates that only up to four humpback whales could be exposed to project-related underwater noise per year during the CTR project.

Killer Whale

Few, if any, killer whales are expected to approach the CTR project area. No killer whales were sighted during previous monitoring programs for POA construction projects, including the 2016 TPP, 2020 PCT, and 2022 SFD projects (Prevel-Ramos *et al.*, 2006; Markowitz and McGuire, 2007; Cornick and Saxon-Kendall, 2008, 2009; Cornick *et al.*, 2010, 2011; ICRC, 2009, 2010, 2011, 2012; Cornick and Pinney, 2011; Cornick and Seagars, 2016; 61N Environmental, 2021, 2022b), except during PCT construction in 2021, when two killer whales were sighted (61N Environmental, 2022a). Previous

sightings of transient killer whales have documented pod sizes in upper Cook Inlet between one and six individuals (Shelden *et al.*, 2003). While unlikely, it is possible that killer whales could approach the POA from the northern portion of Knik Arm, and immediately enter into a Level A harassment zone before PSOs are able to shut down pile driving activities. The POA estimates, and NMFS concurs, that one pod (assumed to be six individuals) could be taken by Level A harassment over the 5 years of the CTR project. NMFS also concurs that no more than one pod (assumed to be six individuals) could occur within the Level B harassment zones during CTR project activities per year.

Harbor Porpoise

Monitoring data recorded from 2005 through 2022 were used to evaluate hourly sighting rates for harbor porpoises in the proposed CTR area (see table 4–3 in the POA's application). During most years of monitoring, no harbor porpoises were observed. However, there has been an increase in harbor porpoise sightings in upper Cook Inlet in recent decades (*e.g.*, 61N Environmental, 2021, 2022a; Shelden *et al.*, 2014). The highest sighting rate for any recorded year during in-water pile installation and removal was an average of 0.037 harbor porpoises per hour during PCT construction in 2021, when observations occurred across most months. Given the uncertainty around harbor porpoise occurrence at the POA and potential that occurrence is increasing, the POA calculated requested takes using a sighting rate of 0.5 harbor porpoises per hour. For the recent NES1 project (88 FR 76576, November 6, 2023), NMFS estimated that a more realistic sighting rate would be closer to approximately 0.07 harbor porpoises per hour (the 2021 rate of 0.037 harbor porpoises per hour doubled). However, the sizes of the ensonified areas for the NES1 project are much smaller than those predicted for the proposed CTR project. Based on the larger ensonified areas, which more

closely resemble the observable area from the PCT project, the cryptic nature of the species, and the potential for increased occurrence of harbor porpoise in and around upper Cook Inlet, NMFS estimates that approximately 0.15 harbor porpoises per hour (four times the maximum observed 2021 rate of 0.037 per hour) may be observed near the proposed CTR area during the 5 years covered under this proposed rulemaking.

Steller Sea Lion

Steller sea lions are anticipated to occur in low numbers within the proposed CTR project area as summarized in the Description of Marine Mammals in the Area of Specified Activities section. Similar to the approach used above for harbor porpoises, the POA used previously recorded sighting rates of Steller sea lions near the POA to estimate requested take for this species. During SFD construction in May and June of 2022, the hourly sighting rate for Steller sea lions was 0.028. The hourly sighting rate for Steller sea lions in 2021, the most recent year with observations across most months, was approximately 0.01. The highest number of Steller sea lions that have been observed during the 2020–2022 monitoring efforts at the POA was nine individuals (eight during PCT Phase 1 monitoring and one during NMFS' 2021 monitoring).

Recent counts of sightings of Steller sea lions around the POA may include multiple re-sights of single individuals. For instance, in 2016, Steller sea lions were observed on 2 separate days. On May 2, 2016, one individual was sighted, while on May 25, 2016, there were five Steller sea lion sightings within a 50-minute period, and these sightings occurred in areas relatively close to one another (Cornick and Seagars, 2016). Given the proximity in time and space, it is believed these five sightings were of the same individual sea lion. The POA is concerned that multiple re-sights of a single individual within a day may overestimate the true number of individuals exposed to sound

levels at or above harassment thresholds over the course of the proposed project. Therefore, given the uncertainty around Steller sea lion occurrence at the POA and potential that occurrence is increasing, the POA estimated that approximately 0.14 Steller sea lions per hour (the May and June 2022 rate of 0.028 Steller sea lions per hour multiplied by a factor of 5) may be observed near the proposed CTR project areas per hour of hammer use. However, the highest number of Steller sea lion sightings during the 2020–2022 monitoring efforts at the POA was nine (eight during PCT Phase 1 monitoring and one during NMFS’ 2021 monitoring).

Given the POA’s estimate assumes a higher Steller sea lion sighting rate (0.14) than has been observed at the POA and results in an estimate that is more than double the maximum number of Steller sea lions observed in a year, NMFS believes that the sighting rate proposed by the POA overestimates potential exposures of this species. Based on the ensonified areas, which closely resemble the observable area from the PCT project, the potential for re-sightings of individual animals, and the uncertainty around increased occurrence of Steller sea lions in and around upper Cook Inlet, NMFS instead proposes that nine Steller sea lions (the maximum number observed in a single year between 2020 and 2022 during projects with similar sized harassment isopleths) may be taken each year during the 5 years covered under this proposed rulemaking, up to a total of 45 individuals over the course of the project.

Harbor Seal

No known harbor seal haulout or pupping sites occur in the vicinity of the POA. In addition, harbor seals are not known to reside in the proposed CTR project area, but they are seen regularly near the mouth of Ship Creek when salmon are running, from July through September. With the exception of newborn pups, all ages and sexes of harbor seals could occur in the CTR project area. Harbor seals often appear

curious about onshore activities and may approach closely. The mouth of Ship Creek, where harbor seals linger, is about 1,500 m from the southern end of the CTR.

The POA evaluated marine mammal monitoring data to calculate hourly sighting rates for harbor seals in the CTR project area (see table 4–1 in the POA’s application). Of the 524 harbor seal sightings in 2020 and 2021, 93.7 percent of the sightings were of single individuals; only 5.7 percent of sightings were of two individual harbor seals, and only 0.6 percent of sightings reported three harbor seals. Sighting rates of harbor seals were highly variable and appeared to have increased during monitoring between 2005 and 2022. It is unknown whether any potential increase was due to local population increases or habituation to ongoing construction activities. The highest individual hourly sighting rate recorded for a previous year was used to quantify take of harbor seals for in-water pile installation and removal associated with CTR. This occurred in 2021 during PCT Phase 2 construction, when harbor seals were observed from May through September. A total of 220 harbor seal sightings were observed over 734.9 hours of monitoring, at an average rate of 0.30 harbor seal sightings per hour. The maximum monthly sighting rate occurred in September 2020 and was 0.51 harbor seal sightings per hour. Based on these data, the POA estimated, and NMFS concurs, that approximately one harbor seal (the maximum monthly sighting rate (0.51) rounded up) may be observed near the CTR project per hour of hammer use.

Beluga Whale

CIBWs are regular and frequent visitors to Knik Arm, sometimes passing by the POA multiple times a day, as documented by the previous PAMP monitoring projects (61N Environmental, 2021, 2022a, 2022b). Distances from CIBW sightings to the CTR project site from the POA and NMFS-funded monitoring programs ranged from less than 10 m up to nearly 15 km. The robust marine mammal

monitoring programs in place at the POA from 2020 through 2022 located, identified, and tracked CIBWs at greater distances from the proposed project site than previous monitoring programs (*i.e.*, Kendall and Cornick, 2015) and has contributed to a better understanding of CIBW movements in upper Cook Inlet (*e.g.*, Easley-Appleyard and Leonard, 2022).

For the NES1 project, NMFS and the POA collaboratively developed a new sighting rate methodology that incorporates a spatial component for CIBW observations, which allows for more accurate estimation of potential take of CIBWs (89 FR 2832, January 14, 2024). We have used this same methodology in the analysis of estimated CIBW incidental take during the CTR project. A detailed description of the differences from the sighting-rate methods used in the PCT and SFD projects can be found in the notice of proposed IHA for the NES1 project (88 FR 76576, November 6, 2023).

During the POA’s and NMFS’ marine mammal monitoring programs for the PCT and SFD projects (table 18), PSOs had an increased ability to detect, identify, and track CIBWs groups at greater distances from the project work site when compared with previous years because of the POA’s expanded monitoring program as described above. This meant that observations of CIBWs in the 2020–2022 dataset (table 18) include sightings of individuals at distances far outside some of the ensonified areas estimated for the CTR project and at ranges close to the extent of the larger ensonified areas (tables 15 and 16). Therefore, it would not be appropriate to group all CIBW observations from these datasets into a single sighting rate as was done for the PCT and SFD projects. Rather, we propose that CIBW observations should be considered in relation to their distance to the CTR project site when determining appropriate sighting rates to use when estimating take for this project. This would help to ensure that the sighting rates used to estimate take are representative of CIBW presence in the proposed ensonified areas.

TABLE 18—MARINE MAMMAL MONITORING DATA USED FOR CIBW SIGHTING RATE CALCULATIONS

Year	Monitoring type and data source	Number of CIBW group fixes	Number of CIBW groups	Number of CIBWs
2020	PCT: POA Construction Monitoring 61N Environmental, 2021	2,653	245	987
2021	PCT: NMFS Monitoring Easley-Appleyard and Leonard, 2022	694	1109	575
2021	PCT: POA Construction Monitoring 61N Environmental, 2021, 2022a	1,339	132	517
2022	SFD: POA Construction Monitoring 61N Environmental, 2022b	151	9	41

¹ This number differs slightly from Table 6–8 in the POA’s application due to our removal of a few duplicate data points in the NMFS data set.

To incorporate a spatial component into the sighting rate methodology, the POA calculated each CIBW group's closest point of approach (CPOA) relative to the CTR proposed project site. The 2020–2022 marine mammal monitoring programs (table 18) enabled the collection, in many cases, of multiple locations of CIBW groups as they transited through Knik Arm, which allowed for track lines to be interpolated for many groups. The POA used these track lines, or single recorded locations in instances where only one sighting location was available, to calculate each group's CPOA. CPOAs were calculated in ArcGIS software using the Geographic Positioning System (GPS) coordinates provided for documented sightings of each group (for details on data collection methods, see 61N

Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022) and the CTR location midpoint, centered on the proposed project site. A CIBW group was defined as a sighting of one or more CIBWs as determined during data collection. The most distant CPOA location to CTR was 11,138 m and the closest CPOA location was 6 m.

The cumulative density distribution of CPOA values represents the percentage of CIBW observations that were within various distances to the CTR action site (figure 4). This distribution shows how CIBW observations differed with distances to the CTR site and was used to infer appropriate distances within which to estimate spatially-derived CIBW sighting rates (figure 4). The POA implemented a piecewise regression

model that detected breakpoints (*i.e.*, points within the CPOA data at which statistical properties of the sequence of observational distances changed) in the cumulative density distribution of the CPOA locations, which they proposed to represent spatially-based sighting rate bins for use in calculating CIBW sighting rates. The POA used the “Segmented” package (Muggeo, 2020) in the R Statistical Software Package (R Core Team, 2022) to determine statistically significant breakpoints in the linear distances of the CIBW data using this regression method (see section 6.5.5.3 of the POA's application for more details regarding this statistical analysis). This analysis identified breakpoints in the CPOA locations at 195.7, 2,337.0, 3,154.7, and 6,973.9 m (figure 4).

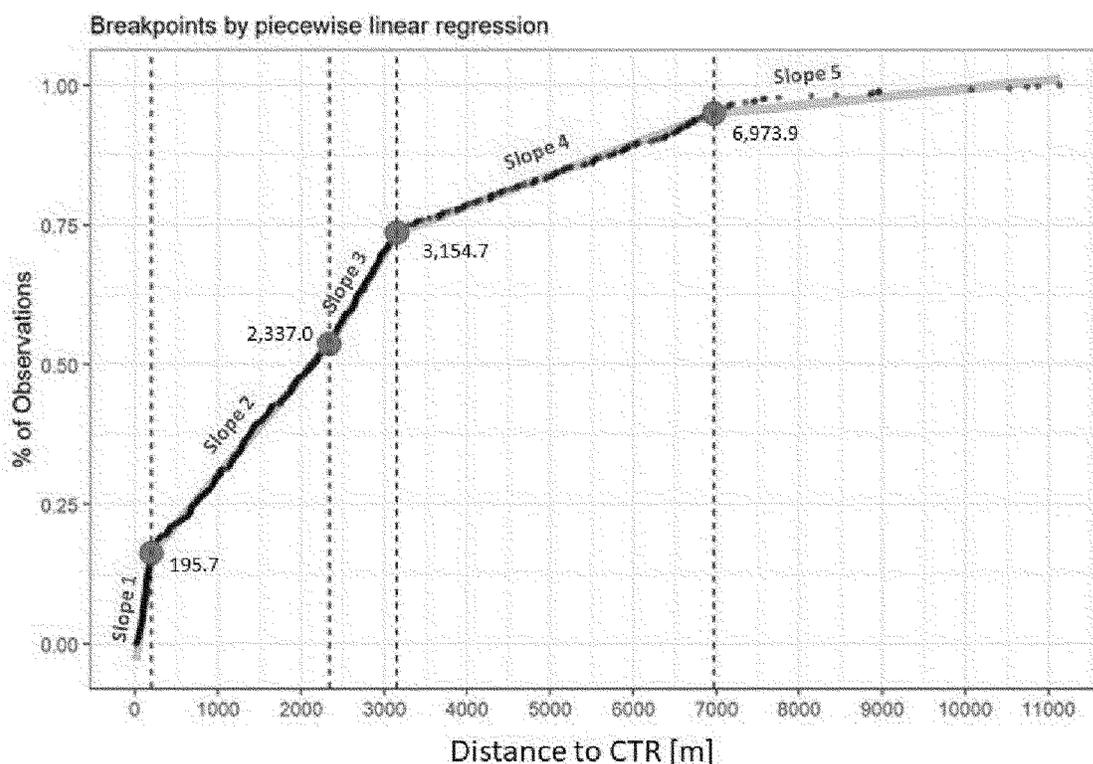


Figure 4 -- Percent of CIBW CPOA Observations in Relation to Distance from the CTR Project Site and Associated Breakpoints Determined by Piecewise Linear Regression

Piecewise regression is a common tool for modeling ecological thresholds (Lopez *et al.*, 2020; Whitehead *et al.*, 2016; Atwood *et al.*, 2016). In a similar scenario to the one outlined above, Mayette *et al.* (2022) used piecewise regression methods to model the distances between two individual CIBWs in a group in a nearshore and a far shore environment. For the POA's analysis, the breakpoints (*i.e.*, 195.7,

2,337.0, 3,154.7, and 6,973.9 m) detect a change in the frequency of CIBW groups sighted and the slope of the line between two points indicates the magnitude of change. A greater positive slope indicates a greater accumulation of sightings over the linear distance (x-axis) between the defining breakpoints, whereas a more level slope (*i.e.*, closer to zero) indicates a lower accumulation of sightings over that linear distance (x-

axis) between those defining breakpoints (figure 4; see table 6–16 in the POA's application for the slope estimates for the empirical cumulative distribution function).

The breakpoints identified by the piecewise regression analysis are in agreement with what is known about CIBW behavior in Knik Arm based on recent monitoring efforts (61N Environmental, 2021, 2022a, 2022b;

Easley-Appleyard and Leonard, 2022). Observation location data collected during POA monitoring programs indicate that CIBWs were consistently found in higher numbers in the nearshore areas, along both shorelines, and were found in lower numbers in the center of the Arm. Tracklines of CIBW group movements collected from 2020 to 2022 show that CIBWs displayed a variety of movement patterns that included swimming close to shore past the POA on the east side of Knik Arm (defined by breakpoint 1 at 195.7 m), with fewer CIBWs swimming in the center of Knik Arm (breakpoints 1 to 2, at 195.7 to 2,337 m). CIBWs commonly swam past the POA close to shore on the west side of Knik Arm, with no CIBWs able to swim farther from the POA in that area than the far shore

(breakpoints 2 to 3, at 2,337 to 3,154.7 m). Behaviors and locations beyond breakpoint 4 (6,973.9 m) include swimming past the mouth of Knik Arm between the Susitna River area and Turnagain Arm; milling at the mouth of Knik Arm but not entering the Arm; and milling to the northwest of the POA without exiting Knik Arm. The shallowness of slope 5, at distances greater than 6,973.9 m, could be due to detection falloff from a proximity (distance) bias, which would occur when PSOs are less likely to detect CIBW groups that are farther away than groups that are closer.

The POA, in collaboration with NMFS, used the distances detected by the breakpoint analysis to define five sighting rate distance bins for CIBWs in the NES1 project area. Each breakpoint

(196, 2,337, 3,155, and 6,974 m, and the complete data set of observations [$>6,974$ m]) was rounded up to the nearest meter and considered the outermost limit of each sighting rate bin, resulting in five identified bins (table 19). All CIBW observations less than each bin's breakpoint distance were used to calculate that bin's respective monthly sighting rates (e.g., all sightings from 0 to 196 m are included in the sighting rates calculated for bin number 1, all sightings from 0 to 2,337 m are included in the sighting rates calculated for bin number 2, and so on). CTR construction is anticipated to take place in the months of April through November over the 5-year timeframe of the proposed rulemaking; therefore, monthly sighting rates were only derived for these months (table 19).

TABLE 19—CIBW MONTHLY SIGHTING RATES FOR DIFFERENT SPATIALLY-BASED BIN SIZES

Bin number	Distance (m)	CIBW/Hour ¹								
		April	May	June	July	August	September	October	November	
1	196	0.05	0.06	0.10	0.04	0.82	0.59	0.51	0.10	
2	2,338	0.34	0.16	0.15	0.09	1.55	1.42	1.09	0.65	
3	3,155	0.36	0.22	0.21	0.09	2.02	1.89	1.98	0.72	
4	6,974	0.67	0.33	0.29	0.13	2.24	2.18	2.42	0.73	
5	$>6,974$	0.71	0.39	0.30	0.13	2.29	2.23	2.56	0.73	

¹ Observation hours have been totaled from the PCT 2020 and 2021 programs, the NMFS 2021 data collection effort, and the SFD 2022 program (61N Environmental 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022).

Take Estimation

In this section, we describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and proposed for authorization.

To quantitatively assess exposure of marine mammals to noise from pile

driving activities, we used the occurrence estimate (number/unit of time; tables 17 and 19) and the estimated work hours per year (table 20) to determine the number of animals potentially exposed to an activity. Because the size of the Level A harassment zones may exceed the shutdown zones (see the Proposed Mitigation section) and the limits of

PSO visibility during impact driving activities, the number of takes by Level A harassment was estimated based on the proportion of work hours allocated to impact pile driving (table 20) for all species except killer whales, which have smaller predicted Level A harassment zones, and CIBWs, which have larger proposed shutdown zones, described in further detail below.

TABLE 20—ESTIMATED PREDICTED NUMBER OF HOURS OF IMPACT AND VIBRATORY HAMMER USE FOR EACH CONSTRUCTION YEAR

Year	Impact duration (hrs)	Vibratory duration (hrs)	Total duration (hrs)	Proportion of impact hammer use
1	98.90	55.00	153.90	0.64
2	87.43	47.92	135.35	0.65
3	38.70	96.50	135.20	0.29
4	87.43	50.42	137.85	0.63
5	81.70	55.50	137.20	0.60

The equation used to calculate estimated take by Level A harassment for species with yearly occurrence estimates is:

$$\text{Level A harassment estimate} = \text{occurrence} \times \text{proportion of impact hammer use}$$

where occurrence per year is taken from table 17, and proportion of impact hammer use per year from table 20. For species with hourly occurrence estimates, the equation is:

$$\text{Level A harassment estimate} = (\text{hourly occurrence} \times \text{total duration in hours}) \times \text{proportion of impact hammer use}$$

Estimates of take by Level A and Level B harassment for all species are based on the best available data. NMFS proposes to authorize total takes for each species by Level A and Level B harassment over the 5-year period of the proposed ITR as calculated and shown in the relevant tables, with annual take by Level A and Level B harassment for

each species not to exceed the maximum annual values shown in tables 21, 22, and 24.

TABLE 21—ESTIMATED TAKE BY LEVEL A HARASSMENT IN EACH OF THE 5 YEARS AND IN TOTAL FOR NON-CIBW MARINE MAMMAL SPECIES IN THE PROPOSED CTR PROJECT AREA ¹

Species	Potential level A harassment by year					
	1	2	3	4	5	Total
Gray whale	4	4	2	4	4	18
Humpback whale	3	3	1	3	2	12
Killer whale	6					6
Harbor porpoise	15	13	6	13	12	59
Steller sea lion	6	6	3	6	5	26
Harbor seal	98	88	39	87	82	394

¹ Annual take may not be distributed exactly as shown; NMFS proposes to authorize total take over the 5 year construction period, with annual take by Level A harassment for each species not to exceed the maximum annual value shown in years 1–5.

Proposed estimates of take by Level B harassment for non-CIBW species were calculated as the difference between the estimated Level A harassment exposures and total estimated yearly occurrence (either the estimated yearly occurrence from table 17 or calculated as the hourly occurrence from table 17 multiplied by the total yearly duration in table 20) for each stock.

TABLE 22—ESTIMATED TAKE BY LEVEL B HARASSMENT IN EACH OF THE 5 YEARS AND IN TOTAL FOR NON-CIBW MARINE MAMMAL SPECIES IN THE PROPOSED CTR PROJECT AREA ¹

Stock	Potential level B harassment by year					
	1	2	3	4	5	Total
Gray whale	2	2	4	2	2	12
Humpback whale	1	1	3	1	2	8
Killer whale	6	6	6	6	6	30
Harbor porpoise	8	7	14	8	8	45
Steller sea lion	3	3	6	3	4	20
Harbor seal	55	47	96	51	55	304

¹ Annual take may not be distributed exactly as shown; NMFS proposes to authorize total take over the 5 year construction period, not to exceed the sum of the maximum annual values shown in years 1–5 in Tables 21 and 22.

Beluga Whale

Potential exposures above harassment thresholds of CIBWs, which we equate with takes, were calculated by multiplying the total number of vibratory installation or removal hours per month for each sized/shaped pile based on the anticipated construction schedule (table 2) with the corresponding sighting rate month and sighting rate distance bin (table 19). For example, the Level B harassment isopleth distance for the vibratory installation of 36-in (91-cm) piles is 4,514 m, which falls within bin number 4 (table 19). Therefore, take for this activity is calculated by multiplying the

total number of hours estimated each month to install 36-in piles via a vibratory hammer by the monthly CIBW sighting rates calculated for bin number 4 (table 19). The resulting estimated CIBW exposures were totaled for all activities in each month (table 23).

In their calculation of CIBW take, the POA assumed that only 36-in template piles would be installed (rather than 24-in) and removed during the project. If 24-in piles are used for temporary stability template piles, it would be assumed that the potential impacts of this alternate construction scenario and method on marine mammals are fungible (*i.e.*, that potential impacts of installation and removal of 24-in steel

pipe piles would be similar to the potential impacts of installation and removal of 36-in steel pipe piles). While removal of 24-in piles may be louder than removal of 36-in piles (tables 9 and 10), installation would be significantly quieter. Given the number of piles to be installed and extracted using vibratory methods, overall impacts from 36-in piles are expected to be greater than those from 24-in piles. Using the monthly activity estimates in hours (table 2) and monthly calculated sighting rates (CIBWs/hour) for the spatially derived distance bins (table 23), we estimated take by Level B harassment for each of the 5 years of the CTR project (table 24).

TABLE 23—ALLOCATION OF EACH LEVEL B HARASSMENT ISOPLETH TO A SIGHTING RATE BIN AND CIBW MONTHLY SIGHTING RATES FOR DIFFERENT PILE SIZES AND HAMMER TYPES

Activity	Level B isopleth distance (m)	Sighting rate bin number and distance	Belugas/Hour							
			Apr	May	Jun	Jul	Aug ¹	Sep ¹	Oct ¹	Nov
Unattenuated Values (without the use of a bubble curtain)										
36-in Vibratory Removal ^{1,2}	1,699	2 (2,338 m)	0.34	0.16	0.15	0.09	1.55	1.42	1.09	0.65
36-in Vibratory Installation ^{1,2}	4,514	4 (6,974 m)	0.67	0.33	0.29	0.13	2.24	2.18	2.42	0.73
72-in Vibratory Installation ³	9,069	5 (>6,974)	0.71	0.39	0.30	0.13	2.29	2.23	2.56	0.73
Concurrent 36-in AND 36-in Vibratory Installation	9,069									
Concurrent 36-in AND 36-in OR 72-in Vibratory Installation ⁴ .	9,363									
36-in Impact Installation ^{1,2}	1,585	2 (2,338 m)	0.34	0.16	0.15	0.09	1.55	1.42	1.09	0.65
72-in Impact Installation ³	7,356	5 (>6,974)	0.71	0.39	0.30	0.13	2.29	2.23	2.56	0.73
Attenuated Values (with the use of a bubble curtain)										
36-in Vibratory Removal ²	1,318	2 (2,338)	0.34	0.16	0.15	0.09	1.55	1.42	1.09	0.65
36-in Vibratory Installation ²	3,575	4 (6,974 m)	0.67	0.33	0.29	0.13	2.24	2.18	2.42	0.73
72-in Vibratory Installation ³	6,119									
Concurrent 36-in AND 36-in Vibratory Installation	5,667									
Concurrent 36-in AND 72-in Vibratory Installation	8,318	5 (>6,974)	0.71	0.39	0.30	0.13	2.29	2.23	2.56	0.73
36-in Impact Installation ^{1,2}	541	2 (2,338)	0.34	0.16	0.15	0.09	1.55	1.42	1.09	0.65
72-in Impact Installation	2,512	3 (3,155 m)	0.36	0.22	0.21	0.09	2.02	1.89	1.98	0.72

¹ Unattenuated vibratory and impact driving of temporary and permanent piles during the months of August through October would be limited to the minimum possible number of piles that must be driven in-water in depths <3 m.
² Unattenuated and attenuated vibratory installation of 36-in temporary piles both result in bin 4; vibratory removal of this pile type results in bin 2 in both attenuated and unattenuated conditions. Unattenuated and attenuated impact pile driving of 36-in piles results in bin 2 in both conditions.
³ Unattenuated vibratory and impact installation of permanent (72-in) piles will be minimized to the extent possible by driving as many piles as possible in the dry for all months of the construction seasons. To account for piles driven in water less than 3 m deep, NMFS has estimated approximately 0.5 unattenuated 72-in piles will be driven (approximately 43 minutes of impact driving and 5 minutes of vibratory driving) each month. Impact driving (attenuated and unattenuated) results in Bin 2; vibratory driving (attenuated and unattenuated) results in Bin 5.
⁴ Both concurrent driving of 2 temporary piles (1 attenuated, 1 unattenuated) and 1 temporary (unattenuated) and 1 permanent (attenuated) piles result in a Level B harassment isopleth of 9,363 m.

For the PCT (85 FR 19294, April 6, 2020), SFD (86 FR 50057, September 7, 2021), and NES1 (89 FR 2832, January 14, 2024) projects, NMFS accounted for the implementation of mitigation measures (e.g., shutdown procedures implemented when CIBWs entered or approached the estimated Level B harassment zone) by applying an adjustment factor to CIBW take estimates. This was based on the assumption that some Level B harassment takes would likely be avoided based on required shutdowns for CIBWs at the Level B harassment zone isopleths (see the Proposed Mitigation section for more information). For the PCT project, NMFS compared the number of observations of CIBW within estimated harassment zones at the POA to the number of authorized takes for previous projects from 2008 to 2017 and found the percentage ranged from 12 to 59 percent with an average of 36 percent (85 FR 19294, April 6, 2020). NMFS then applied the highest percentage of previous potentially realized takes (i.e., number of CIBWs observed within

estimated Level B harassment zones; 59 percent during the 2009–2010 season) to ensure potential takes of CIBWs were fully evaluated. In doing so, NMFS assumed that approximately 59 percent of the takes calculated could be realized during PCT and SFD construction (85 FR 19294, April 6, 2020; 86 FR 50057, September 7, 2021) and that 41 percent of the calculated CIBW Level B harassment takes would be avoided by successful implementation of required mitigation measures. The POA calculated the adjustment for successful implementation of mitigation measures for CTR using the percentage of realized takes for the PCT project (see table 6–20 in the POA’s application). The data from PCT Phase 1 and PCT Phase 2 most accurately reflect the current marine mammal monitoring program, the current program’s effectiveness, and CIBW occurrence in the proposed project area. Between the two phases of the PCT project, 90 total Level B harassment takes were authorized and 53 were potentially realized, equating to an overall percentage of 59 percent. The

SFD Project, during which only 7 percent of authorized take was potentially realized, represents installation of only 12 piles during a limited time period and does not represent the much higher number of piles and longer construction timeframe anticipated for CTR. NMFS proposes that the 59-percent adjustment accurately accounts for the efficacy of the POA’s marine mammal monitoring program and required shutdown protocols, based on past performance. NMFS, therefore, assumes that approximately 59 percent of the takes calculated for CTR may actually be realized (table 24). Take by Level A harassment is not anticipated or proposed to be authorized for CIBWs because the POA will be required to shut down activities when CIBWs approach and or enter the Level B harassment zone, which in all cases is larger than the estimated Level A harassment zones (see the Proposed Mitigation section for more information).

TABLE 24—CALCULATED LEVEL B HARASSMENT TAKES OF CIBWS BY MONTH, YEAR, AND ACTIVITY¹

	Apr	May	Jun	Jul	Aug ²	Sep ²	Oct ²	Nov
Year 1¹								
36" vibratory installation ³	1.68	2.01	1.76	0.78	13.44	13.10	7.26	1.47
36" vibratory removal ³	0.26	0.12	0.11	0.07	1.16	1.06	0.82	0.49

TABLE 24—CALCULATED LEVEL B HARASSMENT TAKES OF CIBWS BY MONTH, YEAR, AND ACTIVITY¹—Continued

	Apr	May	Jun	Jul	Aug ²	Sep ²	Oct ²	Nov
72" vibratory installation (attenuated)	0.50	0.59	0.51	0.23	3.17	3.09	3.43	0.06
72" vibratory installation (unattenuated) ⁴	0.06	0.03	0.03	0.01	0.19	0.19	0.21	0.06
72" impact installation (attenuated)	2.35	3.36	3.19	1.40	24.67	23.08	24.18	3.62
72" impact installation (unattenuated) ⁴	0.49	0.27	0.21	0.09	1.60	1.56	1.79	0.51
Year 1 total								151
With 59% Correction Factor ⁵								90
Year 2¹								
36" vibratory installation ³	2.01	1.67	1.47	0.65	11.20	10.91	6.05	1.47
36" vibratory removal ³	0.26	0.12	0.11	0.07	1.16	1.06	0.82	0.00
72" vibratory installation (attenuated)	0.50	0.47	0.42	0.18	3.17	2.73	3.03	0.43
72" vibratory installation (unattenuated) ⁴	0.06	0.03	0.03	0.01	0.19	0.19	0.21	0.06
72" impact installation (attenuated)	2.35	2.72	2.58	1.14	24.67	20.36	21.34	3.62
72" impact installation (unattenuated) ⁴	0.49	0.27	0.21	0.09	1.60	1.56	1.79	0.51
Year 2 total								137
With 59% Correction Factor ⁵								81
Year 3¹								
36" vibratory installation ³	4.36	4.35	3.82	1.68	29.13	28.38	15.73	1.47
36" vibratory removal ³	0.26	0.37	0.34	0.21	2.33	2.12	0.82	0.49
72" vibratory installation (attenuated)	0.39	0.20	0.17	0.05	0.93	0.91	1.01	0.31
72" vibratory installation (unattenuated) ⁴	0.06	0.03	0.03	0.01	0.19	0.19	0.21	0.06
72" impact installation (attenuated)	1.83	1.12	1.07	0.34	7.28	6.81	7.13	2.59
72" impact installation (unattenuated) ⁴	0.49	0.27	0.21	0.09	1.60	1.56	1.79	0.51
Year 3 total								136
With 59% Correction Factor ⁵								81
Year 4¹								
36" vibratory installation ³	4.36	4.35	3.82	1.68	29.13	28.38	15.73	1.47
36" vibratory removal ³	0.26	0.37	0.34	0.21	2.33	2.12	0.82	0.49
72" vibratory installation (attenuated)	0.39	0.20	0.17	0.05	0.93	0.91	1.01	0.31
72" vibratory installation (unattenuated) ⁴	0.06	0.03	0.03	0.01	0.19	0.19	0.21	0.06
72" impact installation (attenuated)	1.83	1.12	1.07	0.34	7.28	6.81	7.13	2.59
72" impact installation (unattenuated) ⁴	0.49	0.27	0.21	0.09	1.60	1.56	1.79	0.51
Year 4 total								138
With 59% Correction Factor ⁵								82
Year 5¹								
36" vibratory installation ³	1.68	2.01	1.76	0.78	13.44	12.00	13.31	1.84
36" vibratory removal ³	0.26	0.12	0.11	0.07	1.16	1.06	0.82	0.49
72" vibratory installation (attenuated)	0.28	0.47	0.42	0.18	2.80	2.73	3.03	0.31
72" vibratory installation (unattenuated) ⁴	0.06	0.03	0.03	0.01	0.19	0.19	0.21	0.06
72" impact installation (attenuated)	1.31	2.72	2.58	1.14	21.77	20.36	21.34	2.59
72" impact installation (unattenuated) ⁴	0.49	0.27	0.21	0.09	1.60	1.56	1.79	0.51
Year 5 total								143
With 59% Correction Factor ⁵								85
Years 1–5 Total								
Project Total Estimated Exposures								705
With 59% Correction Factor ⁵								419

¹ Concurrent driving scenarios that would improve the production efficiency in the months of April through July have been conservatively excluded from this analysis.
² Unattenuated vibratory driving of temporary and permanent piles during the months of August through October would be limited to the minimum possible number of piles that must be driven in-water in depths <3m.
³ Attenuated and unattenuated bins for this activity are the same.
⁴ Unattenuated vibratory and impact installation of permanent (72-in) piles will be minimized to the extent possible by driving as many piles as possible in the dry for all months of the construction seasons. This calculation assumes 0.5 72-in piles per month may be driven in water depths <3m and thus be unattenuated.
⁵ Corrected exposure estimates have been rounded up for each year (e.g., Year 1 = 0.59 * 151 = 89.1, which has been rounded up to 90).

In summary, the maximum annual amount of Level A harassment and Level B harassment proposed to be

authorized for each marine mammal stock is presented in table 25.

TABLE 25—NUMBER OF PROPOSED TAKES AS A PERCENTAGE OF STOCK ABUNDANCE, BY STOCK AND HARASSMENT TYPE FOR THE MAXIMUM ANNUAL ESTIMATED TAKES OF THE PROJECT

Species	Proposed take			Stock	Percent of stock
	Level A	Level B	Total		
Gray whale	4	2	6	Eastern North Pacific	0.02
Humpback whale ¹	3	1	4	Hawai'i	0.04
				Mexico-North Pacific	² UNK
Beluga whale	0	90	90	Cook Inlet ³	27.2
Killer whale ¹	6	6	12	Eastern North Pacific Alaska Resident ..	0.6
				Eastern North Pacific Gulf of Alaska,	2.04
				Aleutian Islands and Bering Sea Trans-	
				sient.	
Harbor porpoise	16	8	24	Gulf of Alaska	0.08
Steller sea lion	6	3	9	Western	0.015
Harbor seal	99	55	154	Cook Inlet/Sheikof Strait	0.54

¹ NMFS conservatively assumes that all takes occur to each stock

² NMFS does not have an official abundance estimate for this stock and the minimum population estimate is considered to be unknown (Young *et al.*, 2023). See Small Numbers for additional discussion.

³ This abundance estimate is from Goetz *et al.* (2023); which was published after the most recent CIBW SAR (Young *et al.*, 2023).

Proposed Mitigation

In order to promulgate a rulemaking under section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity and other means of effecting the least practicable adverse impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation

(probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider factors such as cost and impact on operations.

The POA presented mitigation measures in section 11 of their application that were modeled after the requirements included in the IHAS issued for Phase 1 and Phase 2 PCT construction (85 FR 19294, April 6, 2020) and for SFD construction (86 FR 50057, September 7, 2021), which were designed to minimize the total number, intensity, and duration of harassment events for CIBWs and other marine mammal species during those projects (61N Environmental, 2021, 2022a, 2022b). NMFS concurs that these proposed measures reduce the potential for CIBWs and other marine mammals to be adversely impacted by the proposed activity.

Noise Mitigation for Pile Installation and Removal—The POA has previously utilized and assessed the effectiveness of bubble curtains for noise mitigation at the project site (Austin *et al.* 2016; Illingworth and Rodkin, LLC (I&R) 2021a, 2021b, 2023). In all previous years of the PAMP, bubble curtains were not used on piles installed or removed in shallow water less than 3 meters deep or piles installed or removed “in the dry” (*e.g.*, at times when the tide is low and the pile’s location is dewatered) because low water levels prevent proper deployment and function of a bubble curtain system. When a pile was installed or removed in the dry, it was assumed that no exposure to received sound levels equated with potential incidental harassment occurred and, therefore, that no take of marine mammals occurred. The same

assumptions and approach to mitigation associated with use of a bubble curtain have been used in the analyses for this project.

NMFS is proposing that the POA must employ the following mitigation measures:

- Ensure that construction supervisors and crews, the monitoring team and relevant POA staff are trained prior to the start of all pile driving, so that responsibilities, communication procedures, monitoring protocols, and operational procedures are clearly understood. New personnel joining during the project must be trained prior to commencing work;
- Employ PSOs and establish monitoring locations as described in the POA’s Marine Mammal Monitoring and Mitigation Plan (see appendix B of the POA’s application). The POA must monitor the project area to the maximum extent possible based on the required number of PSOs, required monitoring locations, and environmental conditions;
- Monitoring must take place from 30 minutes prior to initiation of pile driving (*i.e.*, pre-clearance monitoring) through 30 minutes post-completion of pile driving;
- Pre-start clearance monitoring must be conducted during periods of visibility sufficient for the lead PSO to determine that the shutdown zones indicated in table 26 are clear of marine mammals. Pile driving may commence following 30 minutes of observation when the determination is made that the shutdown zones are clear of marine mammals or when the mitigation measures proposed specifically for CIBWs (below) are satisfied;
- If work ceases for more than 30 minutes, PSOs must observe a 30-minute pre-start clearance period (*i.e.*,

the shutdown zones must be observed for 30 minutes and confirmed clear of marine mammals) prior to reinitiating pile driving. A determination that the shutdown zone is clear must be made during a period of good visibility.

- For all construction activities, shutdown zones must be established following table 26. The purpose of a shutdown zone is generally to define an area within which shutdown of activity

would occur upon sighting of a marine mammal entering or within the defined area. The shutdown zones (table 26) were calculated based on the minimum 100-m shutdown zone proposed by the POA for all pile installation and vibratory extraction activities, as well as the calculated Level A (non-CIBW species) and Level B (CIBWs) harassment isopleths shown in table 16. In most cases, the shutdown zones

exceed the calculated Level A isopleths; exceptions occur during impact pile driving, when the calculated Level A harassment isopleths exceed practicable shutdown zones for non-CIBW species, and during concurrent vibratory driving (the largest Level A isopleth is 161 m during this activity). For CIBWs, the shutdown zones exceed the calculated Level B harassment isopleths in all scenarios.

TABLE 26—PROPOSED SHUTDOWN ZONES DURING SPECIFIED ACTIVITIES

Activity	Pile type/size	Attenuated or unattenuated	Shutdown zone (m)					
			LF cetaceans	Non-CIBW MF ¹ cetaceans	CIBWs	HF ¹ cetaceans	PW	OW
Vibratory Installation	24-in	Unattenuated	100	100	2,250 4,520	100	100	100
	36-in							
	72-in							
	72-in							
	24-in	Attenuated						
	36-in							
Vibratory Removal	24-in	Unattenuated	100	100	2,250 4,520	100	100	100
	36-in							
	24-in	Attenuated						
	36-in							
	24-in							
	36-in							
Impact Installation—1 pile per day.	24-in	Unattenuated	500	500	1,600 550	500 100	100 100	100 100
	36-in							
	24-in	Attenuated						
	36-in							
Impact Installation—1 pile per day.	72-in	Unattenuated	500	500	7,360 2,520	500	100	100
		Attenuated						
Impact Installation—2 piles per day. Impact Installation—3 piles per day. Concurrent—2 Vibratory sources.	36-in	Attenuated/Attenuated	100	100	5,670 9,370 9,070	100	100	100
		AND						
		Unattenuated/Unattenuated						
		AND						
		Attenuated/Attenuated						
		Unattenuated/Attenuated						
Concurrent Vibratory/Impact.	36-in	Attenuated/Attenuated (1 pile per day).	500	500	3,580 4,520	500	100	100
		AND						
		72-in						

Notes: cm = centimeter(s), m = meter(s); POA may elect to use either 36-in or 24-in temporary piles; as 36-in piles are more likely and estimated to have larger ensonified areas, we have used these piles in our analyses of concurrent activities.

¹ In the Updated Technical Guidance (NMFS, 2024), the MF Cetacean hearing group has been re-named the HF Cetacean group; HF Cetaceans from the 2018 Technical Guidance have been re-named VHF Cetaceans.

- Marine mammals observed anywhere within visual range of the PSO must be tracked relative to construction activities. If a marine mammal is observed entering or within the shutdown zones indicated in table 26, pile driving must be delayed or halted. If pile driving is delayed or halted due to the presence of a marine

mammal, the activity may not commence or resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown zone (table 26), or 15 minutes (non-CIBWs) or 30 minutes (CIBWs) have passed without re-detection of the animal;

- The POA must use bubble curtains for all piles during both vibratory and impact pile driving in water depths greater than 3 m during the months of August through October. No bubble curtain is required for vibratory pile driving of temporary (24-in or 36-in) piles in the months of April–July (see discussion below). Bubble curtains must

be used for all permanent (72-in) piles during both vibratory and impact pile driving in waters deeper than 3 m in the months of April–November. The bubble curtain must be operated as necessary to achieve optimal performance. At a minimum, the bubble curtain must distribute air bubbles around 100 percent of the piling circumference for the full depth of the water column; the lowest bubble ring must be in contact with the substrate for the full circumference of the ring; and air flow to the bubble curtain must be balanced around the circumference of the pile.

- The POA must use soft start techniques when impact pile driving. Soft start requires contractors to provide an initial set of three strikes at reduced energy, followed by a 30-second waiting period, then two subsequent reduced energy strike sets. A soft start must be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer. PSOs shall begin observing for marine mammals 30 minutes before "soft start" or in-water pile installation or removal begins;

- Pile driving activity must be halted upon observation of either a species for which incidental take is not authorized or a species for which incidental take has been authorized but the authorized number of takes has been met, entering or within the harassment zone; and

- The POA must avoid direct physical interaction with marine mammals during non-pile-driving construction activities, including barge positioning and pile cutting. If a marine mammal comes within 10 m of such activity, operations shall cease. Should a marine mammal come within 10 m of a vessel in transit, the boat operator will reduce vessel speed to the minimum level required to maintain steerage and safe working conditions. If human safety is at risk, based on the best judgment of the vessel captain or project engineer, the in-water activity is allowed to continue until it is safe to stop.

The following additional mitigation measures are proposed by NMFS for CIBWs:

- Prior to the onset of pile driving, should a CIBW be observed approaching the estimated shutdown zone (table 26) (*i.e.* the CIBWs Level B harassment zone column in tables 15 and 16), pile driving must not commence until the whale(s) moves at least 100 m past the estimated shutdown zone and on a path away from the zone, or the whale has not been re-sighted within 30 minutes;

- If pile installation or removal has commenced and a CIBW(s) is observed within or likely to enter the shutdown

zone, pile installation or removal must shut down and not re-commence until the whale has traveled at least 100 m beyond the shutdown zone and is on a path away from such zone or until no CIBW has been observed in the shutdown zone for 30 minutes; and

- If during installation and removal of piles, PSOs can no longer effectively monitor the entirety of the CIBW shutdown zone due to environmental conditions (*e.g.*, fog, rain, wind), pile driving may continue only until the current segment of the pile is driven; no additional sections of pile or additional piles may be driven until conditions improve such that the shutdown zone can be effectively monitored. If the shutdown zone cannot be monitored for more than 15 minutes, the entire shutdown zone will be cleared again for 30 minutes prior to pile driving.

In addition to these mitigation measures being proposed by NMFS, NMFS requested that the POA restrict all pile driving and removal work to April to July, when CIBWs are typically found in lower numbers. However, the POA stated that given the scale of the project, construction sequencing requirements, critical nature of the CTR infrastructure and overall PAMP, and vulnerability of the existing cargo terminals to seismic events, it cannot commit to restricting pile driving and removal to April to July. Instead, the POA would complete as much work as is practicable in April to July to reduce the amount of pile driving and removal activities in August through November. The POA is aware that August through October are months with high CIBW abundance and plans to complete in-water work as early in the construction season as possible. The POA also recognizes that more work shutdowns for CIBW are likely to take place in high abundance months, which provides incentive to complete work earlier in the season.

Due to the deterioration of the current facilities and complexity of the PAMP, it is important that the POA attempt to complete the CTR project as currently proposed (6 years in total), which requires the POA to make full use of the available annual construction window (August through October/November). Potential consequences of pausing the construction season (*e.g.*, stopping work from August through October) include de-rating of the structural capacity of the existing cargo terminals, a shutdown of dock operations due to deteriorated conditions, or an actual collapse of one or more dock structures. The potential for collapse increases with schedule delays due to both worsening deterioration and the higher probability

of a significant seismic event occurring before T1 and T2 replacement.

For previous IHAs issued to the POA (PCT: 85 FR 19294, April 6, 2020; SFD: 86 FR 50057, September 7, 2021), the use of a bubble curtain to reduce noise has been required as a mitigation measure for certain pile driving scenarios. The POA has concerns about effectiveness of bubble curtains in the far-field during vibratory pile driving (see Appendix A of the POA's application for further details). NMFS disagrees with the POA's assertion of effectiveness but acknowledges the use of bubble curtains on all piles has the potential to drive the in-water construction schedule further into the late summer months, which are known for higher CIBW abundance in the project area, thus lengthening the duration of potential interactions between CIBW and in-water work. Therefore, NMFS is concerned that use of a bubble curtain for all piles in all months may ultimately result in increased impacts to CIBW. Given the extensive proposed visual monitoring and mitigation measures in place, and in order to facilitate increased production when CIBW abundance at POA is expected to be lowest, NMFS concurs that the POA's proposal to use vibratory hammers to install and extract temporary piles with no bubble curtain during the months of April through July affects the least practicable adverse impact on marine mammals. A bubble curtain would be required during all installation of permanent piles in all months, and for vibratory driving of temporary piles in August through October.

NMFS considered additional mitigation and monitoring requirements for the CTR project, including sound-source verification measurements and passive acoustic monitoring of marine mammals near the POA. Sound source verification is time-intensive and expensive, and the POA has previously collected data on most of the pile types proposed for the CTR project (Illingworth and Rodkin, 2021a, b). Following discussion with the POA, NMFS determined that conducting additional sound source verification measurements would not be practicable or provide support for additional mitigation value due to schedule concerns and the volume of data already collected and, therefore, this measure was eliminated from the suite of proposed mitigation requirements. However, depending on future project conditions, the POA may choose to conduct sound source verification measurements and work with NMFS to

revise the estimated harassment zones as indicated by the data collected.

With respect to passive acoustic monitoring, available technologies to detect marine mammals in near real-time require a surface buoy for the device, and mooring locations would be limited by ongoing port operations, construction activities, and dredging. The high noise environment at the POA (from both anthropogenic and natural sources) would add additional limitations to the detection range of such devices. Therefore, NMFS believes that the POA's extensive and successful visual monitoring program represents the best possible method of minimizing effects to marine mammals, including CIBWs to pile driving noise, and that passive acoustic monitoring would not provide additional benefits to marine mammals in this case.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures provide the means of affecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to promulgate a rulemaking for an activity, section 101(a)(5)(A) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the specified geographical region. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (e.g., presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (e.g., source

characterization, propagation, ambient noise); (2) affected species (e.g., life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (e.g., age, calving or feeding areas);

- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (e.g., marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and,
- Mitigation and monitoring effectiveness.

The POA's draft Marine Mammal Monitoring and Mitigation Plan is Appendix B of the LOA application, and is available on [regulations.gov](https://www.regulations.gov) and at <https://www.fisheries.noaa.gov/action/incidental-take-authorization-port-alaskas-construction-activities-port-alaska-modernization>. The POA proposes to implement a marine mammal monitoring and mitigation strategy intended to avoid and minimize impacts to marine mammals. Marine mammal monitoring would be conducted at all times when in-water pile installation and removal is taking place. Prior to the beginning of construction, POA would submit a revised Marine Mammal Mitigation and Monitoring Plan containing additional details of monitoring locations and methodology for NMFS concurrence.

The marine mammal monitoring and mitigation program that is planned for CTR construction would be modeled after the successful monitoring and mitigation programs outlined in the IHAs for Phase 1 and Phase 2 PCT construction (85 FR 19294, April 6, 2020) and the IHAs for SFD (86 FR 50057, September 7, 2021) and NES1 (89 FR 2832, January 14, 2024) construction. These monitoring programs have provided the best available data on CIBW and other marine mammal presence at the POA and continue to be used successfully as of July 2024 at the NES1 project.

Visual Monitoring

Monitoring must be conducted by qualified, NMFS-approved PSOs, in accordance with the following:

- PSOs must be independent of the activity contractor (e.g., employed by a

subcontractor) and have no other assigned tasks during monitoring periods. At least one PSO at each monitoring station must have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued ITA or Letter of Concurrence. Other PSOs may substitute other relevant experience (including relevant Alaska Native traditional knowledge), education (degree in biological science or related field), or training for prior experience performing the duties of a PSO. PSOs must be approved by NMFS prior to beginning any activity subject to this ITA;

- The POA must employ PSO stations at a minimum of four locations from which PSOs can effectively monitor the shutdown zones (table 24). PSO stations must be positioned at the best practical vantage points that are determined to be safe. Likely locations include the Anchorage Downtown Viewpoint near Point Woronzof, the Anchorage Public Boat Dock at Ship Creek, the CTR Project site, and the North End of POA property (see figure 13–1 in the POA's application for potential locations of PSO stations). Areas near Cairn Point or Port MacKenzie have safety, security, and logistical issues, which would need to be considered. Cairn Point proper is located on military land and has bear presence, and restricted access does not allow for the location of an observation station at this site. Tidelands along Cairn Point are accessible only during low tide conditions and have inherent safety concerns of being trapped by rising tides. Port MacKenzie is a secure port that is relatively remote, creating safety, logistical, and physical staffing limitations due to lack of nearby lodging and other facilities. The roadway travel time between port sites is approximately 2–3 hours. An additional possible monitoring location is proposed north of the proposed project site, pending selection of the Construction Contractor and more detailed discussions before the start of construction. Temporary staffing of a northerly monitoring station during peak marine mammal presence time periods and/or when shutdown zones are large would be considered by the POA, NMFS, and the construction contractor based on evaluation of CIBW occurrence reported in the required weekly monitoring reports. At least one PSO station must be able to fully observe the non-CIBW shutdown zones; multiple PSO stations will be necessary to fully observe the CIBW shutdown zones (table 24);

- PSO stations must be elevated platforms constructed on top of shipping containers or a similar base

that is at least 8'6" high (*i.e.*, the standard height of a shipping container) that can support at least three PSOs and their equipment. The platforms must be stable enough to support use of a theodolite and must be located to optimize the PSO's ability to observe marine mammals and the harassment zones;

- Each PSO station must have at least two PSOs on watch at any given time; one PSO must be observing and one PSO would be recording data (and observing when there are no data to record). Teams of three PSOs would include one PSO who would be observing, and one PSO who would be recording data (and observing when there are no data to record). The third PSO may help to observe, record data, or rest. In addition, if POA is conducting in-water work on other projects that includes PSOs, the CTR PSOs must be in real-time contact with those PSOs, and both sets of PSOs must share all information regarding marine mammal sightings with each other;

- A designated lead PSO must always be on site. The lead observer must have prior experience performing the duties of a PSO during in-water construction activities pursuant to a NMFS-issued ITA or Letter of Concurrence. Each PSO station must also have a designated Station Lead PSO specific to that station and shift. These Station Lead PSOs must have prior experience working as a PSO during in-water construction activities;

- PSOs would use a combination of equipment to perform marine mammal observations and to verify the required monitoring distance from the project site, which may include 7 by 50 binoculars, 20x/40x tripod mounted binoculars, 25 by 150 "big eye" tripod mounted binoculars, and theodolites;

- PSOs must record all observations of marine mammals, regardless of distance from the pile being driven. PSOs shall document any behavioral reactions in concert with distance from piles being driven or removed;

PSOs must have the following additional qualifications:

- Ability to conduct field observations and collect data according to assigned protocols;

- Experience or training in the field identification of marine mammals, including the identification of behaviors;

- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;

- Writing skills sufficient to record required information including but not limited to the number and species of marine mammals observed; dates and

times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and

- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

Reporting

NMFS would require the POA to submit interim weekly monitoring reports within 14 calendar days after the conclusion of each calendar week (that include raw electronic data sheets) during the CTR construction seasons, including for weeks during which no in-water work occurred (an email notification for weeks with no in-water work would be sufficient). These reports must include a summary of marine mammal species observed and behavioral observations, mitigation actions implemented, construction delays, and construction work completed. They also must include an assessment of the amount of construction remaining to be completed (*i.e.*, the number of estimated hours of work remaining), in addition to the number of CIBWs observed within estimated harassment zones to date for the current construction year.

NMFS would also require the POA to submit annual reports after the end of each construction season and a comprehensive final report following the conclusion of year 5 construction activities. Draft annual marine mammal monitoring reports must be submitted to NMFS within 90 days after the completion of each construction season or 60 days prior to a requested date of issuance of any future incidental take authorization for projects at the same location, whichever comes first. Annual reports must detail the monitoring protocol and summarize the data recorded during monitoring, and associated PSO data sheets in electronic tabular format. Specifically, the reports must include:

- Dates and times (begin and end) of all marine mammal monitoring;

- Construction activities occurring during each daily observation period, including the number and type of piles driven or removed and by what method (*i.e.*, impact or vibratory, the total equipment duration for vibratory installation and removal, and the total number of strikes for each pile during impact driving);

- PSO locations during marine mammal monitoring;

- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance;

- Upon observation of a marine mammal, the following information: name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; time of sighting; identification of the animal(s) (*e.g.*, genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species; distance and bearing of each marine mammal observed relative to the pile being driven for each sighting (if pile driving was occurring at time of sighting); estimated number of animals (minimum, maximum, and best estimate); estimated number of animals by cohort (adults, juveniles, neonates, group composition, sex class, *etc.*); animal's closest point of approach and estimated time spent within the harassment zone; group spread and formation (for CIBWs only; see ethogram in Appendix B of the POA's application); description of any marine mammal behavioral observations (*e.g.*, observed behaviors such as feeding or traveling), including an assessment of behavioral responses that may have resulted from the activity (*e.g.*, no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);

- Number of marine mammals detected within the harassment zones, by species;

- Detailed information about any implementation of mitigation action (*e.g.*, shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any;

If no comments are received from NMFS within 30 days, the draft annual or comprehensive reports would constitute the final reports. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

Reporting Injured or Dead Marine Mammals

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, the POA must immediately cease the specified activities and report the incident to the Office of Protected Resources, NMFS

(*PR.ITP.MonitoringReports@noaa.gov*, *ITP.hotchkinn@noaa.gov*) and to the Alaska Regional Stranding Coordinator as soon as feasible. If the death or injury was clearly caused by the specified activity, the POA must immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHA. The POA must not resume their activities until notified by NMFS. The report must include the following information:

- Time, date, and location (latitude and longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

Adaptive Management

These proposed regulations governing the take of marine mammals incidental to POA's CTR construction activities contain an adaptive management component. Our understanding of the effects of pile driving and other coastal construction activities (*e.g.*, acoustic stressors) on marine mammals continues to evolve, which makes the inclusion of an adaptive management component both valuable and necessary within the context of 5-year regulations.

The monitoring and reporting requirements are associated with information that helps us to better understand the impacts of the project's activities on marine mammals and informs our consideration of whether any changes to mitigation and monitoring are appropriate. The use of adaptive management allows NMFS to consider new information from different sources to determine (with input from the POA regarding practicability) if such modifications will have a reasonable likelihood of more effectively accomplishing the goals of the measures.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) results from monitoring reports, including the weekly, situational, and annual reports required; (2) results from research on marine mammals, noise impacts, or

other related topics; and (3) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or LOAs issued pursuant to these regulations. Adaptive management decisions may be made at any time, as new information warrants it.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be "taken" through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.*, intensity, duration), the context of any impacts or responses (*e.g.*, critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.*, as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, this introductory discussion of our analysis applies to all the species listed in table 25 except CIBWs given that many of the anticipated effects of this project on different marine mammal stocks are expected to be relatively similar in nature. For CIBWs, there are meaningful differences in anticipated individual responses to activities, impact of expected take on the population, or impacts on habitat; therefore, we provide a separate detailed analysis for CIBWs following the analysis for other species for which we propose to authorize incidental take.

NMFS has identified key factors which may be employed to assess the level of analysis necessary to conclude whether potential impacts associated with a specified activity should be considered negligible. These include, but are not limited to, the type and magnitude of taking, the amount and importance of the available habitat for the species or stock that is affected, the duration of the anticipated effect to the species or stock, and the status of the species or stock. The potential effects of the specified activities on gray whales, humpback whales, killer whales, harbor porpoises, Steller sea lions, and harbor seals are discussed below. Some of these factors also apply to CIBWs; however, a more detailed analysis for CIBWs is provided in a separate subsection below.

Species Other than CIBW. Pile driving associated with the project, as outlined previously, has the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level B harassment and, for some species, Level A harassment, from underwater sounds generated by pile driving. Potential takes could occur if marine mammals are present in zones ensniffed above the thresholds for Level B harassment or Level A harassment, identified above, while activities are underway.

The POA's proposed activities and associated impacts would occur within a limited, confined area of the stocks' range (other than CIBW). The work would occur in the vicinity of the CTR site, and sound from the proposed activities would be blocked by the coastline along Knik Arm along the eastern boundaries of the site and for those harassment isopleths that extend more than 3,000 m, directly across the Arm along the western shoreline (see figures 6–10 and 6–11 in the POA's application). The intensity and duration of take by Level A and Level B harassment would be minimized through use of mitigation measures described herein. Further, the number of takes proposed to be authorized is small when compared to stock abundance (see table 25). In addition, NMFS does not anticipate that serious injury or mortality will occur as a result of the POA's planned activity given the nature of the activity, even in the absence of required mitigation.

Exposures to elevated sound levels produced during pile driving may cause behavioral disturbance of some individuals. Behavioral responses of marine mammals to pile driving at the proposed project site are expected to be mild, short term, and temporary. Effects on individuals that are taken by Level

B harassment, as enumerated in the Estimated Take section, on the basis of reports in the literature as well as monitoring from other similar activities at the POA and elsewhere, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging if such activity were occurring (*e.g.*, Ridgway *et al.*, 1997; Nowacek *et al.*, 2007; Thorson and Reyff, 2006; Kendall and Cornick, 2015; Goldbogen *et al.*, 2013b; Blair *et al.*, 2016; Wisniewska *et al.*, 2018; Piwetz *et al.*, 2021). Marine mammals within the Level B harassment zones may not show any visual cues they are disturbed by activities or they could become alert, avoid the area, leave the area, or display other mild responses that are not visually observable such as exhibiting increased stress levels (*e.g.*, Rolland *et al.* 2012; Lusseau, 2005; Bejder *et al.*, 2006; Rako *et al.*, 2013; Pirotta *et al.*, 2015b; Pérez-Jorge *et al.*, 2016). They may also exhibit increased vocalization rates, louder vocalizations, alterations in the spectral features of vocalizations, or a cessation of communication signals (Hotchkiss and Parks 2013). However, as described in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section of this proposed rule, marine mammals, except CIBWs, observed within Level A and Level B harassment zones related to recent POA construction activities have not shown any acute, visually observable reactions to pile driving activities that have occurred during the PCT and SFD projects (61N Environmental, 2021, 2022a, 2022b).

Some of the species present in the region will only be present temporarily based on seasonal patterns or during transit between other habitats. These temporarily present species will be exposed to even smaller periods of noise-generating activity, further decreasing the impacts. Most likely, individual animals will simply move away from the sound source and be temporarily displaced from the area. Takes may also occur during important feeding times. The project area though represents a small portion of available foraging habitat and impacts on marine mammal feeding for all species is expected to be minimal.

The activities analyzed here are similar to numerous other construction activities conducted in Southern Alaska (*e.g.*, 86 FR 43190, August 6, 2021; 87 FR 15387, March 18, 2022), including the PCT and SFD projects within Upper Knik Arm (85 FR 19294, April 6, 2020; 86 FR 50057, September 7, 2021, respectively) which have taken place with no known long-term adverse

consequences from behavioral harassment. Any potential reactions and behavioral changes are expected to subside quickly when the exposures cease, and therefore, no long-term adverse consequences are expected (*e.g.*, Graham *et al.*, 2017). While there are no long-term peer-reviewed studies of marine mammal habitat use at the POA, studies from other areas indicate that most marine mammals would be expected to have responses on the order of hours to days. For example, harbor porpoises returned to a construction area between pile-driving events within several days during the construction of offshore wind turbines near Denmark (Carstensen *et al.*, 2006). The intensity of Level B harassment events would be minimized through use of mitigation measures described herein, which were not quantitatively factored into the take estimates. The POA would use PSOs stationed strategically to increase detectability of marine mammals during in-water construction activities, enabling a high rate of success in implementation of shutdowns to avoid or minimize injury for most species. Further, given the absence of any major rookeries and haulouts within the estimated harassment zones, we assume that potential takes by Level B harassment would have an inconsequential short-term effect on individuals and would not result in population-level impacts.

As stated in the mitigation section, the POA will implement shutdown zones (table 26) that equal or exceed the Level A harassment isopleths (table 16) for most vibratory pile driving and maximize practicability for shutdowns during impact pile driving. Take by Level A harassment is proposed for authorization for some species (gray whales, humpback whales, killer whales, harbor seals, Steller sea lions, and harbor porpoises) to account for the large Level A harassment zones from impact driving and the potential that an animal could enter and remain unobserved within the estimated Level A harassment zone for a duration long enough to incur auditory injury. Any take by Level A harassment is expected to arise from, at most, a small degree of auditory injury because animals would need to be exposed to higher levels and/or longer duration than are expected to occur here in order to incur any more than a small degree of auditory injury.

Due to the levels and durations of likely exposure, animals that experience auditory injury will likely only receive slight injury (*i.e.*, minor degradation of hearing capabilities within regions of hearing that align most completely with the frequency range of the energy

produced by POA's proposed in-water construction activities (*i.e.*, the low-frequency region below 2 kHz)), not severe hearing impairment or impairment in the ranges of greatest hearing sensitivity. If hearing impairment does occur, it is most likely that the affected animal will lose a few dBs in its hearing sensitivity, which, in most cases, is not likely to meaningfully affect its ability to forage and communicate with conspecifics. There are no data to suggest that a single instance in which an animal incurs auditory injury (or TTS) would result in impacts to reproduction or survival. If auditory injury were to occur, it would be minor and unlikely to affect more than a few individuals. Additionally, and as noted previously, some subset of the individuals that are behaviorally harassed could also simultaneously incur some small degree of TTS for a short duration of time. Because of the small degree anticipated, though, any auditory injury or TTS potentially incurred here is not expected to adversely impact individual fitness, let alone annual rates of recruitment or survival for the affected species or stocks.

Repeated, sequential exposure to pile driving noise over a long duration could result in more severe impacts to individuals that could affect a population (via sustained or repeated disruption of important behaviors such as feeding, resting, traveling, and socializing; Southall *et al.*, 2007). Alternatively, marine mammals exposed to repetitious construction sounds may become habituated, desensitized, or tolerant after initial exposure to these sounds (reviewed by Richardson *et al.*, 1995; Southall *et al.*, 2007). However, given the relatively low abundance of marine mammals other than CIBWs in Knik Arm compared to the stock sizes (table 25), population-level impacts are not anticipated. The absence of any pinniped haulouts or other known non-CIBW home-ranges in the proposed action area further decreases the likelihood of population-level impacts.

The CTR project is also not expected to have significant adverse effects on any marine mammal habitat. The project activities would occur mostly within the same footprint as existing marine infrastructure; the new T1 and T2 would extend approximately 140 ft (47-m) seaward of the existing terminals. The long-term impact on marine mammals associated with CTR would be a small permanent decrease in low-quality potential habitat because of the expanded footprint of the new cargo terminals T1 and T2. Installation and removal of in-water piles would be

temporary and intermittent, and the increased footprint of the facilities would destroy only a small amount of low-quality habitat, which currently experiences high levels of anthropogenic activity. Impacts to the immediate substrate are anticipated, but these would be limited to minor, temporary suspension of sediments, which could impact water quality and visibility for a short amount of time but which would not be expected to have any effects on individual marine mammals. Further, there are no known BIAs near the project zone, except for CIBWs, that will be impacted by the POA's planned activities.

Impacts to marine mammal prey species are also expected to be minor and temporary and to have, at most, short-term effects on foraging of individual marine mammals and likely no effect on the populations of marine mammals as a whole. Overall, the area impacted by the CTR project is very small compared to the available surrounding habitat and does not include habitat of particular importance. The most likely impact to prey would be temporary behavioral avoidance of the immediate area. During construction activities, it is expected that some fish and marine mammals would temporarily leave the area of disturbance, thus impacting marine mammals' foraging opportunities in a limited portion of their foraging range. But, because of the relatively small area of the habitat that may be affected and lack of any habitat of particular importance, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences.

In summary, the following factors primarily support our preliminary negligible impact determinations for the affected stocks of gray whales, humpback whales, killer whales, harbor porpoises, Steller sea lions, and harbor seals:

- No takes by mortality or serious injury are anticipated or proposed for authorization;
- Any acoustic impacts to marine mammal habitat from pile driving are expected to be temporary and minimal;
- Take would not occur in places and/or times where take would be more likely to accrue to impacts on reproduction or survival, such as within ESA-designated or proposed critical habitat, BIAs, or other habitats critical to recruitment or survival (e.g., rookery);
- The project area represents a very small portion of the available foraging area for all potentially impacted marine mammal species and does not contain any habitat of particular importance;

- Take will only occur within upper Cook Inlet—a limited, confined area of any given stock's home range;
- Monitoring reports from similar work in Knik Arm have documented little to no observable effect on individuals of the same species impacted by the specified activities;
- The required mitigation measures (i.e., soft starts, pre-clearance monitoring, shutdown zones, bubble curtains) are expected to be effective in reducing the effects of the specified activity by minimizing the numbers of marine mammals exposed to injurious levels of sound and by ensuring that any take by Level A harassment is, at most, a small degree of AUD INJ and of a lower degree that would not impact the fitness of any animals; and
- The intensity of anticipated takes by Level B harassment is low for all stocks consisting of, at worst, temporary modifications in behavior, and would not be of a duration or intensity expected to result in impacts on reproduction or survival.

Cook Inlet Beluga Whales. For CIBWs, we further discuss our negligible impact findings in the context of potential impacts to this endangered stock based on our evaluation of the take proposed for authorization (table 25).

As described in the Recovery Plan for the CIBW (NMFS, 2016b), NMFS determined the following physical or biological features are essential to the conservation of this species: (1) Intertidal and subtidal waters of Cook Inlet with depths less than 9 m mean lower low water and within 8 km of high and medium flow anadromous fish streams; (2) Primary prey species consisting of four species of Pacific salmon (Chinook, sockeye, chum, and coho), Pacific eulachon, Pacific cod, walleye pollock, saffron cod, and yellowfin sole; (3) Waters free of toxins or other agents of a type and amount harmful to CIBWs; (4) Unrestricted passage within or between the critical habitat areas, and (5) Waters with in-water noise below levels resulting in the abandonment of critical habitat areas by CIBWs. The CTR project will not impact essential features 1–3 listed above. All construction will be done in a manner implementing best management practices to preserve water quality, and no work will occur around creek mouths or river systems leading to prey abundance reductions. In addition, no physical structures will restrict passage; however, impacts to the acoustic habitat are relevant and discussed here.

Monitoring data from the POA suggest pile driving does not discourage CIBWs from entering Knik Arm and traveling to critical foraging grounds such as those

around Eagle Bay (e.g., 61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022). As described in greater detail in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section of this notice, sighting rates were not different in the presence or absence of pile driving (Kendall and Cornick, 2015). In addition, large numbers of CIBWs have continued to forage in portions of Knik Arm and pass through the area near the POA during pile driving projects over the past two decades (Funk *et al.*, 2005; Prevel-Ramos *et al.*, 2006; Markowitz and McGuire, 2007; Cornick and Saxon-Kendall, 2008, 2009; ICRC, 2009, 2010, 2011, 2012; Cornick *et al.*, 2010, 2011; Cornick and Pinney, 2011; Cornick and Seagars, 2016; POA, 2019), including during the recent PCT and SFD construction projects (61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022). These findings are not surprising as food is a strong motivation for marine mammals, and preying on seasonal anadromous fish runs in Eagle and Knik Rivers necessitates CIBWs passing the POA. As described in Forney *et al.* (2017), animals typically favor particular areas because of their importance for survival (e.g., feeding or breeding) and leaving may have significant costs to fitness (reduced foraging success, increased predation risk, increased exposure to other anthropogenic threats). Consequently, animals may be highly motivated to maintain foraging behavior in historical foraging areas despite negative impacts (e.g., Rolland *et al.*, 2012).

Previous monitoring data indicates CIBWs may be responding to pile driving noise but not through abandonment of primary foraging areas north of the port. Instead, they may travel faster past the POA, more quietly, and in smaller, tighter groups (Kendall and Cornick, 2015; 61N Environmental, 2021, 2022a, 2022b). CIBW presence at the POA has been extensively monitored during pile driving projects over the last several years, with data gathered during active driving activities and during periods of no construction noise. CIBWs are regularly observed at the POA even during active pile driving as discussed below.

During PCT and SFD construction monitoring, little variability was evident in the behaviors recorded from month to month or between sightings that coincided with in-water pile installation and removal and those that did not (61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022). Of the 386 CIBWs groups sighted during

PCT and SFD construction monitoring, 10 groups were observed during or within minutes of in-water impact pile installation and 56 groups were observed during or within minutes of vibratory pile installation or removal (61N Environmental, 2021, 2022a, 2022b). In general, CIBWs were more likely to display no reaction or to continue to move towards the PCT or SFD during pile installation and removal. In the situations during which CIBWs showed a possible reaction (6 groups during impact driving and 13 groups during vibratory driving), CIBWs were observed either moving away immediately after the pile driving activities started or were observed increasing their rate of travel.

NMFS funded a visual marine mammal monitoring project in 2021 (described in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat) to supplement sighting data collected by the POA monitoring program during non-pile driving days in order to further evaluate the impacts of anthropogenic activities on CIBWs (Easley-Appleyard and Leonard, 2022). Preliminary results suggest that group size ranged from 1 to 34 whales, with an average of 3 to 5.6, depending on the month. September had the highest sighting rate with 4.08 whales per hour, followed by October and August (3.46 and 3.41, respectively). Traveling was recorded as the primary behavior for 80 percent of the group sightings and milling was the secondary behavior most often recorded. Sighting duration varied from a single surfacing lasting less than 1 minute to 380 minutes. Preliminary findings suggest these results are consistent with the results from the POA's PCT and SFD monitoring efforts. For example, group sizes ranged from 2.38 to 4.32 depending on the month and the highest sighting rate was observed in September (1.75). In addition, traveling was the predominant behavior observed for all months and categories of construction activity (*i.e.*, no pile driving, before pile driving, during pile driving, between pile driving, or after pile driving), being recorded as the primary behavior for 86 percent of all sightings, and either the primary or secondary behavior for 95 percent of sightings.

Easley-Appleyard and Leonard (2022) also asked PSOs to complete a questionnaire post-monitoring that provided NMFS with qualitative data regarding CIBW behavior during observations. Specifically during pile driving events, the PSOs noted that CIBW behaviors varied; however, multiple PSOs noted seeing behavioral changes specifically during impact pile

driving and not during vibratory pile driving. CIBWs were observed sometimes changing direction, turning around, or changing speed during impact pile driving, whereas there were numerous instances where CIBWs were seen traveling directly towards the POA during vibratory pile driving before entering the Level B harassment zone (61N Environmental, 2021, 2022a, 2022b). The PSOs also reported that it seemed more likely for CIBWs to show more cryptic behavior during active impact and vibratory pile driving (*e.g.*, surfacing infrequently and without clear direction), though this seemed to vary across months (Easley-Appleyard and Leonard, 2022).

We anticipate that disturbance to CIBWs will manifest in the same manner when they are exposed to noise during the CTR project: whales would move quickly and silently through the area in more cohesive groups. Exposure to elevated noise levels during transit past the POA is not expected to have adverse effects on reproduction or survival as the whales continue to access critical foraging grounds north of the POA. Potential behavioral reactions that have been observed, including changes in group distribution and speed, may help to mitigate the potential for any contraction of communication space for a group. CIBWs are not expected to abandon entering or exiting Knik Arm as this is not evident based on monitoring data from the past two decades of work at POA (*e.g.*, Funk *et al.*, 2005; Prevel-Ramos *et al.*, 2006; Markowitz and McGuire, 2007; Cornick and Saxon-Kendall, 2008, 2009; ICRC, 2009, 2010, 2011, 2012; Cornick *et al.*, 2010, 2011; Cornick and Pinney, 2011; Cornick and Seagars, 2016; POA, 2019; Kendall and Cornick, 2015; 61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022). Finally, as described previously, both telemetry (tagging) and acoustic data suggest CIBWs likely stay in upper Knik Arm (*i.e.*, north of the CTR project site) for several days or weeks before exiting Knik Arm. Specifically, a CIBW instrumented with a satellite link time/depth recorder entered Knik Arm on August 18, 1999 and remained in Eagle Bay until September 12, 1999 (Ferrero *et al.*, 2000). Further, a recent detailed re-analysis of the satellite telemetry data confirms how several tagged whales exhibited this same movement pattern: whales entered Knik Arm and remained there for several days before exiting through lower Knik Arm (Shelden *et al.*, 2018). This longer-term use of upper

Knik Arm will avoid repetitive exposures from pile driving noise.

It is possible that exposure to pile driving at the POA could result in CIBWs avoiding Knik Arm and thereby not accessing the productive foraging grounds north of POA such as Eagle River flats thus, impacting essential feature number five of the designated Critical Habitat. The data previously presented demonstrate CIBWs are not abandoning the area (*i.e.*, continue to access the waters of northern Knik Arm during construction activities). Additionally, results of an expert elicitation (EE) at a 2016 workshop, which predicted the impacts of noise on CIBW survival and reproduction given lost foraging opportunities, helped to inform our assessment of impacts on this stock. The 2016 EE workshop used conceptual models of an interim population consequences of disturbance (PCoD) for marine mammals (NRC, 2005; New *et al.*, 2014; Tollit *et al.*, 2016) to help in understanding how noise-related stressors might affect vital rates (survival, birth rate and growth) for CIBW (King *et al.*, 2015). NMFS (2016b) suggests that the main direct effects of noise on CIBW are likely to be through masking of vocalizations used for communication and prey location and habitat degradation. The 2016 workshop on CIBWs was specifically designed to provide regulators with a tool to help understand whether chronic and acute anthropogenic noise from various sources and projects are likely to be limiting recovery of the CIBW population. The full report can be found at <https://www.smruconsulting.com/publications/> with a summary of the expert elicitation portion of the workshop below.

For each of the noise effect mechanisms chosen for EE, the experts provided a set of parameters and values that determined the forms of a relationship between the number of "days of disturbance" (defined as any day on which an animal loses the ability to forage for at least one tidal cycle (*i.e.*, it forgoes 50–100 percent of its energy intake on that day)) a female CIBW experiences in a particular period and the effect of that disturbance on her energy reserves. Examples included the number of disturbed days during the months of April, May, and June that would be predicted to reduce the energy reserves of a pregnant CIBW to such a level that she is certain to terminate the pregnancy or abandon the calf soon after birth; the number of disturbed days of from April to September required to reduce the energy reserves of a lactating CIBW to a level where she is certain to abandon her calf; and the threshold

disturbed days where a female fails to gain sufficient energy by the end of summer to maintain themselves and their calves during the subsequent winter.

Overall, median values ranged from 16 to 69 days of disturbance depending on the question. However, a “day of disturbance” considered in the context of the report is notably more severe than the Level B harassment expected to result from these activities, which as described is expected to be comprised predominantly of temporary modifications in the behavior of individual CIBWs (e.g., faster swim speeds, more cohesive group structure, decreased sighting durations, cessation of vocalizations) based on the large body of observational data available from previous monitoring efforts at the Port. Also, NMFS proposes to authorize an annual maximum of 90 instances of takes, with the instances representing disturbance events within a day. This means that either 90 different individual CIBWs are disturbed on no more than 1 day each per year or some lesser number of individuals may be disturbed on more than 1 day but with the product of individuals and days not exceeding 90. Given the overall estimated take, it is unlikely that any one CIBW will be disturbed on more than a few days. Further, the mitigation measures NMFS has proposed for the CTR project are designed to avoid the potential that any animal will lose the ability to forage for one or more tidal cycles should they be foraging in the proposed action area, which is not known to be a particularly important feeding area for CIBWs.

While Level B harassment (behavioral disturbance) is proposed to be authorized, the POA’s mitigation measures will limit the severity of the effects of that Level B harassment to behavioral changes such as increased swim speeds, tighter group formations, and cessation of vocalizations, not the loss of foraging capabilities. Regardless, this elicitation recognized that pregnant or lactating females and calves are inherently more at risk than other animals, such as males. Given that individuals in potentially vulnerable life stages, such as pregnancy, cannot be identified by visual observers, pile driving would be shut down for all CIBWs to be protective of potentially vulnerable individuals, and to avoid more severe behavioral reactions.

NMFS proposes required mitigation measures to minimize exposure to CIBWs, specifically, shutting down pile driving should a CIBW approach or enter the Level B harassment zone. These measures are designed to reduce the intensity and duration of potential

harassment CIBWs experience during the POA’s construction activities. Additionally, the proposed mitigation measures would help to ensure CIBWs will not experience degradation of acoustic habitat approaching the threshold set in the Critical Habitat designation (i.e., in-water noise at levels resulting in the abandonment of habitat by CIBWs). The location of the PSOs would allow for detection of CIBWs and behavioral observations prior to CIBWs entering the Level B harassment zone.

Additionally, NMFS proposes to require use of a bubble curtain for all permanent piles in waters deeper than 3 m in all months and for all piles (permanent or temporary) installed or extracted in waters deeper than 3 m during the months of August–October when CIBWs are present in higher numbers in Knik Arm. This measure is designed to reduce the amount of noise exposure at frequencies to which CIBWs are more sensitive (<100 Hz) during vibratory pile driving and to reduce overall sound levels during impact driving. During impact driving, the POA must implement soft starts, which ideally allows animals to leave a disturbed area before the full-power driving commences (Tougaard *et al.*, 2012). Although NMFS does not anticipate CIBWs will abandon entering Knik Arm in the presence of pile driving, PSOs will be integral to identifying if CIBWs are potentially altering pathways they would otherwise take in the absence of pile driving. Finally, take by mortality, serious injury, or Level A harassment of CIBWs is not anticipated or proposed to be authorized.

In summary, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect the CIBWs through effects on annual rates of recruitment or survival:

- No mortality, serious injury, or Level A harassment is anticipated or proposed to be authorized;
- Any acoustic impacts to marine mammal habitat from pile driving are expected to be temporary and minimal;
- The required mitigation measures (i.e., soft starts, pre-clearance monitoring, shutdown zones, bubble curtains) are expected to be effective in reducing the effects of the specified activity by ensuring that no CIBWs are exposed to noise at injurious levels (i.e., Level A harassment);
- The intensity of anticipated takes by Level B harassment is low, consisting of, at worst, temporary modifications in behavior, and would not be of a

duration or intensity expected to result in impacts on reproduction or survival.

- The area of exposure would be limited to habitat primarily used as a travel corridor. Data demonstrates Level B harassment of CIBWs typically manifests as increased swim speeds past the POA, tighter group formations, and cessation of vocalizations, rather than through habitat abandonment;
- No critical foraging grounds (e.g., Eagle Bay, Eagle River, Susitna Delta) would be affected by pile driving; and
- While animals could be harassed more than once, exposures are not likely to exceed more than a few per year for any given individual and are not expected to occur on sequential days; thereby decreasing the potential severity and interaction between harassment events for affected individuals.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat and taking into consideration the implementation of the required monitoring and mitigation measures, NMFS preliminarily finds that the proposed marine mammal take from the specified activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only incidental take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the maximum estimated number of individuals annually taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted maximum annual number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

For all stocks, except for the Mexico-North Pacific stock of humpback whales whose abundance estimate is unknown, the proposed number of takes is less than one-third of the best available population abundance estimate (i.e., less than 1 percent for 6 stocks; less than 2 percent for 1 stock; and less than 27.2 percent for CIBWs; see table 25). The maximum annual number of animals proposed for authorization to be

taken from these stocks would be considered small relative to the relevant stock's abundances even if each estimated take occurred to a new individual. The number of takes authorized likely represents smaller numbers of individual harbor seals and Steller sea lions. Harbor seals tend to concentrate near Ship Creek and have small home ranges. It is possible that a single individual harbor seal may linger near the POA, especially near Ship Creek and be counted multiple times each day as it moves around and resurfaces in different locations. Previous Steller sea lion sightings identified that if a Steller sea lion is within Knik Arm, it is likely lingering to forage on salmon or eulachon runs and may be present for several days. Therefore, the number of takes authorized likely represents repeat exposures to the same animals in certain circumstances. For all species, PSOs would count individuals as separate unless they can be individually identified.

Abundance estimates for the Mexico-North Pacific stock of humpback whales are based upon data collected more than 8 years ago, and therefore, current estimates are considered unknown (Young *et al.*, 2023). The most recent minimum population estimates (N_{MIN}) for this population include an estimate of 2,241 individuals between 2003 and 2006 (Martinez-Aguilar, 2011) and 766 individuals between 2004 and 2006 (Wade, 2021). NMFS' Guidelines for Assessing Marine Mammal Stocks suggest that the N_{MIN} estimate of the stock should be adjusted to account for potential abundance changes that may have occurred since the last survey and provide reasonable assurance that the stock size is at least as large as the estimate (NMFS, 2023). The abundance trend for this stock is unclear; therefore, there is no basis for adjusting these estimates (Young *et al.*, 2023). Assuming the population has been stable, the maximum annual 4 takes of this stock proposed for authorization represents small numbers of this stock (0.18 percent of the stock assuming a N_{MIN} of 2,241 individuals and 0.52 percent of the stock assuming an N_{MIN} of 766 individuals).

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the estimated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

In order to promulgate regulations, NMFS must find that the takings authorized will not have an "unmitigable adverse impact" on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined "unmitigable adverse impact" in 50 CFR 216.103 as an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

While no significant subsistence activity currently occurs within or near the POA, Alaska Natives have traditionally harvested subsistence resources, including marine mammals, in upper Cook Inlet for millennia. CIBWs are more than a food source; they are important to the cultural and spiritual practices of Cook Inlet Native communities (NMFS, 2008b). Dena'ina Athabascans, currently living in the communities of Eklutna, Knik, Tyonek, and elsewhere, occupied settlements in Cook Inlet for the last 1,500 years and have been the primary traditional users of this area into the present.

NMFS estimated that 65 CIBWs per year (range 21–123) were killed between 1994 and 1998, including those successfully harvested and those struck and lost. NMFS concluded that this number was high enough to account for the estimated 14 percent annual decline in population during this time (Hobbs *et al.*, 2008); however, given the difficulty of estimating the number of whales struck and lost during the hunts, actual mortality may have been higher. During this same period, population abundance surveys indicated a population decline of 47 percent, although the reason for this decline should not be associated solely with subsistence hunting and likely began well before 1994 (Rugh *et al.*, 2000).

In 1999, a moratorium was enacted (Pub. L. 106–31) prohibiting the subsistence harvest of CIBWs except through a cooperative agreement between NMFS and the affected Alaska Native organizations. NMFS began working cooperatively with the Cook Inlet Marine Mammal Council (CIMMC), a group of tribes that traditionally

hunted CIBWs, to establish sustainable harvests. CIMMC voluntarily curtailed its harvests in 1999. In 2000, NMFS designated the Cook Inlet stock of beluga whales as depleted under the MMPA (65 FR 34590, May 31, 2000). NMFS and CIMMC signed Co-Management of the Cook Inlet Stock of Beluga Whales agreements in 2000, 2001, 2002, 2003, 2005, and 2006. CIBW harvests between 1999 and 2006 resulted in the strike and harvest of five whales, including one whale each in 2001, 2002, and 2003, and two whales in 2005 (NMFS, 2008b). No hunt occurred in 2004 due to higher-than-normal mortality of CIBWs in 2003, and the Native Village of Tyonek agreed to not hunt in 2007. Since 2008, NMFS has examined how many CIBWs could be harvested during 5-year intervals based on estimates of population size and growth rate and determined that no harvests would occur between 2008 and 2012 and between 2013 and 2017 (NMFS, 2008b). The CIMMC was disbanded by unanimous vote of the CIMMC member Tribes' representatives in June 2012, and a replacement group of Tribal members has not been formed to date. There has been no subsistence harvest of CIBWs since 2005 (NMFS, 2022d).

Subsistence harvest of other marine mammals in upper Cook Inlet is limited to harbor seals. Steller sea lions are rare in upper Cook Inlet; therefore, subsistence use of this species is not common. However, Steller sea lions are taken for subsistence use in lower Cook Inlet. Residents of the Native Village of Tyonek are the primary subsistence users in the upper Cook Inlet area. While harbor seals are hunted for subsistence purposes, harvests of this species for traditional and subsistence uses by Native peoples have been low in upper Cook Inlet (*e.g.*, 33 harbor seals were harvested in Tyonek between 1983 and 2013; see table 8–1 in the POA's application), although these data are not currently being collected and summarized. As the POA's proposed project activities will take place within the immediate vicinity of the POA, no activities will occur in or near Tyonek's identified traditional subsistence hunting areas. As the harvest of marine mammals in upper Cook Inlet is historically a small portion of the total subsistence harvest and the number of marine mammals using upper Cook Inlet is proportionately small, the number of marine mammals harvested in upper Cook Inlet is expected to remain low.

The potential impacts from harassment on stocks that are harvested in Cook Inlet would be limited to minor

behavioral changes (e.g., increased swim speeds, changes in dive time, temporary avoidance near the POA) within the vicinity of the POA. Some PTS may occur; however, the shift is likely to be slight due to the implementation of mitigation measures (e.g., shutdown zones, pre-clearance monitoring, bubble curtains, soft starts) and the shift would be limited to lower pile driving frequencies which are on the lower end of phocid and otariid hearing ranges. In summary, any impacts to harbor seals would be limited to those seals within Knik Arm (outside of any hunting area) and the very few takes of Steller sea lions in Knik Arm would be far removed in time and space from any hunting in lower Cook Inlet.

The POA will communicate with representative Alaska Native subsistence users and Tribal members to identify and explain the measures that have been taken or will be taken to minimize any adverse effects of CTR on the availability of marine mammals for subsistence uses. In addition, the POA will adhere to the following communication procedures regarding marine mammal subsistence use within the Project area:

(1) Send letters to the Kenaitze, Tyonek, Knik, Eklutna, Ninilchik, Salamatof, and Chickaloon Tribes informing them of the proposed project (i.e., timing, location, and features). Include a map of the proposed project area; identify potential impacts to marine mammals and mitigation efforts, if needed, to avoid or minimize impacts; and inquire about possible marine mammal subsistence concerns they have.

(2) Follow up with a phone call to the environmental departments of the seven Tribal entities to ensure that they received the letter, understand the proposed project, and have a chance to ask questions. Inquire about any concerns they might have about potential impacts to subsistence hunting of marine mammals.

(3) Document all communication between the POA and Tribes.

(4) If any Tribes express concerns regarding proposed project impacts to subsistence hunting of marine mammals, propose a Plan of Cooperation between the POA and the concerned Tribe(s).

The proposed project features and activities, in combination with a number of actions to be taken by the POA during project implementation, should avoid or mitigate any potential adverse effects on the availability of marine mammals for subsistence uses. Furthermore, although construction will occur within the traditional area for

hunting marine mammals, the proposed project area is not currently used for subsistence activities. In-water pile installation and removal will follow mitigation procedures to minimize effects on the behavior of marine mammals and impacts will be temporary.

For the NES1 project, the POA expressed that, if desired, regional subsistence representatives may support project marine mammal biologists during the monitoring program by assisting with collection of marine mammal observations and may request copies of marine mammal monitoring reports. The POA proposes the same option for the CTR project.

Based on the description of the specified activity, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the proposed mitigation and monitoring measures, NMFS has preliminarily determined that there will not be an unmitigable adverse impact on subsistence uses from the POA's proposed activities.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the promulgation of regulations, NMFS consults internally whenever we propose to authorize take for endangered or threatened species, in this case with the NMFS Alaska Regional Office.

NMFS Office of Protected Resources (OPR) is proposing to authorize take of Mexico-North Pacific humpback whales (including individuals from the Mexico DPS), CIBWs, and western DPS Steller sea lions, which are listed under the ESA. NMFS OPR has requested initiation of section 7 consultation on the promulgation of regulations and issuance of a subsequent LOA. NMFS will conclude the ESA consultation prior to reaching a determination regarding the proposed issuance of the authorization.

Proposed Promulgation

As a result of these preliminary determinations, NMFS proposes to promulgate regulations that allow for the authorization of take, by Level A harassment and Level B harassment, incidental to construction activities

associated with the Cargo Terminals Replacement Project at the Don Young Port of Alaska in Anchorage, Alaska for a 5-year period from March 1, 2026, through February 28, 2031, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Request for Information

NMFS requests interested persons to submit comments, information, and suggestions concerning the POA's request and the proposed regulations (see **ADDRESSES**). All comments will be reviewed and evaluated as we prepare a final rule and make final determinations on whether to issue the requested authorization. This proposed rule and referenced documents provide all environmental information relating to our proposed action for public review.

Classification

The Office of Management and Budget has determined that this proposed rule is not significant for purposes of Executive Order 12866.

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The POA is an enterprise activity of the Municipality of Anchorage, Alaska, meaning that it is a department of the Municipality which generates adequate revenue to support its operational costs and annual payments to the Municipality. The POA is the sole entity that would be subject to the requirements in these proposed regulations, and the POA is not a small governmental jurisdiction, small organization, or small business, as defined by the RFA, because it is a department of the local government. Because of this certification, a regulatory flexibility analysis is not required and none has been prepared.

This proposed rule contains a collection-of-information requirement subject to the provisions of the Paperwork Reduction Act (PRA). Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number. These requirements have been approved by OMB under control number 0648–

0151 and include applications for regulations, subsequent LOAs, and reports.

List of Subjects in 50 CFR Part 217

Acoustics, Administrative practice and procedure, Construction, Endangered and threatened species, Marine mammals, Mitigation and monitoring requirements, Reporting requirements, Wildlife.

Dated: October 18, 2024.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For reasons set forth in the preamble, NMFS proposes to amend 50 CFR part 217 to read as follows:

PART 217—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 217 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

■ 2. Add subpart B, consisting of §§ 217.11 through 217.19, to read as follows:

Subpart B—Taking Marine Mammals Incidental to the Port of Alaska Modernization Program Phase 2B: Cargo Terminals Replacement Project in Anchorage, Alaska

Sec.

- 217.11 Specified activity and specified geographical region.
- 217.12 Effective dates.
- 217.13 Permissible methods of taking.
- 217.14 Prohibitions.
- 217.15 Mitigation requirements.
- 217.16 Requirements for monitoring and reporting.
- 217.17 Letters of Authorization.
- 217.18 Modifications of Letters of Authorization.
- 217.19 [Reserved]

Subpart B—Taking Marine Mammals Incidental to the Port of Alaska Modernization Program Phase 2B: Cargo Terminals Replacement Project in Anchorage, Alaska

§ 217.11 Specified activity and specified geographical region.

(a) The incidental taking of marine mammals by the Port of Alaska (POA) may be authorized in a Letter of Authorization (LOA) only if it occurs at or around the Port of Alaska, including waters of Knik Arm and Upper Cook Inlet near Anchorage, Alaska incidental to the specified activities outlined in paragraph (b) of this section.

(b) The specified activities are construction and demolition activities associated with the Cargo Terminals

Replacement Project under the Port of Alaska Modernization Program at the Don Young Port of Alaska in Anchorage, Alaska.

§ 217.12 Effective dates.

Regulations in this subpart are effective from March 1, 2026, until February 28, 2031.

§ 217.13 Permissible methods of taking.

Under a LOA issued pursuant to § 216.106 of this chapter and § 217.17, the POA and those persons it authorizes or funds to conduct activities on its behalf may incidentally, but not intentionally, take marine mammals within the specified geographical region by harassment associated with the specified activities provided they are in compliance with all terms, conditions, and requirements of the regulations in this subpart and the applicable LOA.

§ 217.14 Prohibitions.

(a) Except for the takings permitted in § 217.13 and authorized by a LOA issued under § 216.106 of this chapter and § 217.17, it is unlawful for any person to do any of the following in connection with the specified activities:

(1) Violate or fail to comply with the terms, conditions, and requirements of this subpart or a LOA issued under this subpart;

(2) Take any marine mammal not specified in such LOA;

(3) Take any marine mammal specified in such LOA in any manner other than specified;

(4) Take a marine mammal specified in such LOA if NMFS determines such taking results in more than a negligible impact on the species or stocks of such marine mammal; or

(5) Take a marine mammal specified in such LOA after NMFS determines such taking results in an unmitigable adverse impact on the species or stock of such marine mammal for taking for subsistence uses.

(b) [Reserved]

§ 217.15 Mitigation requirements.

(a) When conducting the specified activities identified in § 217.11(b), POA must implement the mitigation measures contained in this section and any LOA issued under §§ 216.106 of this chapter and 217.17. These mitigation measures include, but are not limited to:

(1) A copy of any issued LOA must be in the possession of the POA, its designees, and work crew personnel operating under the authority of the issued LOA.

(2) The POA must ensure that construction supervisors and crews, the monitoring team and relevant POA staff

are trained prior to the start of all pile driving so that responsibilities, communication procedures, monitoring protocols, and operational procedures are clearly understood. New personnel joining during the project must be trained prior to commencing work.

(3) The POA must employ Protected Species Observers (PSOs) and establish monitoring locations pursuant to § 217.16 and as described in a NMFS-approved Marine Mammal Monitoring and Mitigation Plan.

(i) For all pile driving activities, land-based PSOs must be stationed at the best vantage points practicable to monitor for marine mammals and implement shutdown/delay procedures. A minimum of 4 locations must be used to monitor the designated harassment zones to the maximum extent possible based on daily visibility conditions. Additional PSOs must be added if warranted by site conditions and/or the level of marine mammal activity in the area. PSOs must be able to implement shutdown or delay procedures when applicable through communication with the equipment operator.

(ii) If during pile driving activities, PSOs can no longer effectively monitor the entirety of the Cook Inlet beluga whale (CIBW) shutdown zone due to environmental conditions (*e.g.*, fog, rain, wind), pile driving may continue only until the current segment of the pile is driven; no additional sections of pile or additional piles may be driven until conditions improve such that the shutdown zone can be effectively monitored. If the shutdown zone cannot be monitored for more than 15 minutes, the entire zone must be cleared again for 30 minutes prior to reinitiating pile driving.

(4) Pre-start Clearance Monitoring must take place from 30 minutes prior to initiation of pile driving activity (*i.e.*, pre-start clearance monitoring) through 30 minutes post-completion of pile driving activity.

(i) Pre-start clearance monitoring must be conducted during periods of visibility sufficient for the Lead PSO to determine that the shutdown zones are clear of marine mammals.

(ii) Pile driving may commence if, following 30 minutes of observation, it is determined by the Lead PSO that the shutdown zones are clear of marine mammals and for CIBW, any observed whale(s) is at least 100 meters past the shutdown zone and on a path away from the zone or the whale has not been re-sighted for 30 minutes.

(5) For all pile driving activity, the POA must implement shutdown zones with radial distances as identified in a

LOA issued under § 216.106 of this chapter and § 217.17.

(i) If a marine mammal is observed entering or within the shutdown zone, all pile driving activities, including soft starts, at that location must be halted. If pile driving is halted or delayed due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily left and is been visually confirmed beyond the shutdown zone or 15 minutes (non-CIBWs) or 30 minutes (CIBWs) have passed without re-detection of the animal. Specific to CIBW, if a CIBW(s) is observed within or on a path towards the shutdown zone, pile driving activities, including soft starts, must shut down and not recommence until the whale has traveled at least 100 m beyond the shutdown zone and is on a path away from such zone or until no CIBW has been observed in the shutdown zone for 30 minutes.

(ii) In the event of a delay or shutdown of activity resulting from marine mammals in the shutdown zone, animal behavior must be monitored and documented.

(iii) If work ceases for more than 30 minutes, the shutdown zones must be cleared again for 30 minutes prior to reinitiating pile driving. A determination that the shutdown zone is clear must be made during a period of good visibility.

(iv) If a shutdown procedure should be initiated but human safety is at risk, as determined by the best professional judgment of the vessel operator or project engineer, the in-water activity, including pile driving, is allowed to continue until the risk to human safety has dissipated. In this scenario, pile driving may continue only until the current segment of the pile is driven; no additional sections of pile or additional piles may be driven until the Lead PSO has determined that the shutdown zones are clear of marine mammals and for Cook Inlet beluga whales (CIBW), any observed whale(s) is at least 100 meters past the shutdown zone and on a path away from the zone.

(v) For in-water construction activities other than pile driving (e.g., barge positioning; use of barge-mounted excavators; dredging), if a marine mammal comes within 10 m, POA must cease operations and reduce vessel speed to the minimum level required to maintain steerage and safe working conditions. If human safety is at risk, as determined by the best professional judgment of the vessel operator or project engineer, the in-water activity is allowed to continue until the risk to human safety has dissipated.

(6) The POA must use soft start techniques when impact pile driving. Soft start requires contractors to conduct three sets of strikes (three strikes per set) at reduced hammer energy with a 30-second waiting period between each set. A soft start must be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer.

(7) The POA must use bubble curtains for all temporary (36- or 24-in diameter) piles during both vibratory and impact pile driving in water depths greater than 3 meters (9.8 ft) between August 1 and October 31. Bubble curtains must be used for all permanent piles (72-in diameter) during both vibratory and impact pile driving in waters deeper than 3 meters (9.8 feet). The bubble curtain must be operated to achieve optimal performance. At a minimum, the bubble curtain must:

(i) The bubble curtain must distribute air bubbles around 100 percent of the piling perimeter for the full depth of the water column.

(ii) The lowest bubble ring must be in contact with the mudline and/or rock bottom for the full circumference of the ring, and the weights attached to the bottom ring shall ensure 100 percent mudline and/or rock bottom contact. No parts of the ring or other objects shall prevent full mudline and/or rock bottom contact.

(iii) Air flow to the bubblers must be balanced around the circumference of the pile.

(8) Pile driving activity must be halted upon observation of a species entering or within the harassment zone for either a species for which incidental take is not authorized or a species for which incidental take has been authorized but the authorized number of takes has been met.

(b) [Reserved]

§ 217.16 Requirements for monitoring and reporting.

(a) The POA must submit a Marine Mammal Monitoring and Mitigation Plan to NMFS for approval at least 90 days before the start of construction and abide by the Plan, if approved.

(b) Monitoring must be conducted by qualified, NMFS-approved PSOs, in accordance with the following conditions:

(1) PSOs must be independent of the activity contractor (e.g., employed by a subcontractor) and have no other assigned tasks during monitoring duties.

(2) PSOs must be approved by NMFS prior to beginning work on the specified activities.

(3) PSOs must be trained in marine mammal identification and behavior.

(i) A designated Project Lead PSO must always be on site. The Project Lead PSO must have prior experience performing the duties of a PSO during in-water construction activities pursuant to a NMFS-issued ITA or Letter of Concurrence.

(ii) Each PSO station must also have a designated Station Lead PSO specific to that station and shift. These Station Lead PSOs must have prior experience working as a PSO during in-water construction activities;

(iii) Other PSOs may substitute other relevant experience (including relevant Alaska Native traditional knowledge), education (degree in biological science or related field), or training for prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization.

(4) PSO stations must be elevated platforms constructed on top of shipping containers or a similar base that is at least 8'6" high (i.e., the standard height of a shipping container) that can support at least three PSOs and their equipment. The platforms must be stable enough to support use of a theodolite and must be located to optimize the PSO's ability to observe marine mammals and the shutdown zones. Each PSO station must have at least two PSOs on watch at any given time, including the Station Lead PSO.

(5) If the POA is conducting in-water work for other projects that includes PSOs, the PSOs for the Cargo Terminals Replacement Project must be in real-time contact with those PSOs, and both sets of PSOs must share all information regarding marine mammal sightings with each other.

(c) The POA must submit weekly monitoring reports within 14 days after the conclusion of each calendar week during each Cargo Terminals Replacement Project construction season. These reports must include a summary of marine mammal species and behavioral observations, construction shutdowns or delays, and construction work completed during the reporting period. The weekly reports also must include an assessment of the amount of construction remaining to be completed (i.e., the number of estimated hours of work remaining), in addition to the number of beluga whales observed within estimated harassment zones to date.

(d) The POA must submit a draft annual summary monitoring report on all monitoring conducted during each construction season which includes final electronic data sheets within 90

calendar days after the completion of each construction season or 60 days prior to a requested date of issuance of any future incidental take authorization for projects at the same location, whichever comes first. A draft comprehensive 5-year summary report must also be submitted to NMFS within 90 days of the end of year 5 of the project. The reports must detail the monitoring protocol and summarize the data recorded during monitoring. If no comments are received from NMFS within 30 days of receipt of the draft report, the report may be considered final. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments. At a minimum, the reports must contain:

(1) Dates and times (begin and end) of all marine mammal monitoring;

(2) Construction activities occurring during each daily observation period, including how many and what type of piles were driven or removed, by what method (*i.e.*, impact or vibratory), the total duration of driving time for each pile (vibratory driving), and number of strikes for each pile (impact driving);

(3) Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), Beaufort sea state, and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance (if less than the harassment zone distance);

(4) Upon observation of a marine mammal, the following information should be collected:

(i) Name of the PSO who sighted the animal, observer location, and activity at time of sighting;

(ii) Time of sighting;

(iii) Identification of the animal (*e.g.*, genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species;

(iv) Distances and bearings of each marine mammal observed in relation to the pile being driven for each sighting (if pile driving was occurring at time of sighting);

(v) Estimated number of animals (min/max/best);

(vi) Estimated number of animals by cohort (adults, juveniles, neonates, group composition, *etc.*);

(vii) Animal's closest point of approach and estimated time spent within the harassment zone;

(viii) Description of any marine mammal behavioral observations (*e.g.*, observed behaviors such as feeding or

traveling), including an assessment of behavioral responses to the activity (*e.g.*, no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);

(ix) Detailed information about any implementation of any mitigation (*e.g.*, shutdowns and delays), a description of specific actions that ensued, and resulting changes in the behavior of the animal, if any; and

(x) All PSO datasheets and raw sightings data in electronic spreadsheet format.

(e) In the event that personnel involved in the construction activities discover an injured or dead marine mammal, the POA must report the incident to NMFS Office of Protected Resources (OPR) and to the Alaska Regional Stranding Coordinator no later than 24 hours after the initial observation. If the death or injury was caused by the specified activity, the POA must immediately cease the specified activities until NMFS OPR is able to review the circumstances of the incident. The POA must not resume their activities until notified by NMFS. The report must include the following information:

(1) Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);

(2) Species identification (if known) or description of the animal(s) involved;

(3) Condition of the animal(s) (including carcass condition if the animal is dead);

(4) Observed behaviors of the animal(s), if alive;

(5) If available, photographs or video footage of the animal(s); and

(6) General circumstances under which the animal was discovered.

§ 217.17 Letters of Authorization.

(a) To incidentally take marine mammals pursuant to these regulations, the POA must apply for and obtain an LOA.

(b) An LOA, unless suspended or revoked, may be effective for a period of time not to exceed the effective dates of this subpart.

(c) If an LOA expires prior to the end of the effective dates of this subpart, the POA may apply for and obtain a renewal of the LOA.

(d) In the event of projected changes to the activity or to mitigation and monitoring measures required by an LOA, the POA must apply for and obtain a modification of the LOA as described in § 217.18.

(e) The LOA must set forth the following information:

(1) Permissible methods of incidental taking;

(2) Means of effecting the least practicable adverse impact (*i.e.*, mitigation) on the species, its habitat, and on the availability of the species for subsistence uses; and

(3) Requirements for monitoring and reporting.

(f) Issuance of the LOA must be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under this subpart.

(g) Notice of issuance or denial of an LOA must be published in the **Federal Register** within 30 days of a determination.

§ 217.18 Modifications of Letters of Authorization.

(a) A LOA issued under §§ 216.106 of this chapter and 217.17 for the specified activities may be modified upon request by the POA, provided that:

(1) The specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for this subpart; and

(2) NMFS determines that the mitigation, monitoring, and reporting measures required by the previous LOA were implemented.

(b) For LOA modification by the POA that includes changes to the specified activity or the mitigation, monitoring, or reporting measures that do not change the findings made for the regulations in this subpart or result in no more than a minor change in the total estimated number of takes (or distribution by species or years), NMFS may publish a notice of proposed LOA in the **Federal Register**, including the associated analysis of the change and solicit public comment before issuing the LOA.

(c) A LOA issued under § 216.106 of this chapter and § 217.17 for the specified activity may be modified by NMFS under the following circumstances:

(1) NMFS may modify the existing mitigation, monitoring, or reporting measures, after consulting with the POA regarding the practicability of the modifications, if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring measures;

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in an LOA include, but are not limited to:

(A) Results from the POA's monitoring;

(B) Results from other marine mammal and/or sound research or studies; and

(C) Any information that reveals marine mammals may have been taken

in a manner, extent or number not authorized by this subpart or subsequent LOAs; and

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS shall publish a notice of proposed LOA in the **Federal Register** and solicit public comment;

(2) If NMFS determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in a LOA issued pursuant to § 216.106 of this chapter and § 217.17, a LOA may be modified without prior notice or opportunity for public comment. Notification will be published in the

Federal Register within 30 days of the action.

§ 217.19 [Reserved]

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Part IV

Department of the Treasury

Internal Revenue Service

26 CFR Part 54

Department of Labor

Employee Benefits Security Administration

29 CFR Part 2590

Department of Health and Human Services

45 CFR Part 147

Enhancing Coverage of Preventive Services Under the Affordable Care Act; Proposed Rule

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[REG-110878-24]

RIN 1545-BR35

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210-AC25

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 147**

[CMS 9887-P]

RIN 0938-AV57

Enhancing Coverage of Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Proposed rule.

SUMMARY: This document sets forth proposed rules that would amend the regulations regarding coverage of certain preventive services under the Public Health Service Act. Specifically, this document proposes rules that would provide that medical management techniques used by non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage with respect to such preventive services would not be considered reasonable unless the plan or issuer provides an easily accessible, transparent, and sufficiently expedient exceptions process that would allow an individual to receive coverage without cost sharing for the preventive service that is medically necessary with respect to the individual, as determined by the individual's attending provider, even if such service is not generally covered under the plan or coverage. These proposed rules also contain separate requirements that would apply to coverage of contraceptive items that are preventive services under the Public Health Service Act. Specifically, these proposed rules would require plans and issuers to cover certain recommended

over-the-counter contraceptive items without requiring a prescription and without imposing cost-sharing requirements. In addition, the proposed rules would require plans and issuers to cover certain recommended contraceptive items that are drugs and drug-led combination products without imposing cost-sharing requirements, unless a therapeutic equivalent of the drug or drug-led combination product is covered without cost sharing. Finally, this document proposes to require a disclosure pertaining to coverage and cost-sharing requirements for over-the-counter contraceptive items in plans' and issuers' Transparency in Coverage internet-based self-service tools or, if requested by the individual, on paper. These proposed rules would not modify Federal conscience protections related to contraceptive coverage for employers, plans and issuers.

DATES: To be assured consideration, comments must be received at one of the addresses provided below by December 27, 2024.

ADDRESSES: Written comments may be submitted to the address specified below. Any comment that is submitted will be shared with the Department of the Treasury, Internal Revenue Service, and the Department of Health and Human Services (HHS). Commenters should not submit duplicates.

Comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the internet exactly as received and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, please refer to file code 1210-AC25.

Comments must be submitted in one of the following two ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By mail.* You may mail written comments to the following address **ONLY:** Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, Washington, DC 20210, Attention: 1210-AC25.

Always allow sufficient time for mailed comments to be received before

the close of the comment period. Because of staff and resource limitations, the Departments cannot accept comments by facsimile (FAX) transmission.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. The comments are posted on the following website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a summary of these proposed rules of not more than 100 words in length, in plain language, may be found at <https://www.regulations.gov/>.

FOR FURTHER INFORMATION CONTACT: Regan Rusher, Internal Revenue Service, Department of the Treasury, at (202) 317-5500. Matthew Meidell, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335. Rebecca Miller, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335. Geraldine Doetzer, Centers for Medicare & Medicaid Services, Department of Health and Human Services at (667) 290-8855. Kendra May, Centers for Medicare & Medicaid Services, Department of Health and Human Services at (301) 448-3996.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor (DOL) concerning employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the DOL's website (www.dol.gov/ebsa). In addition, information from HHS on private health insurance coverage and on non-Federal governmental plans can be found on the Centers for Medicare & Medicaid Services (CMS) website (www.cms.gov/ccio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:**I. Background***A. Coverage of Preventive Services Under the Affordable Care Act and Implementing Regulations*

The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) was enacted on March

30, 2010. These statutes are collectively known as the Affordable Care Act (ACA). The ACA reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The ACA added section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA)¹ and section 9815(a)(1) to the Internal Revenue Code (Code)² to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans.

Section 2713 of the PHS Act,³ as added by section 1001 of the ACA and incorporated into ERISA and the Code, and its implementing regulations require that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage (plans and issuers) provide coverage without imposing any cost-sharing requirements for the following items and services:⁴

- Evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved, except for the recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued in or around November 2009;⁵ ⁶

- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on

Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved;⁷

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and
- With respect to women,⁸ such additional preventive care and screenings not described in the USPSTF recommendations in PHS Act section 2713(a)(1), as provided for in comprehensive guidelines supported by HRSA.⁹

On August 1, 2011, HRSA established the HRSA-supported Women’s Preventive Services Guidelines (HRSA-supported Guidelines) based on recommendations from a Department of Health and Human Services’ (HHS) commissioned study by the Institute of Medicine.¹⁰ Among other recommended

⁷ In addition, under section 3203 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), enacted on March 27, 2020 (Pub. L. 116–136), plans and issuers must cover, without cost-sharing requirements, any qualifying coronavirus preventive service pursuant to section 2713(a) of the PHS Act and its implementing regulations (or any successor regulations). The term “qualifying coronavirus preventive service” means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID–19) and that is (1) an evidence-based item or service that has in effect a rating of “A” or “B” in the current USPSTF recommendations; or (2) an immunization that has in effect a recommendation from ACIP with respect to the individual involved. See FAQs about Families First Coronavirus Response Act, Coronavirus Aid, Relief, and Economic Security Act, and Health Insurance Portability and Accountability Act Implementation Part 58, Q4 (Mar. 29, 2023), available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-58.pdf> and <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/faqs-part-58.pdf>.

⁸ Consistent with the terminology in the statute, for purposes of coverage of contraceptive items, these proposed rules use the term “women” to refer to all individuals potentially capable of becoming pregnant. Plans and issuers are required to cover contraceptive services for all such individuals consistent with the requirements in 26 CFR 54.9815–2713, 29 CFR 2590.715–2713, and 45 CFR 147.130. See FAQs about Affordable Care Act Implementation Part XXVI, Q5 (May 11, 2015), available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

⁹ For accommodations and exemptions with respect to coverage of recommended contraceptive services, see 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A, and 45 CFR 147.131 through 147.133.

¹⁰ See HRSA (2011), “Women’s Preventive Services: Required Health Plan Coverage,” available at: <https://web.archive.org/web/20130526033922/https://www.hrsa.gov/womensguidelines/index.html>; see also Institute of Medicine, “Clinical Preventive Services for Women: Closing the Gaps” (2011), available at <https://nap.nationalacademies.org/read/13181/chapter/7>.

items and services, the 2011 HRSA-supported Guidelines addressed contraceptive methods and counseling as a type of preventive service and included all Food and Drug Administration (FDA)-approved “contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.”¹¹ The HRSA-supported Guidelines’ recommendation on contraception has been updated several times, including in 2016,¹² and most recently in 2021.¹³ The 2011 HRSA-supported Guidelines included for each type of preventive service a column labeled “Frequency,” which for contraceptive methods and counseling, stated, “as prescribed.” The “Frequency” column does not appear in the 2016, 2019, or 2021 updated HRSA-supported Guidelines for any preventive service, and the updated HRSA-supported Guidelines do not contain language that specifies frequency in accordance with a prescription for contraceptive methods (or contraceptives) by a health care provider. Plans and issuers are required to provide coverage of women’s preventive services, including contraceptive items and services, without cost sharing, consistent with the 2021 HRSA-supported Guidelines, for plan years and policy years beginning on or after December 30, 2022.¹⁴ The 2021 HRSA-supported Guidelines refer, under the header

¹¹ The references in this preamble to “contraception,” “contraceptive,” “contraceptive coverage,” “contraceptive services,” “contraceptive product,” or “contraceptive item” generally include all contraceptives, sterilization, and related patient education and counseling recommended by the currently applicable HRSA-supported Guidelines, unless otherwise indicated.

¹² The HRSA-supported Guidelines, as amended in December 2016, refer, under the header “Contraception,” to: “the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures,” “contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method),” and “instruction in fertility awareness-based methods, including the lactation amenorrhea method.” See <https://www.hrsa.gov/womens-guidelines-2016/index.html>.

¹³ See HRSA, “Women’s Preventive Services Guidelines: Current Guidelines,” available at <https://www.hrsa.gov/womens-guidelines>.

¹⁴ The Departments’ regulations under section 2713 of the PHS Act at 26 CFR 54.9815–2713T, 29 CFR 2590.715–2713, and 45 CFR 147.130 require that plans and issuers provide coverage of recommended preventive services generally for plan years (in the individual market, policy years) that begin on or after September 23, 2010, or, if later, for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued.

¹ 29 U.S.C. 1185d.

² 26 U.S.C. 9815.

³ 42 U.S.C. 300gg–13.

⁴ The items and services described in these recommendations and guidelines are referred to in this preamble as “recommended preventive services.”

⁵ The USPSTF published updated breast cancer screening recommendations in April 2024. However, section 223 of title II of Division D of the Further Consolidated Appropriations Act, 2024 (Pub. L. 118–47) requires that for purposes of PHS Act section 2713, USPSTF recommendations relating to breast cancer screening, mammography, and prevention issued before 2009 remain in effect until January 1, 2026.

⁶ On September 19, 2024, the Departments filed a petition for a writ of certiorari requesting U.S. Supreme Court review of the decision of the U.S. Court of Appeals for the Fifth Circuit in *Braidwood Management v. Becerra*, which found in part that the actions taken by the Departments under section 2713(a) of the PHS Act to require coverage of certain preventive services recommended by the USPSTF are unconstitutional and unenforceable by the Departments as to the named plaintiffs. See 104 F.4th 930 (5th Cir. 2024), *petition for cert. filed* (U.S. Sept. 19, 2024) (No. 24–316).

“Contraception,” to “the full range of contraceptives and contraceptive care to prevent unintended pregnancies and improve birth outcomes.” The term “contraceptive methods” was replaced in 2021 by “contraceptives.”¹⁵ With the removal of the phrase “female-controlled,” as HRSA explained,¹⁶ male condoms are included in the 2021 HRSA-supported Guidelines, which also include “screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period)” including “follow-up care (e.g., management, evaluation and changes, including the removal, continuation, and discontinuation of contraceptives).”¹⁷ The 2021 HRSA-supported Guidelines recommend “the full range of U.S. Food and Drug Administration (FDA)-approved, -granted, or -cleared contraceptives, effective family planning practices, and sterilization procedures be available as part of contraceptive care.”¹⁸

The Departments of the Treasury, Labor, and HHS (the Departments) previously issued rulemaking to implement the preventive services requirements of section 2713 of the PHS Act, using their authority under section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.¹⁹ On July 19, 2010, the Departments issued interim final rules (July 2010 interim final rules) at 26 CFR 54.9815–2713T, 29 CFR 2590.715–2713, and 45 CFR 147.130, which require that plans and issuers provide coverage of recommended preventive services generally for plan years or policy years that begin on or after September 23, 2010; or, if later, for plan years or policy years that begin on or after the date that is one year after the recommendation or guideline is issued.²⁰ Among other provisions, the July 2010 interim final rules allow plans and issuers to rely on the relevant clinical evidence base to impose reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health item or service, to the extent not specified in the applicable

recommendation or guideline.²¹ Additionally, if a plan or issuer has a provider in its network that can provide a recommended preventive service, the July 2010 interim final rules specify that the plan or issuer is not required to provide coverage or waive cost sharing for the item or service when delivered by an out-of-network provider.²² However, if a plan or issuer does not have in its network a provider who can provide a recommended preventive service (or the plan or coverage does not have a network), the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose any cost-sharing requirements with respect to the item or service. The Departments finalized these rules on July 14, 2015.²³

The Departments have also previously issued rules that provide exemptions from the contraceptive coverage requirement for entities and individuals with moral or religious objections to contraceptive coverage, and accommodations through which objecting entities are not required to contract, arrange, pay, or provide a referral for contraceptive coverage, while at the same time ensuring that participants, beneficiaries, and enrollees enrolled in coverage sponsored or arranged by an objecting entity could separately obtain contraceptive services at no additional cost.²⁴ Most recently, on February 2, 2023, the Departments issued proposed rules (2023 proposed rules) to rescind the moral exemption to the contraceptive coverage requirement and to establish a new “individual contraceptive arrangement,” an independent pathway that individuals enrolled in plans or coverage sponsored, arranged, or provided by objecting

entities could use to obtain contraceptive services at no cost directly from a provider or facility that furnishes contraceptive services.²⁵

B. Guidance Related to the Coverage of Recommended Preventive Services

Since publishing the July 2010 interim final rules, the Departments have issued extensive guidance related to the requirement to cover recommended preventive services, including contraceptive services, without cost sharing under section 2713 of the PHS Act and its implementing regulations. These guidance documents respond to questions from interested parties regarding the requirement to provide coverage for recommended preventive services without cost sharing.²⁶ Cumulatively, this body of guidance interprets key elements of the preventive health services recommendations and guidelines and coverage requirements, including with respect to the allowed use of reasonable medical management techniques.²⁷ These guidance documents include:

²⁵ 88 FR 7236.

²⁶ See FAQs about Affordable Care Act Implementation Part XII (Feb. 20, 2013), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-xii.pdf> and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html; FAQs about Affordable Care Act Implementation Part XXVI (May 11, 2015), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf; FAQs about Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women’s Health and Cancer Rights Act Implementation (April 20, 2016), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-31.pdf> and https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-31_final-4-20-16.pdf; FAQs about Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act, and Coronavirus Aid, Relief, and Economic Security Act Implementation (Jan. 10, 2022), available at <https://www.dol.gov/sites/dolgov/files/ebbsa/about-ebbsa/our-activities/resource-center/faqs/aca-part-51.pdf> and <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/FAQs-Part-51.pdf>; FAQs about Affordable Care Act Implementation Part 54 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>; and FAQs about Affordable Care Act Implementation Part 64 (Jan. 22, 2024) available at <https://www.dol.gov/agencies/ebbsa/about-ebbsa/our-activities/resource-center/faqs/aca-part-64> and <https://www.cms.gov/files/document/faqs-part-64.pdf>.

²⁷ As noted in section I.A of the preamble to these proposed rules, under 26 CFR 54.9815–2713T(a)(4), 29 CFR 2590.715–2713(a)(4), and 45 CFR 147.130(a)(4), plans and issuers may use “reasonable medical management techniques” to determine the frequency, method, treatment, or setting for a recommended preventive service, to the extent this information is not specified in a

²¹ 26 CFR 54.9815–2713T(a)(4); 29 CFR 2590.715–2713(a)(4); and 45 CFR 147.130(a)(4).

²² 26 CFR 54.9815–2713T(a)(3); 29 CFR 2590.715–2713(a)(3); and 45 CFR 147.130(a)(3).

²³ 80 FR 41318 (July 14, 2015).

²⁴ These proposed rules would not modify Federal conscience protections related to contraceptive coverage for employers, plans and issuers. The rules related to optional accommodations for certain eligible entities (26 CFR 54.9815–2713A, 29 CFR 2510.3–16 and 2590.715–2713A, and 45 CFR 147.131) and religious (45 CFR 147.132) and moral (45 CFR 147.133) exemptions in connection with the coverage of certain recommended preventive services—as well as the conscience protections that apply to certain health care providers, patients, and other participants (45 CFR part 88)—are outside the scope of these proposed rules. For a detailed overview of the regulatory and judicial history of Departmental rules specifically related to optional accommodations and religious and moral exemptions from the contraceptive coverage requirement, see 88 FR 7236, 7237–40 (Feb. 2, 2023). For additional information on the Department of Health and Human Services’ final rule on enforcement of religious freedom and conscience laws, see 89 FR 2078 (Jan. 11, 2024).

¹⁵ See 86 FR 59741, 59742 (Oct. 28, 2021).

¹⁶ HRSA stated that this change was made to allow women to purchase male condoms for pregnancy prevention. See *id.*

¹⁷ See HRSA, Women’s Preventive Services Guidelines, available at <https://www.hrsa.gov/womens-guidelines/index.html> (version last reviewed March 2024, accessed September 25, 2024).

¹⁸ *Id.*

¹⁹ 26 U.S.C. 9833, 29 U.S.C. 1191c, and 42 U.S.C. 300gg–92.

²⁰ 75 FR 41726 (July 19, 2010).

• Frequently Asked Questions on February 20, 2013 (FAQs Part XII), which, among other things, clarified the scope of reasonable medical management with respect to recommended preventive services, including contraceptive items and services. The FAQs specified that plans and issuers must cover “the full range of FDA-approved contraceptive methods” and must design reasonable medical management techniques to include accommodations for the specific medical needs of an individual. FAQs Part XII, Q14 noted that plans may, for example, cover a generic drug without cost sharing and impose cost sharing for equivalent branded drugs. If, however, a generic version is not available, or would not be medically appropriate for the patient (as determined by the attending provider, in consultation with the patient), then a plan or issuer must have a mechanism to provide coverage for the brand name drug without any cost sharing.²⁸ FAQs Part XII also interpreted the statutory and regulatory requirements to cover recommended preventive services without cost sharing to mean that recommended preventive services (including contraceptive products) that are generally available without a prescription must be covered without cost sharing only when prescribed by a health care provider.²⁹

• Frequently Asked Questions on May 11, 2015 (FAQs Part XXVI), which clarified that plans and issuers must cover, without cost sharing, at least one form of contraception in each method³⁰

recommendation or guideline. Plans and issuers may rely on established techniques and the relevant clinical evidence base to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health item or service where cost sharing must be waived. Whether a medical management technique is reasonable depends on all the relevant facts and circumstances. See FAQs Part 54, Q8 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-eba/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

²⁸ See FAQs Part XII, Q14 (Feb. 20, 2013), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-eba/our-activities/resource-center/faqs/aca-part-xii.pdf> and https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/aca_implementation_faqs12.

²⁹ See *id.* at Q4 and Q15. As noted elsewhere in this section I.B, the language “as prescribed” appeared in the HRSA-supported Guidelines until 2016.

³⁰ As noted in FDA’s Birth Control Guide (Chart), published in May 2024, available at <https://www.fda.gov/media/150299/download>, the FDA approves, clears, and grants marketing authorization for individual contraceptive products, not “methods.” However, for purposes of this chart, which includes birth control options broader than products, the term “methods” is used. Similarly, FAQs Part XXVI used the term “methods” consistent with the then-current FDA Birth Control Guide.

that is identified by the FDA in its Birth Control Guide.³¹ FAQs Part XXVI further clarified the scope of reasonable medical management techniques by specifying that if multiple services and FDA-approved items within a contraceptive category are medically appropriate for an individual, the plan or issuer may use reasonable medical management techniques to determine which specific products to cover without cost sharing with respect to that individual and, subject to the relevant facts and circumstances, generally may impose cost sharing (including full cost sharing) on some items and services to encourage an individual to use other specific items and services within the chosen contraceptive category.³² However, if the individual’s attending provider³³ recommends a particular

³¹ FAQs Part XXVI referenced the then-current 2015 FDA Birth Control Guide, which identified 18 contraceptive methods for women, but noted that the “FDA Birth Control Guide additionally lists sterilization surgery for men and male condoms, but the HRSA Guidelines exclude services relating to a man’s reproductive capacity.” See FAQs Part XXVI, fn. 12, available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-eba/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf. The 2021 HRSA-supported Guidelines incorporated by reference a subsequent update of the FDA Birth Control Guide (as published on December 22, 2021), and now describes the full range of contraceptives to include: “(1) sterilization surgery for women, (2) implantable rods, (3) copper intrauterine devices, (4) intrauterine devices with progestin (all durations and doses), (5) injectable contraceptives, (6) oral contraceptives (combined pill), 7) oral contraceptives (progestin only), (8) oral contraceptives (extended or continuous use), (9) the contraceptive patch, (10) vaginal contraceptive rings, (11) diaphragms, (12) contraceptive sponges, (13) cervical caps, (14) condoms, (15) spermicides, (16) emergency contraception (levonorgestrel), and (17) emergency contraception (ulipristal acetate), and any additional contraceptives approved, granted, or cleared by the FDA.” See FAQs Part 64 (Jan. 22, 2024), available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-eba/our-activities/resource-center/faqs/aca-part-64.pdf> and <https://www.cms.gov/files/document/faqs-part-64.pdf>. The 2021 HRSA-supported Guidelines also state: “Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.”

³² See FAQs Part XXVI, Q3 (May 11, 2015), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-eba/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf. For example, a plan could use cost sharing to encourage use of one of several FDA-approved intrauterine devices (IUDs) with progestin by imposing cost sharing on the more costly IUD with progestin while waiving cost sharing for a less costly IUD with progestin.

³³ See *id.* at Q1, fn. 13 (“An attending provider means an individual who is licensed under applicable State law, who is acting within the scope of the provider’s license, and who is directly responsible for providing care to the patient relating to the recommended preventive services. Therefore, a plan, issuer, hospital, or managed care organization is not an attending provider.”)

service or FDA-approved, -cleared, or -granted item based on a determination of medical necessity with respect to that individual, the plan or issuer must defer to the determination of the attending provider with respect to the individual involved, and cover that item or service without cost sharing.³⁴ Additionally, FAQs Part XXVI specified that to the extent a plan or issuer uses reasonable medical management techniques within a specified method of contraception, the plan or issuer must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as a patient’s authorized representative) to ensure coverage without cost sharing of any service or FDA-approved item within the specified method of contraception that has been recommended by the individual’s attending provider based on a determination of medical necessity.³⁵

• Frequently Asked Questions on April 20, 2016 (FAQs Part 31), which further clarified the requirements on plans and issuers with respect to the development and implementation of an exceptions process, including that plans and issuers that meet all other requirements are permitted to develop and utilize a standard exceptions process form (such as the Medicare Part D Coverage Determination Request Form) and instructions as part of the exceptions process.³⁶

• Frequently Asked Questions on July 19, 2021 (FAQs Part 47), which followed USPSTF’s release on June 11, 2019 of a recommendation with an “A” rating that clinicians offer preexposure prophylaxis (PrEP) with “effective antiretroviral therapy to persons who are at high risk of human immunodeficiency virus (HIV) acquisition.”³⁷ FAQs Part 47 clarified

³⁴ See *id.* at introduction and Q3.

³⁵ *Id.* at Q2.

³⁶ FAQs Part 31, Q2 (April 20, 2016), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-eba/our-activities/resource-center/faqs/aca-part-31.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf.

³⁷ FAQs about Affordable Care Act Implementation Part 47 (July 19, 2021), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-eba/our-activities/resource-center/faqs/aca-part-47.pdf> and <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/faqs-part-47.pdf>. Note that USPSTF subsequently updated the recommendation referenced in FAQs Part 47. See USPSTF, Prevention of Acquisition of HIV: Preexposure Prophylaxis, updated August 22, 2023, available at <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

that plans and issuers are required to cover, without cost sharing, all items and services that USPSTF recommends should be received prior to being prescribed PrEP and for ongoing follow-up and monitoring. These items and services include specific baseline and monitoring services, such as laboratory testing and adherence counseling. The FAQs also clarified that plans and issuers utilizing reasonable medical management must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as an authorized representative).

- Frequently Asked Questions on January 10, 2022 (FAQs Part 51), which acknowledged complaints received about compliance with the contraceptive coverage requirement and clarified currently applicable guidance. Specifically, FAQs Part 51, Q9 was issued in response to complaints and public reports of potential violations of the contraceptive coverage requirement, including that plans and issuers and pharmacy benefit managers (PBMs) were not adhering to requirements for utilizing reasonable medical management techniques. The FAQs also highlighted several examples of such potential violations, including denying coverage for all or particular brand name contraceptives, even after the individual's attending provider determines and communicates to the plan or issuer that a particular service or FDA-approved, -cleared, or -granted contraceptive product is medically necessary with respect to that individual; requiring individuals to fail first using numerous other services or FDA-approved, -cleared, or -granted contraceptive products within the same method of contraception before the plan or issuer will approve coverage for a service or FDA-approved, -cleared, or -granted contraceptive product that is medically appropriate for the individual, as determined by the individual's attending health care provider; requiring individuals to fail first using numerous other services or FDA-approved, -cleared, or -granted contraceptive products in other contraceptive methods before the plan or issuer will approve coverage for a service or FDA-approved, -cleared, or -granted contraceptive product that is medically appropriate for the individual, as determined by the individual's attending health care provider; and failing to provide an acceptable exceptions process (for example, by requiring individuals to appeal an adverse benefit determination

using the plan's or issuer's internal claims and appeals process, rather than providing an exceptions process that is easily accessible, transparent, sufficiently expedient, and not unduly burdensome).³⁸

- Frequently Asked Questions on July 28, 2022 (FAQs Part 54), which further clarified the contraceptive coverage requirement and currently applicable guidance. These FAQs clarified that plans and issuers must cover, without imposing cost-sharing requirements, items and services that are integral to a recommended contraceptive service.³⁹ The FAQs also stated that plans and issuers must cover any FDA-approved, -cleared, or -granted contraceptive products and services that an individual and their attending provider have determined to be medically appropriate for the individual, regardless of whether those products or services are specifically identified in the categories listed in the HRSA-supported Guidelines.⁴⁰ For contraceptive services or FDA-approved, -cleared, or -granted contraceptive products not included in a category described in the HRSA-supported Guidelines, the FAQs stated that plans and issuers may use reasonable medical management techniques to determine which specific products to cover without cost sharing only if multiple, substantially similar services or products that are not included in a category described in the HRSA-supported Guidelines are medically appropriate for the individual. The FAQs further stated that if the individual's attending provider recommends a particular service or FDA-approved, -cleared, or -granted product not included in a category described in the HRSA-supported Guidelines based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or product without cost sharing. The plan or issuer must defer to the determination of the attending provider and must make available an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome so the individual or their provider (or other individual acting as the individual's authorized

³⁸ FAQs Part 51, Q9 (Jan. 10, 2022), available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf>.

³⁹ FAQs Part 54, Q1 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

⁴⁰ *Id.* at Q2.

representative) can obtain coverage for the medically necessary service or product for the individual without cost sharing as required under PHS Act section 2713 and its implementing regulations and guidance.⁴¹ The FAQs also encouraged plans and issuers to cover over-the-counter (OTC) emergency contraceptive products with no cost sharing when they are purchased by consumers without a prescription.⁴² FAQs Part 54, Q8 further acknowledged that the Departments continued to receive complaints and reports that participants, beneficiaries, and enrollees were being denied contraceptive coverage, in some cases due to the application of medical management techniques that were not reasonable based on all of the relevant facts and circumstances. In addition to summarizing ongoing complaints similar to those highlighted in FAQs Part 51, Q9, the Departments also noted that they were aware of complaints that plans and issuers or PBMs were imposing age limits on contraceptive coverage rather than providing these benefits to all individuals with reproductive capacity. FAQs Part 54, Q13 also described actions within the scope of the authority of the Departments of Labor and HHS to enforce the requirements of PHS Act section 2713.⁴³

- Frequently Asked Questions on January 22, 2024 (FAQs Part 64), which provided further clarifications regarding contraceptive coverage requirements, including providing guidance regarding a therapeutic equivalence approach. The FAQs explained that plans and issuers could adopt a therapeutic equivalence approach (in combination with an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome) to ensure the plan's or issuer's medical management techniques for contraceptive drugs and drug-led devices⁴⁴ that are required to

⁴¹ *Id.* at Q3.

⁴² *Id.* at Q5.

⁴³ See FAQs Part 54, Q5, Q8, and Q13 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

⁴⁴ In FAQs Part 64, the term "drug-led device" referred to a combination product, as defined under 21 CFR 3.2(e), that is comprised of a drug and a device, and for which the drug component provides the primary mode of action. The primary mode of action of a combination product is the single mode of action (that is, the action provided by the drug, device, or biological product) that provides the most important therapeutic action of the combination product. See 21 U.S.C. 353(g)(1)(C) and 21 CFR 3.2(m). As further discussed in section II.A.2 of the preamble to these proposed rules, the Departments propose a substantially similar definition of the term "drug-led combination

be covered under PHS Act section 2713 are reasonable.⁴⁵ Specifically, with respect to FDA-approved contraceptive drugs and drug-led devices, if a plan or issuer utilizes medical management techniques within a specified category described in the HRSA-supported Guidelines (or group of substantially similar products that are not included in a specified category), the Departments will generally consider such medical management techniques to be reasonable if the plan or issuer covers all FDA-approved contraceptive drugs and drug-led devices in that category (or group of substantially similar products) without cost sharing, other than those for which there is at least one therapeutic equivalent drug or drug-led device that the plan or issuer covers without cost sharing.

C. Executive Orders on the Affordable Care Act and Reproductive Health

On January 28, 2021, President Biden issued Executive Order 14009, “Strengthening Medicaid and the Affordable Care Act” (E.O. 14009).⁴⁶ Section 3 of E.O. 14009 directs the Secretaries of the Departments (the Secretaries) to review all existing regulations, guidance documents, and policies to determine whether such actions are inconsistent with protecting and strengthening Medicaid and the ACA and making high-quality health care accessible and affordable for every American.

On April 5, 2022, President Biden issued Executive Order 14070, “Continuing To Strengthen Americans’ Access to Affordable, Quality Health Coverage” (E.O. 14070).⁴⁷ Section 2 of E.O. 14070 reaffirms the goals and policy of E.O. 14009 and further directs agencies with responsibilities related to Americans’ access to health coverage to consider and pursue agency actions that improve the comprehensiveness of coverage and protect consumers from low-quality coverage.

Following the U.S. Supreme Court decision in *Dobbs v. Jackson Women’s Health Organization* (*Dobbs*),⁴⁸ President Biden issued Executive Order 14076, “Protecting Access to Reproductive Healthcare Services” (E.O. 14076) on July 8, 2022. Section 3 of E.O.

14076 requires the Secretary of HHS to identify potential actions to “protect and expand access to the full range of reproductive healthcare services, including actions to enhance family planning services such as access to emergency contraception” and identify “ways to increase outreach and education about access to reproductive healthcare services, including by launching a public awareness initiative to provide timely and accurate information about such access, which shall . . . include promoting awareness of and access to the full range of contraceptive services.”⁴⁹

On June 23, 2023, President Biden issued Executive Order 14101, “Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services” (E.O. 14101).⁵⁰ Section 2 of E.O. 14101 directs the Secretaries to consider issuing guidance “to further improve Americans’ ability to access contraception, without out-of-pocket expenses, under the Affordable Care Act” and to consider additional actions “to promote increased access to affordable over-the-counter contraception, including emergency contraception.”⁵¹

D. FDA Approval of Daily Over-the-Counter Oral Contraceptive

On July 13, 2023, the FDA announced that it had approved a progestin-only birth control pill as the first daily oral contraceptive for use in the United States available without a prescription.^{52 53} Interested parties, including health care provider associations, have supported the availability of a daily OTC oral contraceptive for its potential to improve access to affordable contraception, thereby improving management of family planning and reducing unintended pregnancies.⁵⁴

⁴⁹ 87 FR 42053.

⁵⁰ 88 FR 41815.

⁵¹ *Id.*

⁵² FDA (July 13, 2023), “FDA Approves First Nonprescription Daily Oral Contraceptive,” available at <https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive>.

⁵³ Progestin-only oral contraceptives are a product that is already available in a prescription form and are a category of contraceptives listed in the FDA Birth Control Guide, as referenced in the HRSA-supported Guidelines.

⁵⁴ See American Medical Association (2023), “AMA Applauds FDA Approval of OTC Birth Control,” available at <https://www.ama-assn.org/press-center/press-releases/ama-applauds-fda-approval-otc-birth-control>; The American College of Obstetricians and Gynecologists (2023), “ACOG Praises FDA Approval of Over-the-Counter Access to Birth Control Pill,” available at <https://www.acog.org/news/news-releases/2023/07/acog-praises-fda-approval-of-over-the-counter-access-to-birth-control-pill>.

Studies have shown that challenges with access and costs are among the most common reasons cited by women for not using contraception or having gaps in contraceptive use.⁵⁵ One large, nationally representative study found 29 percent of women reported encountering barriers to obtaining or filling an initial prescription or refills of oral contraceptive pills, specifically citing insurance coverage, getting an appointment, not having a regular provider, and difficulty accessing a pharmacy.⁵⁶ Accordingly, the availability of a daily OTC oral contraceptive could improve access to contraception if the product is affordable, including if it is covered by insurance without cost sharing, and as a result, could reduce the number of unintended pregnancies.⁵⁷ Beginning in March 2024, an OTC oral contraceptive has become widely available for sale online and in stores under the brand name Opill®, with a manufacturer’s

⁵⁵ See Key, K., Wollum, A., Asetoyer, C., Cervantes, M., Lindsey, A., Rivera, R., Robinson Flint, J., Zuniga, C., Sanchez, J., and Baum, S. (2023), “Challenges accessing contraceptive care and interest in over-the-counter oral contraceptive pill use among Black, Indigenous, and people of color: An online cross-sectional survey,” *Contraception*, available at <https://doi.org/10.1016/j.contraception.2023.109950>; Thompson, E. L., Galvin, A. M., Garg, A., Diener, A., Deckard, A., Griner, S. B., and Kline, N. S. (2023), “A socioecological perspective to contraceptive access for women experiencing homelessness in the United States,” *Contraception*, available at <https://doi.org/10.1016/j.contraception.2023.109991>; Bessett, D., Prager, J., Havard, J., Murphy, D. J., Agénor, M., and Foster, A. M. (2015), “Barriers to contraceptive access after health care reform: Experiences of young adults in Massachusetts,” *Women’s Health Issues*, available at <https://doi.org/10.1016/j.whi.2014.11.002>; and Johnson, E. R. (2022), “Health care access and contraceptive use among adult women in the United States in 2017,” *Contraception*, available at <https://doi.org/10.1016/j.contraception.2022.02.008>.

⁵⁶ Grindlay, K., Grossman, D. (2016), “Prescription Birth Control Access Among U.S. Women At Risk of Unintended Pregnancy,” *Journal of Women’s Health*, available at <https://www.liebertpub.com/doi/10.1089/jwh.2015.5312>.

⁵⁷ A recent study found that over 12 million adult women and nearly two million young women aged 15–17 would likely be interested in using an OTC oral contraceptive if it were free to them, but the numbers declined to 7.1 million adult women and 760,000 young women if the out-of-pocket cost of the contraceptive was \$15. The same study indicated that the levels of interest would translate to an estimated eight percent decrease in unintended pregnancies (approximately 320,000 fewer) in one year among adult women when cost sharing was \$0, and an estimated five percent decrease (approximately 199,000 fewer unintended pregnancies) if there were a monthly out-of-pocket cost of \$15. See Wollum, A., Trussell, J., Grossman, D., and Grindlay, K. (2020), “Modeling the Impacts of Price of an Over-the-Counter Progestin-Only Pill on Use and Unintended Pregnancy among U.S. Women,” *Women’s Health Issues*, available at <https://www.sciencedirect.com/science/article/pii/S1049386720300037/pdfft?md5=903aee27ef3468f62abaf9091e0a957c&pid=1-s2.0-S1049386720300037-main.pdf>.

product” in these proposed rules to refer to the same products for which the term “drug-led device” was used in FAQs Part 64.

⁴⁵ FAQs Part 64 (Jan. 22, 2024), available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-64.pdf> and <https://www.cms.gov/files/document/faqs-part-64.pdf>.

⁴⁶ 86 FR 7793.

⁴⁷ 87 FR 20689.

⁴⁸ 597 U.S. 215 (2022).

suggested retail price ranging from \$19.99 for a 1-month supply to \$89.99 for a 6-month supply.⁵⁸

E. OTC Preventive Products Request for Information

As discussed in sections I.A and I.C of this preamble, the Biden-Harris Administration has prioritized access to comprehensive, high-quality contraception and family planning services as critical components of women's reproductive health and overall public health. In response to E.O. 14009, E.O. 14070, E.O.14076, and E.O. 14101, and following the FDA approval of an OTC oral contraceptive, as discussed in section I.D of this preamble, the Departments issued a "Request for Information; Coverage of Over-the-Counter Preventive Services" on October 4, 2023 (OTC Preventive Products RFI).⁵⁹ The Departments issued the OTC Preventive Products RFI to gather public feedback regarding the potential benefits and costs of requiring plans and issuers to cover OTC preventive products⁶⁰ without cost sharing and without a prescription; learn of any potential challenges associated with providing such coverage; understand whether and how providing such coverage would benefit consumers; and assess any potential burden that plans and issuers would face if required to provide such coverage.

The Departments received 376 unique comments in response to the OTC Preventive Products RFI, including comments from individuals; plans and issuers; PBMs; State government agencies; and advocacy organizations representing consumers, health care providers, group health plans, hospitals, and durable medical equipment suppliers. The Departments reviewed comments received in response to the OTC Preventive Products RFI as part of the development of these proposed rules. However, these proposed rules do not address all the issues on which information was requested.

Many commenters stated that requiring plans and issuers to cover all recommended preventive services would promote health equity and improve health outcomes by reducing costs and administrative barriers to

accessing preventive health care. Many commenters highlighted that prescription and cost-sharing requirements represent a particular barrier for people with lower incomes and Black, Indigenous, and People of Color (BIPOC) communities, and that requiring coverage of OTC preventive products without cost sharing and without a prescription would significantly lower these barriers, thereby increasing access to OTC preventive products in a manner that would be especially beneficial to lower-income and underserved populations.

Many commenters highlighted the particular benefit to women of requiring plans and issuers to cover OTC contraceptive items without requiring a prescription and without cost-sharing requirements. Several commenters pointed out that neither section 2713 of the PHS Act nor its implementing regulations impose a specific prescription requirement on recommended contraceptive items. These commenters also highlighted HRSA's removal of "as prescribed" language which appeared in the 2011 HRSA-supported Guidelines but does not appear in the 2016 or any subsequent version of the HRSA-supported Guidelines.⁶¹ In the view of these commenters, the existing prescription requirement is therefore based only on agency guidance that is within the authority of the Departments to revise.⁶²

Another commenter noted that, in the United States, approximately one-third of childbearing-aged women and those capable of becoming pregnant experience difficulties obtaining hormonal contraception, and that coverage of OTC oral contraception without a prescription and without cost sharing would improve access to reproductive care for this group. Several commenters highlighted the burdens of a prescription requirement on people seeking contraception, including requesting time off from work, unnecessary visits to the doctor, appointment wait times, and finding childcare, while a few other commenters specifically emphasized the importance of waiving cost sharing to make OTC contraceptive services truly accessible. One commenter noted that access to affordable contraception was particularly important within the

context of widespread Medicaid coverage losses following the termination on March 31, 2023 of the continuous enrollment condition previously associated with the COVID-19 public health emergency (PHE).⁶³ Many other commenters supported requiring coverage of OTC contraceptive services in order to ensure that women can access effective, affordable means of preventing unintended pregnancies in the wake of the *Dobbs* decision.

In addition to comments highlighting the benefits to women of removing prescription and cost-sharing requirements for coverage of OTC contraceptive items, several commenters noted that consumers would benefit from increased access to other specific OTC preventive products if plans and issuers were required to cover those other products without a prescription and without cost sharing. For example, several commenters stated that coverage based on prescription requirements limits access to OTC tobacco cessation products. One of these commenters emphasized that prescription requirements are a particular barrier with respect to tobacco cessation because of the nature of nicotine addiction, which typically requires multiple quit attempts. In that commenter's view, removing cost-sharing and prescription requirements would allow people to access evidence-based treatment when they are motivated to make a quit attempt, without having to wait for a medical appointment. Conversely, another commenter who acknowledged that removing cost sharing on OTC tobacco cessation products could have a positive effect on access to these products, particularly for people with low incomes, also emphasized the role of clinicians in screening for and diagnosing tobacco use disorder and recommending or prescribing effective treatments. This commenter encouraged the Departments to make an effort to preserve the clinician-patient relationship with respect to tobacco cessation products to ensure that patients are properly connected to care, including biomedical and psychiatric services that may be comorbid with tobacco use disorder.

Another commenter noted that a woman who is not pregnant or planning

⁵⁸ Lupkin, S., NPR (March 18, 2024). "First over-the-counter birth control pill now for sale online," available at <https://npr.org/sections/health-shots/2024/03/04/1235404522/opill-over-counter-birth-control-pill-contraceptive-shop>.

⁵⁹ 88 FR 68519 (Oct. 4, 2023).

⁶⁰ For consistency with the OTC Preventive Products RFI, this preamble uses the term "OTC preventive products" to refer to recommended preventive services that may be made available to an individual without a prescription.

⁶¹ See section I.A of this preamble for a discussion of the "as prescribed" language.

⁶² See, e.g., FAQs Part XII, Q4 (Feb. 20, 2013), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-xii.pdf> and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca-implementation_faqs12.html.

⁶³ See Center for Medicare and Medicaid Services (CMS), Center for Consumer Information and Insurance Oversight, Temporary Special Enrollment Period (SEP) for Consumers Losing Medicaid or the Children's Health Insurance Program (CHIP) Coverage Due to Unwinding of the Medicaid Continuous Enrollment Condition—Frequently Asked Questions (FAQ) (Jan. 27, 2023), available at <https://www.cms.gov/technical-assistance-resources/temp-sep-unwinding-faq.pdf>.

to become pregnant may not be under the care of a prescribing health care provider but could still benefit from the USPSTF recommendation that women who could become pregnant should consume a daily folic acid supplement. A few commenters described the disparate occurrence of spina bifida in newborns born to Spanish-speaking people, which commenters believe could be reduced if plans and issuers were required to cover OTC folic acid without cost sharing or prescription requirements.

However, several commenters identified operational barriers to widespread implementation of a requirement to cover all recommended OTC preventive products without cost sharing or a prescription. A few commenters noted potential strains on pharmacies, retailers, and the existing health care delivery system; fraud and abuse threats; and potential cost increases for plan sponsors and plan participants. For example, one commenter cited the administrative and cost burdens that pharmacies and retailers could incur if they were required to cover the upfront costs of OTC preventive products and pursue post-claim reimbursements. In that commenter's view, requiring plans and issuers to provide coverage of OTC preventive products without cost sharing could also facilitate fraudulent behavior, including sale to unauthorized persons or re-sale outside of the health care market, that could in turn create a shadow market based on overuse and misuse. This commenter highlighted the existing significant clinical and administrative burdens that already strain pharmacist and retailer resources (ranging from filling and dispensing medications to providing immunizations, patient counseling, and information about insurance eligibility and coverage), and expressed concern that the responsibility for educating consumers about potential access to and appropriateness of OTC contraceptives would fall to pharmacists and retailers at the point of sale. Another commenter noted that requiring coverage of OTC preventive products such as contraceptives, OTC naloxone, and smoking cessation products without cost sharing or a prescription would increase access to such products but advised that such requirements would increase administrative burden on pharmacists by increasing workload and costs and decreasing reimbursement for vital patient counseling and additional services. One commenter indicated that using a credit card (rather than a debit card or paper reimbursement system)

would facilitate coverage of OTC preventive products, but also noted that the use of a credit card without a fixed spending limit would be more likely to lead to fraud and would necessitate implementing systems for freezing or repaying cards in the case of misuse. Another commenter indicated general support for access to recommended preventive products without cost sharing but stated that prescription requirements were necessary for many products to ensure that individual patients receive appropriate care. In that commenter's view, the cost associated with applying a market-wide OTC preventive products coverage requirement would disrupt and likely outweigh any benefits of changing long-established coverage patterns. This commenter recommended that the Departments consider establishing a standing order for Opill® only, in order to conduct a targeted roll-out of a potential broader OTC preventive products coverage requirement without overburdening the health care system by attempting to implement the changes for all OTC preventive products at once. The same commenter, however, warned against requiring coverage of OTC products that do not have meaningful market competition, such as Opill®, to avoid inadvertently driving up retail prices. Another commenter shared similar concerns regarding the potential for generating demand for preventive items and services that would ultimately be unused. A few commenters noted the particular cost and negative environmental impact that could be realized if OTC breastfeeding supplies with no cost sharing led to overconsumption of such products. One commenter urged the Departments to avoid rushing to require coverage of all OTC preventive products in order to provide sufficient advanced notice to allow plan sponsors to address operational and implementation issues.

While several commenters expressed concern that current prescription requirements restrict access to breastfeeding services and supplies, many commenters stated that removing the prescription requirement for breastfeeding services and supplies could have a detrimental effect on breastfeeding parents and newborns. These commenters stated that consumers currently benefit from the expertise provided by lactation consultants and other specially trained staff at durable medical equipment suppliers contracted with plans and issuers to provide breast pumps. These commenters also expressed the view that removing the prescription

requirement would make it more likely that a consumer would be forced to select breastfeeding supplies in a retail environment with fewer breast pump options and less privacy and support.

In the OTC Preventive Products RFI, the Departments also requested feedback from interested parties based on their experiences with the requirement to cover OTC COVID-19 diagnostic tests during the COVID-19 PHE.⁶⁴ During the COVID-19 PHE, plans and issuers were required to cover OTC COVID-19 diagnostic tests without a prescription from a health care provider and without imposing any cost-sharing requirements, prior authorization, or other medical management requirements. However, the Departments permitted plans and issuers that met certain safe harbor requirements to implement cost and quantity limits to contain costs and combat potential fraud and abuse with respect to coverage of OTC COVID-19 diagnostic tests. A few commenters encouraged the Departments to use experiences with coverage of OTC COVID-19 diagnostic tests as a roadmap for future coverage of other recommended preventive services. However, another commenter cautioned the Departments against regulating the routine use of recommended preventive services by applying requirements used during an unprecedented public health emergency, in order to avoid issues the commenter reported taking place during the COVID-19 PHE, such as overconsumption of COVID-19 diagnostic tests, price gouging of products by manufacturers, and limited opportunities for health plans to contain waste and abuse. Another commenter acknowledged that coverage requirements for OTC COVID-19 diagnostic tests improved patient access to the tests by removing the barriers related to out-of-pocket costs and obtaining prescriptions but described a number of other issues associated with the testing coverage requirement. According to this commenter, implementation challenges included below-cost reimbursement, inconsistent requirements across plans and providers, and lack of reimbursement for pharmacies. In particular, this commenter noted that the average cost to a retail pharmacy provider to dispense a drug—separate from the cost of acquiring the medication itself—is \$12.40, and that any future OTC coverage requirements should reimburse pharmacies for both the acquisition and dispensing of products. Another commenter, citing the speed with which

⁶⁴ See 88 FR 68519, 68523–24 (Oct. 4, 2023).

the OTC COVID-19 diagnostic testing program was implemented, urged the Departments to proceed deliberately with the implementation of any broader OTC preventive products coverage requirements. According to this commenter, the rapid implementation of the testing coverage requirements during the PHE contributed to consumer confusion and led to many thousands of consumers failing to seek reimbursement for tests that were eligible to be covered.

F. Transparency in Coverage Under the ACA and Implementing Regulations

Section 2715A of the PHS Act⁶⁵ provides that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must comply with section 1311(e)(3) of the ACA,⁶⁶ which addresses transparency in health coverage and imposes certain reporting and disclosure requirements for health plans that are seeking certification as qualified health plans (QHPs) to be offered on an American Health Benefits Exchange (generally referred to as an Exchange or Marketplace) (as defined by section 1311(b)(1) of the ACA). A plan or issuer of coverage that is not offered through an Exchange and that is subject to section 2715A of the PHS Act is required to submit the required information to the Secretary of HHS and the relevant State's insurance commissioner, and to make that information available to the public.

Section 1311(e)(3)(C) of the ACA requires plans, as a requirement of certification as a QHP, to permit individuals to learn about the amount of cost sharing (including deductibles, copayments, and coinsurance) that the individual would be responsible for paying with respect to the furnishing of a specific item or service by an in-network provider in a timely manner upon the request of the individual. Section 1311(e)(3)(C) of the ACA specifies that, at a minimum, such information must be made available to the individual through an internet website and through other means for individuals without access to the internet.

On March 27, 2012, HHS issued the "Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers" final rule (Exchange Establishment final rule) that implemented sections 1311(e)(3)(A) through (C) of the ACA at 45 CFR

155.1040(a) through (c) and 156.220.⁶⁷ The Exchange Establishment final rule created standards for QHP issuers to submit specific information related to transparency in coverage.

On November 12, 2020, the Departments issued "Transparency in Coverage" final rules (Transparency in Coverage final rules) implementing transparency reporting requirements for non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage.⁶⁸ Implementing section 1311(e)(3)(C) of the ACA and section 2715A of the PHS Act, these rules require plans and issuers to disclose cost-sharing information for all covered items and services available to a participant, beneficiary, or enrollee through an internet-based self-service tool via the plan's or issuer's member portal or, if requested by the individual, on paper.⁶⁹ The requirement to disclose cost-sharing information for all covered items and services includes covered contraceptive items or services.

The Transparency in Coverage final rules enumerate seven cost-related elements that plans and issuers must disclose in response to a search query by a participant, beneficiary, or enrollee for a covered item or service furnished by a provider or providers. The self-service tool must provide an estimate of the participant's, beneficiary's, or enrollee's cost-sharing liability for the covered item or service, which is calculated based on the following elements: (a) accumulated amounts with respect to any deductibles or maximum out-of-pocket limits; and either (b) the in-network rate, comprising a negotiated rate or underlying fee schedule rate as applicable to the payment model; or (c) an out-of-network allowed amount or any other rate that provides a more accurate estimate of an amount a plan or issuer will pay for the requested covered item or service from an out-of-network provider. Self-service tool results must also reflect a list of the items and services included in a bundled payment arrangement, if applicable; notification that coverage of a specific item or service is subject to a prerequisite, as applicable; and certain

disclaimers in plain language describing the limitations of the estimate or other qualifications regarding the cost-sharing information disclosed.

With respect to requests for cost-sharing information for items or services that are recommended preventive services under section 2713 of the PHS Act, if the plan or issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the cost-sharing liability that applies for non-preventive purposes along with a statement that the item or service may not be subject to cost sharing if it is billed as a preventive service.

Displaying a non-zero cost-sharing liability in these circumstances helps protect against unexpected medical bills by ensuring participants, beneficiaries, and enrollees are aware of their potential cost-sharing liability while the statement ensures that consumers are made aware they can access recommended preventive services without cost sharing. Alternatively, the Transparency in Coverage final rules permit a plan or issuer to allow a participant, beneficiary, or enrollee to request cost-sharing information for the specific preventive or non-preventive item or service by including terms such as "preventive," "non-preventive," or "diagnostic" as a means to request the most accurate cost-sharing information.

Plans and issuers must ensure users can search for cost-sharing information for a covered item or service by a specific in-network provider or by all in-network providers using either a descriptive term or a billing code. For covered items or services furnished by out-of-network providers, users can search for an out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a plan or issuer will pay for a covered item or service provided by out-of-network providers. Users must also be able to input other factors utilized by the plan or issuer that are relevant for determining the applicable cost-sharing information or out-of-network allowed amount, such as location of service, facility name, or dosage and permit refining and reordering of search results.

II. Overview of the Proposed Rules

A. Coverage of Recommended Preventive Services

1. Reasonable Medical Management of Recommended Preventive Services: Exceptions Process

The Departments' regulations implementing section 2713 of the PHS Act aim to strike a balance between

⁶⁵ 42 U.S.C. 300gg-15a.

⁶⁶ 42 U.S.C. 18031(e)(3).

⁶⁷ 77 FR 18310 (Mar. 27, 2012).

⁶⁸ 85 FR 72158 (Nov. 12, 2020).

⁶⁹ The Consolidated Appropriations Act, 2021 imposed a largely duplicative requirement and added a requirement that the information also be provided by telephone, upon request. See also FAQs Part 49, Q3 (Aug. 20, 2021), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf>.

ensuring participants, beneficiaries, and enrollees do not face undue barriers to accessing their coverage of recommended preventive services as required by law and allowing plans and issuers to contain costs, promote efficient delivery of care, and minimize risks of fraud, waste, and abuse. To this end, current regulations permit plans and issuers to use reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive service, to the extent not specified in the applicable recommendation or guideline.⁷⁰ The Departments have previously explained, in the context of certain recommended preventive services, that they generally do not consider medical management techniques with respect to recommended preventive services to be reasonable absent the availability of an exceptions process.⁷¹

As noted in previously issued guidance and described in section I.B of this preamble, the Departments continue to receive complaints of potential violations related to the application of medical management techniques that are not reasonable, including failing to provide an exceptions process that meets the standards set forth in guidance.⁷² Further, the U.S. House of Representatives' Committee on Oversight and Reform (Oversight Committee) published a report in October 2022 documenting the findings of its investigation into contraceptive coverage for individuals enrolled in private health coverage. The Oversight Committee found that insurers and PBMs surveyed denied an average of at least 40 percent of exception requests related to contraceptive coverage, with one PBM denying more than 80 percent of requests in a year.⁷³ To reinforce the

requirement that medical management techniques must be reasonable, the Departments propose to codify that plans and issuers that utilize reasonable medical management techniques with respect to recommended preventive services would be required to accommodate any individual for whom a particular item or service would not be medically appropriate, as determined by the individual's attending provider, by having a mechanism for covering or waiving the otherwise applicable cost sharing for the medically necessary item or service. Specifically, under these proposed rules, consistent with previous guidance,⁷⁴ if utilizing reasonable medical management techniques, a plan or issuer would be required to have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other person acting as the individual's authorized representative) under which the plan or issuer covers without cost sharing the recommended preventive service according to the frequency, method, treatment, or setting determined to be medically necessary with respect to the individual, as determined by the individual's attending provider. The exceptions process would ensure that an individual can access medically necessary recommended preventive services without cost sharing and would prevent medical management from functioning

Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance," available at <https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.CCR%20PBM-Insurer%20Report.pdf>.

⁷⁴ See FAQs Part XXVI, Q3 (May 11, 2015), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf; FAQs Part 31, Q2 (Apr. 20, 2016), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-31.pdf> and https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-31_final-4-20-16.pdf. See also FAQs Part XII, Q14 (Feb. 20, 2013), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-12.html>; FAQs Part 51, Q8–9 (Jan. 10, 2022), available at <https://www.dol.gov/sites/dolgov/files/ebbsa/about-ebbsa/our-activities/resource-center/faqs/aca-part-51.pdf> and <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/FAQs-Part-51.pdf>; FAQs Part 54, Q9, (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>; FAQs Part 64 (Jan. 22, 2024) available at <https://www.dol.gov/agencies/ebbsa/about-ebbsa/our-activities/resource-center/faqs/aca-part-64> and <https://www.cms.gov/files/document/faqs-part-64.pdf>.

as an unreasonable barrier to coverage under section 2713 of the PHS Act. The Departments are authorized to issue this proposal, implementing section 2713 of the PHS Act, by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. Nothing in this proposal, if finalized, would require an entity to provide coverage or payments for a contraceptive for which they have an exemption under 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A, and 45 CFR 147.131 through 45 CFR 147.133.

While prior guidance has generally focused on the use of an exceptions process in the context of coverage of contraceptive services, it has not been limited to that context. For example, the Departments' guidance with respect to coverage of PrEP to prevent HIV acquisition has similarly stated that where a plan or issuer uses reasonable medical management techniques—such as covering a generic version of PrEP without cost sharing and imposing cost sharing on an equivalent branded version—a plan or issuer must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as an authorized representative) that waives otherwise applicable cost sharing for the particular PrEP medication (generic or branded) for any individual for whom the plan's or issuer's preferred medication “would be medically inappropriate, as determined by the individual's health care provider.”⁷⁵

Therefore, the Departments propose to reorganize and amend 26 CFR 54.9815–2713(a)(4), 29 CFR 2590.715–2713(a)(4), and 45 CFR 147.130(a)(4) by adding a new paragraph (a)(4)(i) to include existing language with minor technical edits for clarity and to add a new paragraph (a)(4)(ii) to specify that, in order for a plan's or issuer's medical management techniques with respect to a recommended preventive service to be considered reasonable, the plan or issuer would be required to have an

⁷⁵ See FAQs Part 47, introduction to Q3 (July 19, 2021), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-47.pdf> and <https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-47.pdf> (“[T]he Departments have clarified in previous guidance that plans and issuers must accommodate any individual for whom a particular medication (generic or brand name) would be medically inappropriate, as determined by the individual's health care provider, by having a mechanism for waiving the otherwise applicable cost sharing for the brand or non-preferred brand version. If utilizing reasonable medical management techniques, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome.”)

⁷⁰ 26 CFR 54.9815–2713(a)(4); 29 CFR 2590.715–2713(a)(4); and 45 CFR 147.130(a)(4).

⁷¹ See FAQs Part XXVI, Q2 (May 11, 2015), available at <https://www.dol.gov/sites/dolgov/files/ebbsa/about-ebbsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf; FAQs Part 64, Q4 (Jan. 22, 2024), available at <https://www.dol.gov/sites/dolgov/files/ebbsa/about-ebbsa/our-activities/resource-center/faqs/aca-part-64.pdf> and <https://www.cms.gov/files/document/faqs-part-64.pdf>.

⁷² See, e.g., FAQs Part 51, Q9 (Jan. 10, 2022), available at <https://www.dol.gov/sites/dolgov/files/ebbsa/about-ebbsa/our-activities/resource-center/faqs/aca-part-51.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf>; FAQs Part 54, Q8 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

⁷³ U.S. House of Representatives Committee on Oversight and Reform, (Oct. 25, 2022). “Barriers to

easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on a participant, beneficiary, or enrollee or attending provider⁷⁶ (or other person acting as the individual's authorized representative). Under this proposal, an exceptions process would be required to ensure that an individual can receive coverage, without cost-sharing requirements, for a recommended preventive service according to the frequency, method, treatment, or setting that is medically necessary with respect to the individual, as determined by the individual's attending provider. For example, a plan or issuer may typically provide coverage without cost sharing for only a generic version of a recommended preventive service; an individual who experiences side effects from the covered generic version and whose attending provider has determined that the brand-name version of the recommended preventive services is medically necessary for the individual would be able to use the exceptions process to obtain the brand-name version without cost sharing, even though the plan or issuer typically does not provide coverage for the brand-name version (or provides coverage with cost sharing). This proposed change is necessary to effectuate the statutory requirement under PHS Act section 2713 that plans and issuers provide coverage of recommended preventive services without cost sharing, because without such an exceptions process, a plan's or issuer's medical management techniques could have the effect of preventing an individual from receiving coverage without cost sharing of medically necessary recommended preventive services.

Under this proposal and consistent with previous guidance, a plan or issuer would be required to defer to the determination of an individual's attending provider regarding medical necessity with respect to the individual. Previously issued guidance has used the

⁷⁶ For purposes of these proposed rules, consistent with previous guidance described in section I.B of this preamble, an attending provider would mean an individual who is licensed under applicable State law, who is acting within the scope of the provider's license, and who is directly responsible for providing care to the patient relating to the recommended preventive services. Therefore, a plan, issuer, hospital, or managed care organization would not be an attending provider. The reference to an "attending provider" (rather than simply a "provider," as referenced in previously issued guidance) is based on the Departments' understanding that an attending provider is likely to act as an individual's authorized representative when pursuing an exceptions process, and for consistency with the requirement that an attending provider determine medical necessity. *See also*, fn. 33.

terms "medically necessary" and "medically appropriate" interchangeably when referring to the appropriate standard for this clinical determination. However, in these proposed rules, the Departments propose to use the phrase "medically necessary" to establish uniform terminology and avoid confusion from the use of different terms.⁷⁷ The Departments have determined that a standard based on "medical necessity" would more accurately comport with the goal of allowing plans and issuers to use reasonable medical management techniques to control costs, while ensuring every participant, beneficiary, and enrollee receives coverage without cost sharing for a form of a recommended preventive service that is suitable for the individual.

These proposed rules use the term "medically appropriate" to refer to a range of potential options that are generally acceptable to address a condition or achieve a preventive health goal. However, a preventive service that is medically appropriate for most individuals (to whom the recommendation or guidelines applies) may not be medically appropriate to address a condition or achieve a preventive health goal in the context of other health factors specific to a certain individual. In these cases, another form of the preventive service would be medically necessary for that individual. In making a determination of whether a service is medically necessary, a provider might consider factors such as severity of side effects, differences in permanence and reversibility of a recommended preventive service, and ability to adhere to the appropriate use of the recommended preventive service, as determined by the attending provider. Under these proposed rules, if the recommended preventive service covered by the plan or issuer is not medically appropriate for the individual, as determined by the individual's attending provider, the plan or issuer would be required, through the exceptions process, to cover without cost sharing an alternative recommended preventive service that the individual's attending provider determines is medically necessary for that individual.⁷⁸

⁷⁷ The Departments proposal to use the term and standard of "medically necessary" with respect to the exceptions process in these proposed rules should not be interpreted as changing the standard or meaning of the Departments' previously published guidance with respect to the coverage of preventive services.

⁷⁸ Similarly, if the plan or issuer uses reasonable medical management techniques to limit the frequency or setting under which a recommended

For example, if a plan typically covers a generic tobacco cessation product (Gum A) without cost sharing, but an individual is allergic to an inactive ingredient in Gum A and the individual's attending provider determines that Gum B is medically necessary for the individual to achieve the preventive health benefits of the recommended preventive service without adverse side effects, then the plan or issuer would be required to provide coverage of Gum B without cost sharing through the exceptions process. However, if Gum A is medically appropriate for the individual, the plan would not be required to provide coverage of Gum B without cost sharing through the exceptions process solely on the basis that Gum B is also medically appropriate for the individual.

The Departments request comment on the terminology used in the context of the exceptions process. The Departments also request comment generally on any operational or technical barriers to implementing the proposed requirement that plans and issuers defer to the attending provider's determination of medical necessity using an exceptions process for recommended preventive services separate from the required internal claims and appeals process,⁷⁹ and what additional guidance or requirements would support implementation of this requirement (for example, with respect to documentation of the determination or communication with the individual or their attending provider or other representative regarding a request for a coverage exception).

Consistent with prior guidance, the Departments would determine whether a plan's or issuer's exceptions process is easily accessible, transparent, sufficiently expedient, and not unduly burdensome based on all relevant facts and circumstances, including whether and how a plan or issuer provides notice of the availability of an exceptions process and what steps an individual or their provider or other authorized representative is required to

preventive service is covered without cost sharing and the individual's attending provider makes a determination that a different frequency or setting is medically necessary for a participant, beneficiary, or enrollee, under these proposed rules, the plan or issuer would be required to provide coverage without cost sharing for the recommended preventive service according to the frequency or setting the individual's attending provider determines to be medically necessary with respect to the individual.

⁷⁹ *See* section 2719 of the PHS Act (42 U.S.C. 300gg-19); 26 CFR 54.9815-2719; 29 CFR 2590.715-2719; and 45 CFR 147.136.

initiate and complete in order to seek an exception.⁸⁰

For this purpose, the Departments would consider an exceptions process to be easily accessible if plan documentation includes relevant information regarding the exceptions process under the plan or coverage, including how to access the exceptions process without initiating an appeal pursuant to the plan's or issuer's internal claims and appeals procedures, the types of reasonable information the plan or issuer requires as part of a request for an exception, and contact information for a representative of the plan or issuer who can answer questions related to the exceptions process. The Departments would also encourage plans and issuers to make this information available in a format and manner that is readily accessible, such as electronically (on a website, for example) and on paper. The Departments request comment on how plans and issuers could ensure that this information is readily available and accessible, such as any specific formats, mechanisms, or other best practices that could promote access to information about the exceptions process.

The Departments would consider an exceptions process to be transparent if, at a minimum, the information relevant to the exceptions process (including, if used, a standard exceptions process form with instructions) is included and prominently displayed in plan documents (including in, or along with, the summary plan description for plans subject to ERISA), and in any other plan materials, including on the plan's or issuer's website, that describe the terms of the plan's or issuer's coverage of preventive services. The Departments request comment on the extent to which plans and issuers currently make such information available and accessible and to whom (for example, to prospective and current participants, beneficiaries, and enrollees and their providers), whether any additional individuals or groups should have access to this information if this proposal is finalized, and whether the Departments should finalize more specific standards regarding transparency or accessibility of information about the exceptions process in regulation.

The Departments would consider an exceptions process to be sufficiently expedient if it makes a determination of a claim according to a timeframe and in

a manner that takes into account the nature of the claim (for example, pre-service or post-service) and the medical exigencies involved for a claim involving urgent care. The Departments request comment on appropriate additional standards for an exceptions process to be considered sufficiently expedient under these proposed rules. Specifically, the Departments request comment on whether the regulations should contain specific timeframes, and if so, what timeframes would be appropriate, as well as whether the regulations should specify the manner in which plans and issuers should issue a determination (for example, on paper, electronically, or both).

For example, as the Departments specifically noted in prior guidance, it would be unduly burdensome on participants, beneficiaries, and enrollees for a plan or issuer to deny coverage without cost sharing and require an individual or their authorized representative to file an appeal under the plan's or issuer's process for appealing adverse benefit determinations in order to obtain an exception to the standard contraceptive coverage policy.⁸¹ Under 26 CFR 54.9815-2719, 29 CFR 2560.503-1, 29 CFR 2590.715-2719, and 45 CFR 147.136, plans and issuers must render a determination on an internal appeal in no more than 15 calendar days (in the case of a pre-service claim) or no more than 30 calendar days (in the case of a post-service claim). Because most claims for recommended preventive services likely would not meet the definition of a "claim involving urgent care,"⁸² the expedited timelines that

⁸¹ FAQs Part 54, Q10 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>. An adverse benefit determination means an adverse benefit determination as defined in 29 CFR 2560.503-1, as well as any rescission of coverage, as described in 45 CFR 147.128 (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time). See 26 CFR 54.9815-2719, 29 CFR 2560.503-1, 29 CFR 2590.715-2719, and 45 CFR 147.136 for regulations related to internal claims and appeals processes.

⁸² A "claim involving urgent care," defined at 29 CFR 2560.503-1(m)(1) and adopted at 26 CFR 54.9815-2719(b)(2)(ii)(B), 29 CFR 2590.715-2719(b)(2)(ii)(B), and 45 CFR 147.136(b)(2)(ii)(B), is "any claim for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations—(A) Could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function, or, (B) In the opinion of a physician with knowledge of the claimant's medical condition, would subject the claimant to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim." Plans and issuers generally must render determinations regarding claims involving urgent

apply to an appeal of a claim involving urgent care likely would not apply to a claim for a recommended preventive service. In the absence of a separate exceptions process, an individual could therefore be required to pursue a standard internal appeals process to seek coverage of a recommended preventive service, which could result in a coverage delay of up to 30 calendar days for a post-service claim or 15 calendar days for a pre-service claim. Such a delay, when combined with the ability of plans and issuers to use medical management techniques to limit coverage of recommended preventive services outside of an exceptions process, is not aligned with the statutory requirement to provide coverage without cost sharing for all required preventive services, because many individuals would be compelled to pay out-of-pocket for the recommended preventive service determined by their attending provider to be medically necessary or accept the form of the recommended preventive service covered by the plan or issuer as a result of medical management techniques, even if it may cause adverse effects that an alternate form of the recommended preventive service would not cause.

Therefore, a plan or issuer would not have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual (or provider or other person acting as the individual's authorized representative) under these proposed rules if the plan or issuer requires participants, beneficiaries, or enrollees to appeal an adverse benefit determination using the plan's or issuer's internal claims and appeals process as the means to obtain an exception. The Departments request comment on whether plans and issuers should be permitted to require an individual or their authorized representative to use the existing process for urgent care claims under 26 CFR 54.9815-2719(b)(2)(ii)(B), 29 CFR 2560.503-1(b)(2)(ii)(B), and 45 CFR 147.136(b)(2)(ii)(B) (regardless of whether the recommended preventive service meets the definition of a "claim involving urgent care") to obtain an exception to the standard preventive services coverage policy. The Departments also request comment on whether a health plan that is subject to the essential health benefit (EHB) prescription drug exception process

care as soon as possible, accounting for medical exigencies, and not later than 72 hours after receipt of the claim by the plan.

⁸⁰ FAQs Part 54, Q9 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

standards at 45 CFR 156.122(c)⁸³ should be permitted to require an individual or their authorized representative to use the existing standard or expedited prescription drug exception request process when seeking an exception for a recommended preventive service that is a prescription drug, or all recommended preventive services.

The Departments previously noted that plans and issuers may develop a standard exceptions process form with instructions as part of ensuring that the plan's or issuer's exceptions process is easily accessible, transparent, sufficiently expedient, and not unduly burdensome on the individual or provider (or other individual acting as a patient's authorized representative).⁸⁴ A standardized form that is not unnecessarily long and that has clear instructions could reduce burden on individuals or their authorized representative. The proposed amendments at 26 CFR 54.9815–2713(a)(4)(ii), 29 CFR 2590.715–2713(a)(4)(ii), and 45 CFR 147.130(a)(4)(ii) would not require that plans and issuers develop and utilize a standard exceptions process form. However, the Departments continue to encourage plans and issuers to make any such standard exceptions process form, whether developed by a plan or issuer, or the Medicare Part D Coverage Determination form, readily available, both in paper and electronically (such as on a website). The Departments request comment on whether the Medicare Part D Coverage Determination form, or another existing format, would be an appropriate model for plans and issuers implementing a standardized exceptions process under these proposed rules. Alternatively, the Departments request comment on whether it would be beneficial to interested parties if the Departments developed and made available a new standard form for an exceptions process, what information should be included in any such form, and whether use of such a standardized form should be required

⁸³ Separately from requirements related to appeals of adverse benefit determinations, HHS regulations at 45 CFR 156.122(c) state that a health plan does not provide essential health benefits (EHBs) unless it provides a standard and expedited exceptions process for prescription drugs through which an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) can receive a coverage determination within 72 hours (for a standard exception) or no later than 24 hours (for an expedited exception, in the case of exigent circumstances).

⁸⁴ FAQs Part 54, Q9 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-eba/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

or optional. The Departments anticipate that most, if not all, plans and issuers have an existing exceptions process for recommended preventive services, or a process for other services that can be adapted to meet these requirements for recommended preventive services at minimal cost. The Departments request comment on this assumption and on all other aspects of this proposal.

2. Coverage of Contraceptive Items

Section 2713(a)(4) of the PHS Act was enacted to ensure that plans and issuers cover women's preventive health needs. Contraceptive coverage is an essential component of women's health care, as recognized by its inclusion in the HRSA-supported Guidelines, in part because contraception is effective at reducing unintended pregnancies and associated negative maternal-infant outcomes.⁸⁵ Unintended pregnancies, which account for approximately 42 percent of pregnancies annually in the United States, are a major public health concern.^{86 87} Coverage requirements that promote equitable access to medically appropriate contraceptive items and services are an essential component of high-quality reproductive health care with wide-ranging social and economic benefits.⁸⁸ Research shows that many women are not using their contraceptive

⁸⁵ Nelson, H., Darney, B., Ahrens, K., Burgess, A., Jungbauer, R., Cantor, A., Atchison, C., Eden, K., Goueth, R., Fu, R. (2002). "Associations of Unintended Pregnancy With Maternal and Infant Health Outcomes: A Systematic Review and Meta-analysis," *JAMA*, available at <https://jamanetwork.com/journals/jama/fullarticle/2797874>.

⁸⁶ See CDC, "Reproductive Health, Unintended Pregnancy," available at <https://www.cdc.gov/reproductive-health/hcp/unintended-pregnancy/index.html>.

⁸⁷ See Bradford, K., Costanza, K., Fouladi, F., Hill, T., Nguyen, K., and Speer, K., NCSL (2023). "Supporting Moms' Health in the Postpartum Period," available at <https://www.ncsl.org/health/supporting-moms-health-in-the-postpartum-period>; Nelson, et al., *supra* fn. 75; Cruz-Bendezú, A., Lovell, G. Roche, B., Perkins, M., Blake-Lamb, T., Taveras, E., and Simone M. (2020). "Psychosocial status and prenatal care of unintended pregnancies among low-income women," *BMC Pregnancy and Childbirth*, available at <https://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-020-03302-2>; Blake, S., Kiely, Gard, C., El-Mohandes, A., El-Khorazaty, M.N. (2007). "Pregnancy Intentions and Happiness Among Pregnant Black Women at High Risk for Adverse Infant Health Outcomes," *American Journal of Public Health*, available at <https://doi.org/10.1363/3919407>; Finer, L., and Zolna, M. (2014). "Shifts in intended and unintended pregnancies in the United States, 2001–2008," *American Journal of Public Health*, available at <https://pubmed.ncbi.nlm.nih.gov/24354819>.

⁸⁸ *Id.*, see also Sonfield, A., Hasstedt, K., Kavanaugh, M., and Anderson, R., (2013). "The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children," *Guttmacher Institute*, available at https://www.guttmacher.org/sites/default/files/report_pdf/social-economic-benefits.pdf.

of choice, for reasons that include concerns about side effects, cost, lack of availability, or inability to get a provider appointment.⁸⁹ Coverage that allows individuals to identify and obtain a medically necessary contraceptive (accounting for variables such as hormonal properties, side effects, and delivery mechanisms, among other factors) without cost sharing could improve quality of life, reduce behaviors such as discontinuing contraception, and result in more effective use of contraception to prevent unintended pregnancy.⁹⁰ As noted in the preamble to the 2023 proposed rules, increased contraceptive coverage can improve access to care, and therefore also help to address racial inequities in reproductive health care that contribute to lifelong disproportionate health outcomes for women in underserved communities, including disparate maternal health outcomes.⁹¹

Additionally, there has been significant activity related to coverage of contraceptive services and several new developments, including legal developments, that have affected women's needs regarding access to affordable contraception since the publication of the July 2010 interim final rules. The Departments continue to receive complaints and are aware of other reports documenting plans' and issuers' failure to provide coverage of the full range of contraceptive services. Coverage issues leading to lack of access to contraception were also substantiated in comments received in response to the OTC Preventive Products RFI. Other developments have included the *Dobbs* decision and subsequent State-level restrictions on access to abortion and emergency contraception, which have made it more challenging for women in some States to obtain contraception and quality family planning care, including because health care providers have been forced to close or chosen to relocate to

⁸⁹ Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," available at <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings>.

⁹⁰ Steinberg, J., Marthey, D., Xie, L., Boudreaux, M. (2021). "Contraceptive method type and satisfaction, confidence in use, and switching intentions," *Contraception*, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8286312>.

⁹¹ See 88 FR 7236, 7241 (Feb. 2, 2023), citing Sutton, M. Y., Anachebe, N. F., and Skanes H. (2021). "Racial and Ethnic Disparities in Reproductive Health Services and Outcomes, 2020," *Obstetrics and Gynecology*, available at <https://doi.org/10.1097/AOG.0000000000004224>; White House Blueprint for Addressing the Maternal Health Crisis (2022), available at <https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf>.

a different State;⁹² Executive Orders related to reproductive health care; and FDA approval of the first daily OTC oral contraceptive. As a result, the Departments have determined that it is necessary to propose amendments to the regulations governing how plans and issuers cover contraception and, as discussed in section II.B of this preamble, how they communicate information about this coverage to participants, beneficiaries, and enrollees.

The Departments are interested in minimizing barriers to coverage and expanding the scope of coverage without cost sharing for all recommended preventive services, in alignment with section 2713 of the PHS Act. The Departments also recognize that the proposals described in this section II.A.2 of this preamble, if finalized, could require significant changes to current plan and issuer operations. Therefore, the Departments propose an incremental approach in this rulemaking with respect to the types of recommended services addressed that is focused initially on expanding coverage of contraception. This incremental approach would facilitate implementation for plans, issuers, and other interested parties and allow the Departments to gather additional feedback on challenges and benefits of adopting these proposed policies before considering whether and how to propose similar requirements with respect to other recommended preventive services. Focusing first on contraceptive items is appropriate due to ongoing and widely reported concerns regarding challenges faced by consumers in accessing contraceptive items and services without cost sharing, as well as recent developments affecting access to reproductive health care.⁹³

⁹² See, e.g., Murphy, C., Shin, P., Jacobs, F., and Johnson, K. (2024). "In States with Abortion Bans, Community Health Center Patients Face Challenges Getting Reproductive Health Care," Commonwealth Fund, available at <https://www.commonwealthfund.org/blog/2024/states-abortion-bans-community-health-center-patients-face-challenges-getting>; Harper, C., Brown, K., and Arora, K. (2024). "Contraceptive Access in the US Post-Dobbs," JAMA Internal Medicine, available at <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2823682>; Qato, D., Myerson, R., Shoostari, A., Guadamuz, J., Alexander, G.C., (2024). "Use of Oral and Emergency Contraceptives After the US Supreme Court's Dobbs Decision," available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2820370>.

⁹³ See, e.g., Adler, A., Biggs, A.M., Kaller, S., Schroeder, R., Ralph, L. (2023). "Changes in the Frequency and Type of Barriers to Reproductive Health Care from 2017 to 2021," JAMA Network Open, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10087056>; Qato, D., Myerson, R., Shoostari, A., Guadamuz, J., Alexander, G.C., (2024). "Use of Oral and Emergency Contraceptives

As described in FAQs Part 51, Q9, FAQs Part 54, Q8, and sections I.B and II.A.2 of this preamble, the Departments continue to receive complaints and are aware of other credible reports that some plans and issuers frequently restrict access to contraceptive items and services that should be covered without cost sharing. For instance, in addition to widespread denials of exceptions process requests as described in section II.A.1 of this preamble, the October 2022 Oversight Committee report identified at least 34 different contraceptive items that were commonly excluded from coverage or for which cost-sharing requirements often were applied.⁹⁴ Additionally, a recent investigation by the Vermont Department of Financial Regulation, the agency responsible for regulating issuers in that State, found that three issuers in Vermont violated State and Federal law by failing to provide coverage of contraceptive services without cost sharing. The investigation found that between 2017 and 2021, the issuers inappropriately charged patients \$1.5 million for contraceptive items and services that should have been provided free of any out-of-pocket costs, resulting in a finding that 9,000 people were entitled to receive restitution for cost sharing that was incorrectly applied for contraceptive services.⁹⁵ The investigation prompted a Congressional request to the Government Accountability Office for an investigation into plan and issuer compliance with ACA requirements to cover contraceptive items without cost

After the US Supreme Court's *Dobbs* Decision," available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2820370>; Harper, C., Brown, K., and Arora, K. (2024). "Contraceptive Access in the US Post-Dobbs," JAMA Internal Medicine, available at <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2823682>; Kavanaugh, M. and Friedrich-Karnik, A. (2024). "Has the Fall of *Roe* changed contraceptive access and use? New research from four US states offers critical insights," Health Affairs Scholar, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10986283>; and American Academy of Pediatrics, (updated July 2023) "The Importance of Access to Contraception—Barriers to accessing contraception", available at <https://www.aap.org/en/patient-care/adolescent-sexual-health/equitable-access-to-sexual-and-reproductive-health-care-for-all-youth/the-importance-of-access-to-contraception>.

⁹⁴ U.S. House of Representatives Committee on Oversight and Reform, "Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance" (Oct. 25, 2022), available at <https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf>.

⁹⁵ State of Vermont Department of Financial Regulation (Nov. 13, 2023). "Contraceptive Services Claims Restitution Information," available at <https://dfr.vermont.gov/contraceptive-services-claims-restitution-information>.

sharing.⁹⁶ In addition, the Centers for Medicare & Medicaid Services, as part of targeted market conduct examinations conducted on behalf of HHS, has identified multiple violations of the requirements of section 2713(a)(1) of the PHS Act and implementing regulations related to contraceptive coverage and continues to investigate additional complaints alleging violations.⁹⁷ Additional reports of noncompliance documented by members of Congress, advocacy organizations, and media reports were cited by the Secretaries in their June 27, 2022 letter to group health plan sponsors and issuers.⁹⁸ Given these reported instances of continued obstacles for women in accessing contraception, and within the context of several States' efforts to restrict access to reproductive health care following the *Dobbs* decision, the Departments have determined it is appropriate for these proposed rules to begin with addressing barriers to contraceptive services.

Furthermore, focusing on contraception is consistent with recent Executive Orders. As described in section I.C of this preamble, President Biden issued E.O. 14101, which directed the Secretaries to consider actions that would, to the greatest extent permitted by law, ensure coverage of comprehensive contraceptive care, including all contraceptives approved, cleared, or granted by the FDA, without cost sharing for participants, beneficiaries, and enrollees; and streamline the process for patients and health care providers to request coverage, without cost sharing, of medically necessary contraception. Further, section 2(b) of E.O. 14101 instructed the Secretaries to consider actions that would promote increased access to affordable OTC

⁹⁶ Sen. Bernie Sanders (June 17, 2024). Letter to Hon. Gene Dodaro, Comptroller General of the United States, available at <https://www.documentcloud.org/documents/24764790-61724-go-aca-contraception-coverage-letter>.

⁹⁷ CMS, "Compliance and Enforcement, Federal Market Conduct Examination Final Reports," available at <https://www.cms.gov/marketplace/private-health-insurance/consumer-protections-enforcement>.

⁹⁸ See, e.g., Secretaries Becerra, Yellen, and Walsh (June 27, 2022). Letter on the ACA contraceptive coverage requirement, available at <https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/letter-from-secretaries-becerra-yellen-and-walsh-on-the-aca-contraceptive-coverage-requirement.pdf> (highlighting reports of noncompliance documented by Members of the U.S. House of Representatives (in 2021 and 2022) and the U.S. Senate (in 2021 and 2022), the National Women's Law Center, other nonprofit organizations, and media reports).

contraception.⁹⁹ Consistent with E.O. 14101, and in consideration of the availability of OTC oral contraceptives, these proposed rules would promote coverage and streamline access to all medically necessary contraception, including the newly FDA-approved OTC daily oral contraceptive, by removing prescription and cost barriers for consumers.

The Departments acknowledge the possibility that increasing coverage without cost sharing for recommended preventive services, as discussed in this section II.A.2 of this preamble, could lead to greater demand for those services and potentially higher prices charged by providers. These increased costs could result in higher costs to consumers, both in the form of higher premiums for people with insurance and in the form of higher out-of-pocket costs for people who do not use insurance coverage to obtain OTC contraceptive products. The potential increases in cost further justify the incremental approach taken in these proposed rules. In addition, comments in response to the OTC Preventive Products RFI suggested that requiring coverage of all OTC preventive products may be challenging for some types of preventive care. For these reasons, the Departments propose to amend the preventive services regulations with respect to only contraceptive items¹⁰⁰ at this time by inserting a new paragraph (a)(6) at 26 CFR 54.9815–2713, 29 CFR 2590.715–2713, and 45 CFR 147.130. The Departments' issuance of these proposals implementing section 2713 of the PHS Act is authorized by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

First, the Departments propose to define the terms “drug-led combination product”¹⁰¹ in proposed new paragraph (a)(6)(i)(A) and “therapeutic equivalent” in proposed new paragraph (a)(6)(i)(B) for purposes of the proposed new paragraph (a)(6). Second, the Departments propose in proposed new paragraph (a)(6)(ii) to require that plans and issuers cover, without requiring a

prescription and without imposing cost-sharing requirements, recommended contraceptive items that are available OTC and for which the applicable recommendation or guideline does not require a prescription. Third, the Departments propose in proposed new paragraph (a)(6)(iii) that, in order for medical management techniques to be considered reasonable, plans and issuers would be required to utilize a therapeutic equivalence approach for recommended contraceptive drugs and drug-led combination products.

The Departments request comment on whether to finalize these policies only with respect to contraception as proposed, or to instead finalize these policies with respect to all preventive services, or with respect to a larger subset of preventive services. In particular, the Departments request comment on issues related to coverage of additional specific OTC preventive products without a prescription (for example, tobacco cessation items) in addition to OTC contraceptive items, or all OTC preventive products without a prescription. The Departments also request comment on the experiences (particularly with respect to administrative challenges, consumer experiences, and costs) of any plans and issuers that currently provide coverage for any OTC preventive products without requiring a prescription, and how those experiences could inform the implementation of these proposed rules, if finalized. The Departments further request comment on whether and to what extent these proposals could affect the ability of plans and issuers to negotiate or otherwise limit costs for contraceptive items, including OTC contraceptive items and contraceptive drugs and drug-led combination products, and what additional rulemaking or guidance would be necessary to ensure that plans and issuers retain the ability to do so.

Along with the incremental approach proposed in this rulemaking focused on contraception, the Departments anticipate issuing another notice of proposed rulemaking in the near future to address additional issues related to coverage of preventive services more generally.

a. Coverage of OTC Contraceptive Items Without Cost Sharing

As discussed in section I.B of this preamble, the Departments' previously issued guidance provides that preventive health care items generally available OTC to patients (such as folic acid and certain contraceptive products, including contraceptive sponges, spermicides, and emergency

contraception (levonorgestrel)) must be covered without cost sharing under section 2713 of the PHS Act only when prescribed by a health care provider.¹⁰² This approach reflected the traditional role of health coverage in providing benefits for health care items and services for which there is provider involvement. However, the FDA's approval of a daily OTC oral contraceptive without a prescription, in combination with the reasons outlined earlier in this preamble, have prompted the Departments to revisit this approach. As commenters to the OTC Preventive Products RFI noted, neither section 2713 of the PHS Act and its implementing regulations nor the current HRSA-supported Guidelines require a prescription as a condition of coverage without cost sharing for recommended preventive services that are available OTC, except to the extent a particular recommendation or guideline requires that an individual is prescribed an item or service. Therefore, with respect to contraceptive items that can be lawfully obtained¹⁰³ by a participant, beneficiary, or enrollee without a prescription and for which the applicable recommendation or guideline does not require a prescription, the Departments propose in new paragraph (a)(6)(ii) that a plan or issuer would not be considered to comply with 26 CFR 54.9815–2713(a)(1), 29 CFR 2590.715–2713(a)(1), and 45 CFR 147.130(a)(1), unless the plan or issuer provides coverage for the contraceptive item without requiring a prescription and without imposing any cost-sharing requirements. As noted by many commenters to the OTC Preventive Products RFI, out-of-pocket costs and prescription requirements make it more difficult for women to access contraception, including contraceptive items that are available without a prescription, such as oral contraceptives recently approved by the FDA for OTC sale. The Departments agree with commenters that these

¹⁰² See FAQs Part XII, Q4 and Q15 (Feb. 20, 2013), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-xii.pdf> and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html; FAQs Part 54, Q5–6 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebbsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

¹⁰³ The Departments intend for this proposal to apply only to contraceptive items that are legally sold without a prescription. Nothing in this proposal would require a plan or issuer to provide coverage without cost sharing for a contraceptive item for which the FDA requires a prescription, if a participant, beneficiary, or enrollee acquires the item without a prescription.

⁹⁹ 88 FR 41815 at 41816 (June 23, 2023).

¹⁰⁰ See section II.A.2 of the preamble to these proposed rules for comment solicitation regarding whether to expand the proposed coverage requirements to other recommended preventive services.

¹⁰¹ The Departments are proposing to define the term “drug-led combination products” in these proposed rules instead of the term “drug-led devices” used in FAQs Part 64 to align these proposed rules with existing definitions at 21 CFR 3.2(e). The change in terminology should not be interpreted to suggest that the terms are interchangeable, as the term “drug-led combination products” encompasses “drug-led devices” as well as other drug-led combination products for which the FDA evaluates therapeutic equivalence.

obstacles present greater challenges to women in underserved communities, including those with lower incomes and who are members of underserved racial and ethnic groups, reinforcing structural barriers to health care and contributing to reproductive health disparities. Although some plans and issuers have voluntarily, or as required by State law,¹⁰⁴ provided coverage of OTC contraceptive items without a prescription and without cost-sharing requirements or with limits on cost sharing, the Departments understand that many women lack such coverage. In response to a specific question regarding how commonly plans and issuers provide coverage for OTC preventive products without requiring a prescription, many commenters asserted that most plans and issuers cover OTC preventive products only when they are prescribed. The Departments have determined, therefore, that requiring (rather than encouraging) coverage of OTC contraceptive items without cost sharing and without a prescription, as proposed in these rules, is critical to ensuring that coverage requirements provide women with access to contraceptives as required under section 2713 of the PHS Act and the applicable HRSA-supported Guidelines, and to realizing the goal of promoting access to reproductive health care.

Under this proposal, the requirement to cover OTC contraceptive items would be subject to the specific coverage requirements applicable to all recommended preventive services in 26 CFR 54.9815–2713, 29 CFR 2590.715–2713, and 45 CFR 147.130. However, the Departments recognize that the provision and coverage of OTC contraceptive items present unique issues that plans and issuers may not encounter when covering other recommended services. Therefore, the following sections of this preamble discuss how plans and issuers would be expected to comply with certain

¹⁰⁴ CA, CO, MD, NM, NJ, NY, and WA require some coverage of OTC contraceptive items. See KFF (Updated March 2024). “State Private Insurance Coverage Requirements for OTC Contraception Without a Prescription,” available at <https://www.kff.org/other/state-indicator/state-private-insurance-coverage-requirements-for-otc-contraception-without-a-prescription>. See, e.g., Cal. Health & Saf. Code section 1367.25(b)(1)(A) (barring prescription requirements for OTC FDA-approved contraceptive drugs, devices, and products and requiring point-of-sale coverage of OTC contraception at in-network pharmacies); Md. Code, Ins. section 15–826.1 (requiring coverage without a prescription for all FDA-approved contraceptive drugs available OTC and limiting cost-sharing for OTC contraceptive drugs to the amount that would apply to the same drug dispensed under a prescription).

existing requirements with respect to coverage of OTC contraceptive items.¹⁰⁵

(1) In-Network and Out-of-Network Coverage of OTC Contraceptive Items

Under section 2713 of the PHS Act and its implementing regulations at 26 CFR 54.9815–2713(a)(3)(i) and (ii), 29 CFR 2590.715–2713(a)(3)(i) and (ii), and 45 CFR 147.130(a)(3)(i) and (ii), a plan or issuer is not required to provide coverage for recommended preventive services delivered by an out-of-network provider if the plan or issuer has a network of providers. Similarly, nothing precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements on recommended preventive services delivered by an out-of-network provider. However, if a plan or issuer does not have a provider in its network who can provide a recommended preventive service, the plan or issuer must cover the recommended preventive service, without cost sharing, when furnished by an out-of-network provider.¹⁰⁶ Nothing under section 2713 of the PHS Act nor its implementing regulations requires a plan or issuer to establish a provider network.

The Departments are not proposing to amend these requirements with respect to OTC contraceptive items. Therefore, a plan or issuer that has a network of providers that can provide OTC contraceptive items would not be required to provide coverage, or waive cost sharing, for OTC contraceptive items that are provided by an out-of-network provider. For example, if a plan or issuer has a network of pharmacies (including mail-order pharmacies) that can provide OTC contraceptive items without a prescription, the plan or issuer would not be required to provide coverage (nor waive cost sharing) if a participant, beneficiary, or enrollee obtains a covered OTC contraceptive item at an out-of-network pharmacy or other retailer.¹⁰⁷

The Departments understand, based on responses to the OTC Preventive Products RFI and communications with plans and issuers regarding coverage of

¹⁰⁵ The requirements regarding office visits would not be relevant with respect to coverage of OTC contraceptive items, and the requirements regarding timing do not raise unique issues with respect to OTC contraceptive items.

¹⁰⁶ See FAQs Part XXII, Q3 (Feb. 20, 2013), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-xii.pdf> and <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/aca-implementation-faqs12>.

¹⁰⁷ Nothing in the statute or preventive services regulations prevents a plan or issuer from providing coverage without cost sharing for out-of-network recommended preventive services, and the Departments encourage plans and issuers to do so.

OTC COVID–19 diagnostic tests during and after the COVID–19 PHE, that network contracts between plans and issuers and pharmacies that are located in a retail store typically include only the pharmacies as the in-network providers. The retail stores at which the pharmacies are located are treated as separate entities. In these cases, the pharmacy point of sale would be considered an in-network provider at which an OTC contraceptive would be covered without cost sharing, but a non-pharmacy point of sale (for example, a cash register, self-check-out, or vending machine in the front of a retail store, unaffiliated with the pharmacy department) would not be considered an in-network provider. Although participants, beneficiaries, and enrollees would typically be able to purchase OTC contraceptives from the front of the retail store, these proposed rules would not require a plan or issuer with a network of pharmacies to also cover without cost sharing OTC contraceptive items that are purchased at a retail store that is co-located with an in-network pharmacy. If the plan or issuer has a network of pharmacies that provide coverage for OTC contraceptive items without cost sharing, that plan or issuer would be considered to have a network of providers to provide benefits for OTC contraceptive items and therefore would not be required to cover OTC contraceptive items purchased at a retail store that is not part of its network. For example, emergency contraception could be available in multiple locations in the same retail store: behind the pharmacy counter through an in-network pharmacy where a consumer typically provides health coverage information to allow the pharmacy to process a claim for coverage; and “off the shelf” in a non-pharmacy section of the same store. This could result in a participant, beneficiary, or enrollee being able to access an OTC contraceptive item at an in-network pharmacy without paying any out-of-pocket costs at the pharmacy counter point of sale, while being liable for the full cost of the identical OTC contraceptive item if it was purchased at a non-pharmacy point of sale. The Departments request comment on the potential impact on consumers, pharmacies, and retail stores with this proposed approach.

The Departments would expect that in-network coverage for OTC contraceptive items and services would be provided in a manner that is comparable to coverage for other recommended preventive services. For example, the Departments would expect

that a plan or issuer that does not preference the use of a mail-order pharmacy for coverage of prescription-only recommended preventive services would not preference the use of a mail-order pharmacy for coverage of OTC contraceptives. As another example, a plan or issuer should not impose shipping costs on an OTC contraceptive item that is furnished via mail order if the plan or issuer would not impose shipping costs on a comparable prescription product. Likewise, to the extent that a plan or issuer generally covers a recommended preventive service that requires a prescription without cost sharing at the in-network pharmacy point of sale, without requiring consumers to pursue post-purchase reimbursement, the Departments would expect that the plan or issuer would generally cover OTC contraceptive items at the in-network pharmacy point of sale in the same manner. Plans and issuers that require participants, beneficiaries, or enrollees to present information, such as an insurance card, to allow an in-network pharmacy to process a claim for a prescription-only recommended preventive service may require similar information to process a claim for an OTC contraceptive item. The Departments request comment on the appropriate approach for coverage in a scenario in which a plan's or issuer's preferred OTC contraceptive item is out of stock at an in-network pharmacy, while a non-preferred version is available. Specifically, the Departments request comment on whether plans or issuers should be required to cover the non-preferred version without cost-sharing requirements at the in-network pharmacy, without requiring the consumer to pursue an exceptions process when a preferred version is unavailable at an in-network pharmacy. The Departments also request comment on whether and how plans and issuers should document the unavailability of a preferred OTC contraceptive for coverage purposes.

As noted earlier, plans and issuers are not required to establish a provider network in order to provide coverage of recommended preventive services and would not be required to contract with providers for the purpose of providing in-network coverage of OTC contraceptive items if these proposed rules are finalized. Under 26 CFR 54.9815-2713(a)(3)(ii), 29 CFR 2590.715-2713(a)(3)(ii), and 45 CFR 147.130(a)(3)(ii), a plan or issuer that lacks an in-network provider who can provide an OTC contraceptive item would be obligated to cover the OTC

contraceptive item when provided by an out-of-network provider without imposing cost sharing.

In the absence of a provider network, the Departments encourage plans and issuers to establish processes to ensure that participants, beneficiaries, and enrollees can obtain OTC contraceptive items from out-of-network providers without incurring out-of-pocket costs and without encountering significant barriers to access.¹⁰⁸ The Departments are not proposing to specify in these proposed rules how a plan or issuer would do so, but would encourage plans and issuers to establish a robust approach with multiple entry points to ensure that participants, beneficiaries, and enrollees can access out-of-network OTC contraceptive items with no out-of-pocket costs and without friction at the point of sale. The Departments request comment on what additional standards or guidance would be helpful to ensure that participants, beneficiaries, and enrollees can use their health coverage to access OTC contraceptive items from out-of-network providers without cost sharing, while allowing plans and issuers flexibility to effectively implement the requirement to cover OTC contraceptive items, if finalized.

If these requirements are finalized, plans and issuers should ensure that processes that require participants, beneficiaries, or enrollees to pay out-of-pocket for OTC contraceptive items and pursue reimbursement do not present unreasonable barriers to accessing OTC contraceptive items provided by either an in-network or out-of-network provider. A traditional post-purchase reimbursement process might require consumers to bear the upfront cost of an OTC contraceptive item as well as the administrative burden of requesting reimbursement, providing documentation either on paper or electronically, and absorbing the financial impact of a delayed reimbursement while a reimbursement request is being reviewed and processed

by the plan or issuer. For example, while it would be reasonable for a plan or issuer to require a form and receipt or other proof of purchase, post-purchase reimbursement programs that require an individual to submit multiple documents or involve numerous steps that unduly delay an individual's reimbursement for an OTC contraceptive item would not be reasonable under these proposed rules.

Further, the Departments would strongly encourage plans and issuers to consider implementing additional methods for providing coverage of OTC contraceptive items without cost sharing, in addition to or in lieu of a traditional post-purchase reimbursement process. For example, plans and issuers could consider providing access to pre-paid accounts that are programmed to cover upfront costs associated with OTC contraceptive items at the point of sale, either by issuing physical debit or credit cards or providing access to a linked smartphone application or QR code to participants, beneficiaries, or enrollees, provided funds were sufficient to cover costs associated with OTC contraceptive items, the mechanism for delivery was programmed with sufficient guardrails to prevent funds from being applied to items that were not covered, and the method of access was otherwise implemented consistent with applicable law. Subject to the requirements for utilizing reasonable medical management techniques¹⁰⁹ and consistent with previously issued guidance¹¹⁰ (including providing access to an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual, a provider, or other authorized representative),¹¹¹ plans and issuers would be able to utilize reasonable medical management techniques to contain costs and promote efficient delivery of care, and could consider how to do so within the

¹⁰⁸ The Departments note that plans and issuers would not be required to reimburse the cost of OTC contraceptive items that have already been reimbursed by an account-based plan, such as a health flexible spending arrangement (FSA) or health reimbursement arrangement (HRA). As of January 2020, section 3702 of the CARES Act amended the definition of qualifying medical expenses so that the expenses for certain OTC medications purchased without a prescription are eligible for reimbursement under certain arrangements, such as health savings accounts (HSAs), HRAs, and health FSAs. An individual generally may not submit claims to multiple sources of coverage to be reimbursed more than once for the same medical expense. Therefore, the cost (or the portion of the cost) of OTC contraception that has already been paid or reimbursed by a plan or issuer cannot also be reimbursed by an HSA, HRA, or health FSA.

¹⁰⁹ 26 CFR 54.9815-2713(a)(4), 29 CFR 2590.715-2713(a)(4), and 45 CFR 147.130(a)(4).

¹¹⁰ See, e.g., FAQs Part XII, Q14 (Feb. 20, 2013), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf> and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html; FAQs Part XXVI (May 11, 2015), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

¹¹¹ See section II.A of the preamble to these proposed rules for a description of existing guidance regarding the use of an exceptions process and the proposal in these proposed rules to require plans and issuers to provide an exceptions process when utilizing reasonable medical management for recommended preventive services.

context of such an approach for out-of-network coverage of OTC contraceptive items. For example, a plan or issuer would be able to program a debit or credit card or linked account to limit reimbursement to a set amount within a specified period of time, provided such limitations do not unreasonably limit coverage of covered OTC contraceptive items.

The Departments are aware that some OTC contraceptive items, such as software applications granted marketing authorization by the FDA for use as contraception, are typically not furnished by in-network providers (for example, because consumers purchase them directly from a manufacturer or vendor website). As with other recommended preventive services for which a plan or issuer does not have an in-network provider who can provide the item or service, the plan or issuer would be required to cover the item or service when delivered by an out-of-network provider and could not impose cost sharing with respect to the item or service. The Departments request comment on whether additional guidance is necessary to ensure that individuals would be able to use their health coverage to obtain OTC contraceptive items that are typically obtained outside of the traditional system of network providers with zero cost sharing and without unnecessarily burdensome reimbursement requirements, while permitting plans and issuers to utilize reasonable medical management techniques.

The Departments request comment on how plans and issuers would likely operationalize out-of-network coverage and whether the Departments should adopt specific standards for out-of-network coverage with respect to OTC contraceptive items. In addition, participants, beneficiaries, and enrollees would benefit if plans and issuers provide access to a broad network of providers with the capacity to provide the full range of OTC contraceptive items, and the Departments request comment on how to support and incentivize plans and issuers to develop such networks.

(2) Reasonable Medical Management Techniques for OTC Contraceptive Services

As discussed in section II.A.1 of this preamble, to the extent not specified in the applicable recommendation or guideline, plans and issuers may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended

preventive health service.¹¹² In prior guidance, the Departments have stated that if a plan or issuer utilizes medical management techniques within a specified category of contraception (or, with respect to contraceptive categories not specifically described in the HRSA-supported Guidelines, a group of substantially similar services or products), the use of those techniques will not be considered reasonable unless the plan or issuer has an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or their attending provider (or other individual acting as the individual's authorized representative) allowing such individual to obtain coverage for a service or FDA-approved, -cleared, or -granted product determined to be medically necessary, as determined by the individual's attending provider.¹¹³ The Departments are not proposing amendments to the medical management provisions specific to OTC contraceptive items. Therefore, these standards, as well as the new standards proposed in these rules,¹¹⁴ would apply to a plan's or issuer's use of medical management techniques with respect to OTC contraceptive items in the same manner and to the same extent as they would apply to other recommended preventive services.

The Departments recognize that plans and issuers may encounter unique issues related to medical management if the Departments finalize the proposed requirements to cover OTC contraceptive items. In the OTC Preventive Products RFI, the Departments requested comment on what types of reasonable medical management techniques plans and issuers would consider implementing if recommended OTC preventive products were required to be covered without cost sharing. In response, some commenters suggested plans and issuers could limit the number of products an individual could obtain during a given period as a guardrail for OTC contraceptive services. One commenter stated that quantity limits would help prevent inequitable distribution and

stockpiling for resale of OTC contraceptive services. Another commenter urged the Departments to allow plans and issuers to limit the initial purchase of OTC contraceptive services until there is more understanding of the cost implications and distribution channels for OTC preventive services. Other commenters discouraged the use of quantity limits as a medical management technique out of concern that such limits would discourage continuation of use, by creating new access barriers for individuals that already face challenges engaging with the health care system, in particular individuals that are members of underserved communities. In addition, a commenter expressed concern about the difficulty in predicting the need for emergency contraception.

Some commenters advocated for 12-month quantity limits for monthly OTC contraceptive services in order to balance the health equity concerns of individuals with the implementation challenges that may arise for retailers and plans and issuers transitioning to covering OTC contraceptive services without a prescription and without cost sharing. Some commenters noted that there is already ample precedent for requiring coverage of extended supplies of contraceptives, with at least 25 States and the District of Columbia requiring Medicaid and private payers to cover the dispensing of an extended (usually 12-month) supply of prescription contraceptives.¹¹⁵ One commenter to the OTC Preventive Products RFI stated that purchasing contraceptive items in larger dispensing quantities may create opportunities for plans and issuers to negotiate pricing discounts that will decrease per-unit costs for plans and issuers as well as suppliers and distributors. The Departments note that when the OTC oral contraceptive became available in March 2024 for sale online and in stores under the brand name Opill®, the manufacturer's suggested retail price for a 6-month supply was cheaper (per-month) than

¹¹² 26 CFR 54.9815–2713(a)(4); 29 CFR 2590.715–2713(a)(4); and 45 CFR 147.130(a)(4).

¹¹³ See FAQs Part 54, Q3 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf>.

¹¹⁴ See sections II.A.1 (for discussion of proposal to amend the general requirements related to reasonable medical management) and II.A.2.b (for discussion of proposed amendment regarding reasonable medical management for contraceptive drugs and drug-led combination products, including OTC contraceptive items) of the preamble to these proposed rules.

¹¹⁵ In States that have implemented a 12-month prescription limitation, plans and issuers are required to cover without cost sharing a supply of up to 12 months when indicated by the prescribing provider. See *Power to Decide* (August 2023), "Coverage for an Extended Supply of Contraception," available at <https://powertodecide.org/sites/default/files/2023-08/Extended%20Supply%20of%20Contraception.pdf>. Since the comment submission period for the OTC Preventive Products RFI closed, additional States have enacted coverage requirements related to extended contraceptive supplies. See NCSL, "State Contraception Policies," available at <https://www.ncsl.org/health/state-contraception-policies>.

the manufacturer's suggested retail price for a 1-month supply.¹¹⁶

Literature on contraception shows that dispensing a multi-month supply of prescription oral contraceptive pills at one time during the plan year is generally associated with increased continuation of contraception use, decreased occurrence of unintended pregnancy, and greater cost savings, but also more pill waste, compared to dispensing a single month's supply.¹¹⁷⁻¹¹⁸ Research also shows that advance provision of emergency contraception significantly increases its use without adversely affecting the use of routine contraception,¹¹⁹ which suggests that it may be beneficial for women to receive more than one unit of emergency contraception at a time, in order to realize the benefits of advance provision for future use. Limitations on the supply of OTC contraception dispensed at one time should take into account the clinical evidence base regarding benefits to consumers, including as described in this section II.a.2.

Given the evidence regarding benefits to consumers of a multi-month supply of prescription oral contraceptive pills, the Departments would generally not consider coverage limitations that only allow for a 1-month supply of an OTC oral contraception per instance of dispensing to be reasonable or consistent with the requirement to cover recommended preventive services under

¹¹⁶ Lupkin, S., NPR (March 18, 2024). "First over-the-counter birth control pill now for sale online," available at <https://npr.org/sections/health-shots/2024/03/04/1235404522/opill-over-counter-birth-control-pill-contraceptive-shop>.

¹¹⁷ See Steenland, M., Rodriguez, M., Marchbanks, P., and Curtis, K. (2013). "How does the number of oral contraceptive pill packs dispensed or prescribed affect continuation and other measures of consistent and correct use? A systematic review," *Contraception*, available at <https://www.sciencedirect.com/science/article/pii/S0010782412007317?via%3Dihub>.

¹¹⁸ See Judge-Golden, C. P., Smith, K. J., Mor, M. K., and Borrero, S. (2019). "Financial Implications of 12-Month Dispensing of Oral Contraceptive Pills in the Veterans Affairs Health Care System," *JAMA Internal Medicine*, available at <https://doi.org/10.1001/jamainternmed.2019.1678> (study of the Veterans Affairs health care system finding that a 12-month supply better supports continuous usage of contraceptive items than a 3-month supply and decreases the risk of unwanted pregnancies, and concluding that a 12-month dispensing option would likely result in a \$2 million dollar annual cost-savings for the Veterans Affairs health care system).

¹¹⁹ See Kripke, C. (2000). "Advance Provision for Emergency Oral Contraception," *American Family Physician*, available at <https://www.aafp.org/pubs/afp/issues/2007/0901/p654.html>; Jackson R.A., Bimla Schwarz, E., Freedman L, Darney P. (2003). "Advance supply of emergency contraception: effect on use and usual contraception—a randomized trial," *Obstetrics and Gynecology*, available at <https://pubmed.ncbi.nlm.nih.gov/12850599>.

26 CFR 54.9815–2713(a)(4), 29 CFR 2590.715–2713(a)(4), and 45 CFR 147.130(a)(4) if there is no clinical basis for limiting the quantity to be dispensed at one time. The Departments seek comment, with respect to all forms of OTC contraceptives, on whether other quantity limits (such as a 6-month limit on OTC oral contraception or a 3-unit limit on OTC emergency contraception per instance of dispensing) should be considered reasonable or unreasonable, and what additional facts and circumstances should be considered when determining the reasonableness of a particular quantity limit with respect to OTC contraception, such as initial success with a shorter supply of OTC contraception. The Departments also request comment on the circumstances under which participants, beneficiaries, and enrollees who receive an initial extended quantity of OTC contraception could access a different form of contraception without incurring cost sharing before finishing the initial extended quantity (for example, before a 6-month supply is exhausted).

Some commenters to the OTC Preventive Products RFI suggested individuals should be required to submit evidence to a plan or issuer that a particular form of prescription birth control is inappropriate before receiving coverage for an OTC contraceptive service. The Departments previously issued guidance that it is not a reasonable medical management technique to require individuals to fail first using numerous other services or FDA-approved, -cleared, or -granted contraceptive products before the plan or issuer will approve coverage for the service or FDA-approved, -cleared, or -granted contraceptive product that is medically necessary for the individual, as determined by the individual's attending provider.¹²⁰ Within the context of medical management of OTC contraceptive items, the Departments would not consider it reasonable either to impose a prescription requirement for OTC contraception as a form of medical management, including requiring an individual to fail first using a prescription-only contraceptive item before providing coverage of an OTC contraceptive item without cost sharing, or to require an individual to fail first with numerous prescription or OTC contraceptive items before the plan or issuer will approve coverage for a

¹²⁰ See FAQs Part 54, Q8 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

medically necessary OTC contraceptive item.

Other commenters suggested that a plan or issuer could consider implementing age-based limitations or gender-based requirements instead of offering benefits to all individuals with reproductive capacity. The Departments would not consider age- and gender-based medical management with respect to OTC contraceptive services to be reasonable unless the medical management technique relies on a clinical rationale for limiting access to individuals of a certain age or gender and is consistent with FDA approvals of any particular OTC contraceptive product. The Departments have stated in previous guidance that imposing an age limit on contraceptive coverage instead of providing these benefits to all women would not be considered a reasonable medical management technique.¹²¹

A commenter suggested that implementing prior authorization requirements with respect to certain OTC items would not be an unreasonable medical management technique. However, such medical management techniques create barriers for consumers accessing contraceptive services with a prescription¹²² and would create similar barriers for consumers accessing contraceptives services without a prescription, with the added challenge that consumers seeking to obtain OTC contraceptive items are likely navigating such requirements without the assistance of a provider. Such requirements could be used as a means of circumventing the requirement to provide coverage of contraception without cost sharing and without a prescription. Therefore, under these proposed rules, coverage requirements that, in practice, operate as substitutes for a prescription coverage requirement by requiring the involvement of a provider (such as prior authorization processes that require provider involvement or other clinical expertise or a requirement that individuals receive counseling from a pharmacist prior to accessing an OTC contraceptive item) would not be considered reasonable medical management techniques with respect to OTC contraceptive items.

¹²¹ *Id.*

¹²² See U.S. House of Representatives Committee on Oversight and Reform (Oct. 25, 2022). "Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance," available at <https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf>.

Under these proposed rules, plans and issuers generally could adopt medical management techniques with respect to OTC contraceptive items that are not described as unreasonable in this preamble as long as they are otherwise consistent with proposed 26 CFR 54.9815–2713(a)(4), 29 CFR 2590.715–2713(a)(4), and 45 CFR 147.130(a)(4) and existing guidance and the plan or issuer makes available an exceptions process as described in these proposed rules. The Departments request comment on what other medical management techniques plans and issuers would consider applying to OTC contraceptive items, including whether such techniques should be considered reasonable or unreasonable. The Departments request comment on the proposed interpretation of reasonable medical management requirements with respect to OTC contraceptive items, including whether any final regulations should specify or use examples to illustrate in the regulatory text the Departments' interpretation of reasonable medical management for OTC contraceptive items.

(3) Other Considerations

The Departments acknowledge the concerns raised by commenters to the OTC Preventive Products RFI, such as risks to patient privacy, of overconsumption, and of fraud, waste, or abuse, that some commenters believe could be exacerbated with increased coverage with no cost sharing of OTC contraceptive items. These concerns could be heightened with respect to OTC items and services that do not require the input of a provider in the form of a prescription and may be further increased within the context of out-of-network providers with whom plans and issuers do not have contractual relationships. For example, plans and issuers may wish to ensure that individuals are obtaining OTC contraceptive items to prevent pregnancy rather than solely to address another underlying condition (such as to treat anemia or manage premenstrual symptoms) or to ensure that an individual is obtaining condoms for the use of a woman covered under the plan, rather than for use by another individual. Several commenters to the OTC Preventive Products RFI highlighted concerns that coverage of OTC preventive products without cost sharing could incentivize overconsumption or waste of such products. Additionally, OTC contraceptive items may present particular challenges with respect to patient privacy, given the deeply personal nature of reproductive health

care and the dynamic nature of State laws governing access to reproductive health care.

The Departments anticipate that plans and issuers with a network of providers would mitigate these risks by using existing claims processing systems with respect to in-network coverage, but acknowledge that coverage through pathways other than an in-network pharmacy may present privacy challenges (for example, because non-provider retailers are not required to implement the same privacy and security safeguards as they are with respect to back-pharmacy transactions). The Departments request comment on how best to encourage plans and issuers to develop mechanisms that promote access to OTC contraceptive items in accordance with these proposed regulations, if finalized, while protecting patient privacy and allowing plans and issuers to identify and address risks including waste, fraud, and abuse.

The Departments further request comment on how the proposed exceptions process requirement should apply with respect to OTC contraceptive items, for which no provider involvement is generally required. The proposed exceptions process requirement described in section II.A.1 of this preamble refers to the determination of an individual's attending provider. Thus, the Departments request comment on what information individuals should be required to provide to seek an exception to access coverage for an OTC contraceptive item that is not typically covered, including how plans and issuers could determine whether an OTC contraceptive item is medically necessary, and whether any additional changes are necessary for an exceptions process when used to seek coverage, without cost sharing, for an OTC contraceptive item.

The Departments also request comment on whether it would be beneficial to define a new term to refer to contraception that would be subject to the proposed amendments to 26 CFR 54.9815–2713(a)(6), 29 CFR 2590.715–2713(a)(6), and 45 CFR 147.130(a)(6); and if so, request feedback on the appropriate term and scope of the definition. For example, the Departments request comment on whether to define “contraceptive item,” “contraceptive product,” or “contraceptive items and services” within the context of these proposed rules; and whether the term would refer to all contraceptive items and services recommended under the HRSA-supported Guidelines, all contraceptive

items and services recommended under 26 CFR 54.9815–2713(a)(1), 29 CFR 2590.715–2713(a)(1), and 45 CFR 147.130(a)(1); or another subset of recommended preventive services.

b. Therapeutic Equivalence Approach to Reasonable Medical Management for Contraceptive Drugs and Drug-Led Combination Products

As discussed in section II.A.2 of this preamble, despite repeated clarification in guidance, the Departments have continued to receive complaints and reports that participants, beneficiaries, and enrollees are being denied coverage for contraceptives that their attending providers have prescribed, in some cases due to the application of medical management techniques that are not reasonable based on all the relevant facts and circumstances.¹²³ The Departments are also aware of investigations and other credible reports that have documented plans and issuers using potentially unreasonable medical management techniques.¹²⁴ In response to these reports, the Departments issued FAQs Part 64 on January 22, 2024, which set forth a therapeutic equivalence approach that plans and issuers can, but are not required to, use (in combination with an easily accessible, transparent, and sufficiently expedient exceptions process) to comply with PHS Act section 2713 and its implementing regulations with respect to FDA-approved contraceptive drugs and drug-led devices, as an alternative to standards that had been set forth in previous guidance and described in section II.A.1 of this preamble.¹²⁵ The Departments have determined that it is necessary to require the therapeutic equivalence approach to ensure coverage of the full range of FDA-approved contraceptive items that are drugs and drug-led combination products. The proposed therapeutic equivalence approach would serve as a guardrail against the widespread use of narrow drug formularies, which the Departments

¹²³ See also FAQs Part 54, Q8 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

¹²⁴ See U.S. House of Representatives Committee on Oversight and Reform (Oct. 25, 2022), “Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance,” available at <https://oversightdemocrats.house.gov/sites/evo-sites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf>.

¹²⁵ FAQs Part 64 (Jan. 22, 2024), available at <https://www.dol.gov/agencies/ebsa/about-ebbsa/our-activities/resource-center/faqs/aca-part-64> and <https://www.cms.gov/files/document/faqs-part-64.pdf>.

understand plans and issuers use to limit costs, but can have the effect of limiting access to medically appropriate contraceptive drugs and drug-led combination products.¹²⁶ This proposed regulation would limit the use of such techniques with respect to recommended contraceptive drugs and drug-led combination products.

Therefore, the Departments propose to amend 26 CFR 54.9815–2713, 29 CFR 2590.715–2713, and 45 CFR 147.130 to add a new paragraph (a)(6)(iii) that would specify that a plan's or issuer's medical management techniques are not considered to be reasonable unless the plan or issuer provides coverage for recommended preventive services that are contraceptive drugs and drug-led combination products, other than those items for which there is at least one therapeutic equivalent drug or drug-led combination product, as applicable, for which the plan or issuer provides coverage without imposing any cost-sharing requirements, consistent with the therapeutic equivalence approach described in FAQs Part 64. The Departments also propose to define "therapeutic equivalent" for purposes of this proposed provision as having the meaning given the term "therapeutic equivalents" in 21 CFR 314.3(b), which defines "therapeutic equivalents" as "approved drug products that are pharmaceutical equivalents for which bioequivalence has been demonstrated, and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling."

Under this proposal, consistent with FAQs Part 64, a therapeutic equivalent drug or drug-led combination product would be one that is designated with a code with the first letter "A" in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).¹²⁷ If the Orange Book does not identify a therapeutic equivalent for a given drug or drug-led combination product, that drug or drug-led combination product would have no

therapeutic equivalent for purposes of these proposed rules, and a plan or issuer would not be permitted to use medical management techniques to deny coverage of (or impose cost sharing on) that drug or drug-led combination product. For example, assume that there are six oral contraceptives (Pill A, Pill B, Pill W, Pill X, Pill Y, and Pill Z) listed in the Orange Book that are within the HRSA-supported Guidelines category of contraceptives known as "oral contraceptives (combined pill)." If the Orange Book does not identify a therapeutic equivalent for either Pill A or Pill B, but identifies the latter four (Pill W, Pill X, Pill Y, and Pill Z) as therapeutic equivalents of each other, then under these proposed rules, the plan would be required to cover without cost sharing Pill A and Pill B, for which there are no therapeutic equivalents. The plan could utilize reasonable medical management techniques that result in it covering only one of Pill W, Pill X, Pill Y, or Pill Z without cost sharing because all four are therapeutically equivalent to each other (provided the plan has an exceptions process that ensures an individual can receive coverage, without cost sharing, for any of Pill W, Pill X, Pill Y, or Pill Z, in the circumstances discussed in more detail in section II.A.1 of this preamble).

In the Orange Book, the FDA evaluates only multisource prescription drug products for therapeutic equivalence.¹²⁸ Therefore, the FDA does not evaluate therapeutic equivalence for OTC drugs or OTC drug-led combination products and the Orange Book does not categorize such products as a "therapeutic equivalent" of any other drug or drug-led combination product. As described in section II.A.2, the Departments are proposing to require plans and issuers to provide coverage of OTC contraceptives without cost sharing and without requiring a prescription. If both the therapeutic equivalence proposal described in this preamble section and the OTC contraceptive coverage proposal are finalized, plans and issuers would be required to cover all OTC contraceptive items that are drugs and drug-led combination products without cost sharing. The Departments request comment on the potential impacts to interested parties, including participants, beneficiaries, and enrollees and plans and issuers, if both proposals are finalized. The Departments further request comment on whether an

alternative approach to therapeutic equivalence would be appropriate for OTC contraceptive drugs and drug-led combination products. If so, the Departments request comment on what medical management techniques would be appropriate and reasonable while balancing the goals of increasing consumer access to OTC contraceptive drugs and drug-led combination products and containing costs. For example, the Departments seek comment on whether plans and issuers should be permitted to provide coverage without cost-sharing or prescription requirements of a preferred generic version of an OTC contraceptive, while only covering the brand version without cost-sharing or prescription requirements subject to an exceptions process.

In addition to satisfying the therapeutic equivalence approach, the Departments would not consider a plan's or issuer's medical management techniques with respect to recommended contraceptive services to be reasonable unless the plan or issuer meets existing standards under applicable regulations and guidance, to the extent not superseded by the other proposals in these proposed rules. For example, as described in FAQs Part 54, Q8, a plan's or issuer's medical management techniques would generally be considered reasonable only if the plan or issuer utilizes reasonable medical management techniques *within* a specified category described in the HRSA-supported Guidelines (or group of substantially similar products that are not included in a specified category).¹²⁹ ¹³⁰ Therefore, if a plan or

¹²⁹ FAQs Part 54, Q8 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

¹³⁰ The Departments acknowledge that the proposed therapeutic equivalence standard would require plans and issuers to cover more contraceptive drugs and drug-led combination products than under FAQs Part XXVI, Q2, which specified that a plan or issuer must cover at least one form of contraception in each method that is identified by the FDA. The Departments have determined that this approach is necessary to ensure coverage of the full range FDA-approved contraceptive drugs and drug-led combination products, as required under section 2713 of the PHS Act, while still permitting plans and issuers to contain costs by not requiring plans and issuers to cover items for which there is at least one therapeutic equivalent drug or drug-led combination product, as applicable, for which the plan or issuer provides coverage without imposing any cost-sharing requirements. The FDA defines "therapeutic equivalents" at 21 CFR 314.3(b) as approved drug products that are pharmaceutical equivalents (meaning, in general, that they contain identical amounts of the identical active drug ingredient in the identical dosage form and route of administration) and bioequivalents (meaning, in

¹²⁶ See Dieguez, G., Sawhney, T., and Mirchandani, H., Milliman (2016). "Evolution of the Use of Restrictions in Commercial Formularies," available at <https://www.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/2016/evolution-restrictions-commercial-formularies.ashx>; Rucker, J., Benfield, M., Jenkins, N., Enright, D., Henderson, R., Chambers, J. (2023). "Commercial Coverage of Specialty Drugs, 2017–2021" Health Affairs Scholar, available at <https://academic.oup.com/healthaffairsscholar/article/1/2/qxad030/7236995>.

¹²⁷ FAQs Part 64, Q2 (Jan. 22, 2024), available at <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-64> and <https://www.cms.gov/files/document/faqs-part-64.pdf>.

¹²⁸ FDA, "Orange Book Preface," available at <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface>.

issuer provided coverage consistent with the proposed therapeutic equivalence approach, but used medical management techniques to deny coverage or impose cost sharing for all contraceptives in another category (or other groups of substantially similar products), such as the category for sterilization surgery for women, the plan's or issuer's medical management techniques would not be considered to be reasonable. Similarly, consistent with FAQs Part 54, Q8, the Departments would not consider a plan's or issuer's medical management techniques to be reasonable if the plan or issuer requires an individual to fail first using numerous contraceptives within a category prior to providing coverage consistent with the proposed therapeutic equivalence approach.

In addition, consistent with FAQs Part 64, the Departments would not consider the use of medical management techniques to be reasonable where a plan or issuer provides coverage consistent with the proposed therapeutic equivalence approach but fails to provide an exceptions process that meets the standards proposed in these rules. Requiring plans and issuers that utilize reasonable medical management to both apply the therapeutic equivalence approach and provide an exceptions process would be particularly important in instances where the plan's or issuer's preferred method is not medically appropriate for an individual. Consider an example in which there are three products within the HRSA-supported Guidelines category of "the contraceptive patch" (Patch A, Patch B, and Patch C) and the Orange Book identifies all three products as therapeutic equivalents to each other. Under the proposed therapeutic equivalence approach, a plan or issuer would be permitted to utilize reasonable

general, that the rate and extent of the active ingredient at the site of action are the same), and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling. The contraceptives described in the HRSA-supported Guidelines do not refer to therapeutic equivalence, and as a result, there may be multiple drugs or drug-led combination products within a category that are not therapeutically equivalent to each other. For example, within the "oral contraceptives (combined pill)" category identified in the HRSA-supported Guidelines, there could exist multiple products that are oral contraceptive combined pills but are not therapeutically equivalent because, for example, they contain different amounts of the same active ingredients. Under this proposal, a plan or issuer would be required to cover, without cost sharing, at least one oral contraceptive combined pill that has a therapeutic equivalent, as well as each non-therapeutic equivalent oral contraceptive combined pill, rather than at least one form of an oral contraceptive combined pill in the category.

medical management techniques that result in it generally covering only one of Patch A, Patch B, or Patch C without cost sharing because all are therapeutically equivalent to each other. However, without an exceptions process, a person who, for example, has an allergy to a non-therapeutic ingredient in Patch A such as a dye or an adhesive could not access an alternative such as Patch B or Patch C that is determined to be medically necessary by the individual's attending provider, and as a result, would be denied the coverage required under PHS Act section 2713.

The Departments propose to define "drug-led combination product" at 26 CFR 54.9815–2713(a)(6)(i)(A), 29 CFR 2590.715–2713(a)(6)(i)(A), and 45 CFR 147.130(a)(6)(i)(A) as "a combination product, as defined under 21 CFR 3.2(e), that comprises a drug and a device, and for which the drug component provides the primary mode of action." The term "combination products" refers to the existing FDA definition of "combination product" at 21 CFR 3.2(e), and would apply only to drug-led combination products within the context of the proposed therapeutic equivalence approach discussed in this section II.A.2.b of this preamble. While this proposal would not prevent plans and issuers from applying a therapeutic equivalence approach to other recommended preventive services, the Departments request comment on whether plans and issuers utilizing reasonable medical management of recommended preventive services other than contraceptive drugs and drug-led combination products should be required to apply the therapeutic equivalence approach as described in these proposed rules.

B. Communicating OTC Contraceptive Coverage Requirements

Because plans and issuers have not traditionally provided coverage for health items that can be purchased directly by a consumer without a prescription, participants, beneficiaries, and enrollees may not be aware that their health plan or coverage would cover OTC contraceptive items without cost sharing and without a prescription if these proposed rules are finalized. The Departments expect that without sufficient communication about this new coverage requirement from plans and issuers, consumers' lack of awareness may lead to minimal use of this benefit. Therefore, these proposed rules propose new requirements under 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211 that would ensure participants,

beneficiaries, and enrollees are informed of this new coverage.

Section 2715A of the PHS Act provides that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must comply with section 1311(e)(3) of the ACA. Through section 1311(e)(3)(C) of the ACA, section 2715A of the PHS Act requires plans and issuers to permit individuals to learn the amount of cost sharing (including deductibles, copayments, and coinsurance) associated with a specific item or service furnished by an in-network provider upon the individual's request.

Under the Departments' rulemaking authority in section 9833 of the Code, section 734 of ERISA, and 2792 of the PHS Act to implement section 2715A of the PHS Act, the Departments propose to require that plans and issuers permit individuals to learn the amount of cost sharing associated with OTC contraceptive items covered by their plan or coverage without a prescription. Specifically, the Departments propose to amend 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211 to add a new paragraph (b)(1)(vi) that would require plans and issuers to provide information to participants, beneficiaries, and enrollees explaining that OTC contraceptive items are covered without cost sharing and without a prescription consistent with these proposed rules when participants, beneficiaries, and enrollees request cost-sharing information for any covered contraceptive item or service. By promoting awareness of coverage of OTC contraceptive items without cost-sharing or prescription requirements, these proposals serve as important companions to proposed 26 CFR 54.9815–2713(a)(6), 29 CFR 2590.715–2713(a)(6), and 45 CFR 147.130(a)(6), described in section II.A.2.a of this preamble.

In accordance with PHS Act section 2715A and ACA section 1311(e)(3)(C), under current 26 CFR 54.9815–2715A2(b), 29 CFR 2590.715–2715A2(b), and 45 CFR 147.211(b), plans and issuers must disclose an estimate of the participant's, beneficiary's, or enrollee's cost-sharing liability for all covered items or services furnished by a provider or providers, through the Transparency in Coverage internet-based self-service tool or, if requested by the individual, paper. Under current rules, if a participant, beneficiary, or enrollee uses the self-service tool to look up contraceptive items or services with respect to an in-network pharmacy (or to look up the

out-of-network cost sharing for these items or services for a plan or issuer that does not have a provider in its network that can provide the preventive item), the self-service tool would display the non-zero dollar cost-sharing liability for the individual that is associated with being billed as non-preventive (if applicable), along with a statement that the contraceptive item or service may not be subject to cost sharing if it is billed as preventive. For contraceptive items that are only covered by the plan or coverage for preventive purposes (including because they are only indicated for preventive purposes), current rules require the self-service tool to reflect a zero-dollar cost-sharing liability. The Departments note also that some contraceptive items may be covered for non-preventive purposes (either with or without a prescription), and in this case the self-service tool would reflect the non-zero dollar cost-sharing liability. The Departments also note that under current rules, plans and issuers are not required to disclose any cost-sharing information through the self-service tool for non-covered items and services, including with respect to contraceptive items and services. Nothing in these proposed rules alters these disclosure requirements.

As discussed in section II.A.2 of this preamble, the Departments are proposing to require plans and issuers to cover OTC contraceptive items without a prescription and without imposing cost-sharing requirements. To ensure individuals are aware that OTC contraceptive items are covered consistent with these proposed rules, plans and issuers would be required to inform individuals of this benefit under the plan or coverage. Participants, beneficiaries, and enrollees should have access to more robust information to ensure they understand their plan's or issuer's policies regarding coverage of OTC contraceptive items without a prescription and without cost sharing, and in the Departments' view, the self-service tool would offer an effective means of communicating such information. Therefore, the Departments propose to require plans and issuers to make an additional cost-sharing information disclosure to participants, beneficiaries, and enrollees in new proposed 26 CFR 54.9815–2715A2(b)(1)(vi), 29 CFR 2590.715–2715A2(b)(1)(vi), and 45 CFR 147.211(b)(1)(vi). Specifically, if a participant, beneficiary, or enrollee requests cost-sharing information for any covered contraceptive item or service through a self-service tool, the proposed rules would require the

response through the self-service tool or, if requested, on paper to include with the information a statement explaining that OTC contraceptive items are covered without cost sharing and without a prescription. This statement would be required to include a phone number and internet link that a participant, beneficiary, or enrollee could use to learn more information about the plan's or policy's contraception coverage. This could be a link to an existing web page and a general customer service line that the plan or issuer already maintains.

The requirement to provide this information would be triggered by a search in the self-service tool for any covered contraceptive items or services, including items or services that are not drugs or drug-led combination products or are not available without a prescription, so that any user seeking options to prevent pregnancy would be made aware that OTC contraceptive items are covered without cost sharing. Under this proposed requirement, the disclosure would be required regardless of whether the user is searching for cost-sharing information for contraceptive items and services from an in-network or out-of-network provider, or if the plan or coverage maintains no network of providers. As such, plans and issuers, including those without a network of providers, would be required to disclose that they will cover OTC contraceptive items without cost sharing or a prescription in accordance with proposed 26 CFR 54.9815–2713(a)(6), 29 CFR 2590.715–2713(a)(6), and 45 CFR 147.130(a)(3)(ii). The Departments note that because the self-service tool requirements apply to covered items and services, the disclosure requirements proposed in this section would not apply to plans and issuers that do not cover contraceptive items or services based on an objection under 45 CFR 147.132 or 147.133.¹³¹ The Departments request comment on whether and how these proposed requirements should apply to entities that have an objection to only some contraceptive items and services.

The Departments also request comment on whether plans and issuers should have the option to include in the statement either a phone number or an internet link—rather than both—to where a participant, beneficiary, or enrollee can learn more about the plan's or policy's contraception coverage. The Departments are interested in better

understanding the benefits and burdens associated with each approach.

The Departments also request comment on whether plans and issuers should be required to include in this statement the general names or types of OTC contraceptive items that are covered without a prescription and without cost sharing (for example, “daily oral contraceptive,” “Plan B (levonorgestrel),” or “condoms”). Under this approach, users would not need to call the provided phone number or navigate to the linked web page and could simply copy and paste the provided product names into the self-service tool's search field to find local pharmacies where they can access the product without a prescription and without cost sharing. In particular, the Departments request comment on the burdens on plans and issuers to provide a list that may need to be updated in the self-service tool's statement as circumstances change (such as if additional OTC contraceptive items come to market or new therapeutic equivalents become available) or that could require multiple alternative disclosures for a plan or issuer that has coverage options across geographic regions based on availability in the specific market. In addition, the Departments request comment on potential benefits to consumers of listing in the tool itself the OTC contraceptive items covered without a prescription and without cost sharing, rather than having to gather this information by clicking an internet link or calling a customer service line.

The Departments also request comment on whether plans and issuers should be required to include in the statement information on coverage of therapeutic equivalents or the exceptions process under these proposed rules and, if so, how disclosures should be presented to ensure the additional information is meaningful and actionable for consumers.¹³² For example, the Departments request comment on whether the statement should indicate that an exceptions process is available so individuals can receive coverage for any recommended preventive service, including an OTC contraceptive item, that is medically necessary for the individual; and, if so, how to present this information in a way that would be meaningful and actionable for consumers. Similarly, the Departments request comment on whether the

¹³¹ The Departments issued proposed rules to rescind the moral exemption to the contraceptive coverage requirement under 45 CFR 147.133. 88 FR 7236 (Feb. 2, 2023).

¹³² See sections II.A.1 and II.A.2.b of the preamble to these proposed rules, respectively, for a discussion of the exceptions process and therapeutic equivalence approach proposals.

statement should disclose that plans and issuers must cover all FDA-approved contraceptive drugs and drug-led combination products without cost sharing, other than those for which there is at least one therapeutic equivalent drug or drug-led combination product that the plan or issuer covers without cost sharing; and, if so, how to present this information in a way that would be meaningful and actionable for consumers.

The Departments also request comment regarding the challenges of implementing and maintaining such statements, information about their potential effectiveness in improving access to OTC contraceptive items, and other information that could help inform potential future disclosures related to other recommended preventive services. The Departments also request comment on whether additional self-service tool requirements need to be specified to ensure plans and issuers fully inform participants, beneficiaries, and enrollees of the availability of covered OTC contraceptive items without cost sharing.

Lastly, the Departments believe that broadly disseminating information on the availability and coverage of OTC contraceptive items without cost sharing to eligible individuals and members of the public would increase access to this benefit, if finalized as proposed, and would allow individuals to select the plan that best meets their needs. Therefore, the Departments request comment on how plans and issuers could efficiently and effectively provide such information to eligible individuals, participants, beneficiaries, enrollees, and members of the public, including the relative benefits and burdens of doing so. For example, the Departments are interested in whether it would be feasible for plans and issuers to provide general coverage and cost-sharing information on a public website. Similarly, the Departments are interested in whether plans and issuers should be required to provide more tailored cost and benefit information to participants, beneficiaries, or enrollees when they provide other relevant plan documents, such as Summaries of Benefits and Coverage (SBCs) or drug formularies. The Departments also request comment on how plans and issuers can make information available to participants, beneficiaries, and enrollees about the specific steps they would need to take to access OTC contraceptive items without cost sharing, particularly when plans and issuers do not have network providers available that can provide access to such

items. Lastly, the Departments request comment on additional ways to communicate this information effectively to individuals in vulnerable and underserved communities.

C. Applicability

The proposed amendments to 26 CFR 54.9815–2713(a)(4), 29 CFR 2590.715–2713(a)(4), and 45 CFR 147.130(a)(4) regarding an exceptions process would apply on the effective date of the final rules. The Departments assume that most plans and issuers generally already have in place an exceptions process for recommended preventive services to align with previously issued guidance, although the Departments acknowledge in section IV.B.2.d of this preamble that some plans and issuers could incur costs to develop or update an exceptions process to comply with these proposed rules, if finalized. While prior guidance has generally focused on the use of an exceptions process in the context of contraceptive coverage and coverage of PrEP to prevent HIV, the Departments expect that plans and issuers could adapt existing exceptions processes to accommodate additional recommended preventive services as necessary to comply with the proposed amendments by the effective date of the final rules.

The Departments propose delayed applicability dates for the proposed amendments to the preventive services regulations that are specific to contraceptive items. Specifically, the Departments propose that the proposed provisions of 26 CFR 54.9815–2713(a)(6), 29 CFR 2590.715–2713(a)(6), and 45 CFR 147.130(a)(6) would apply for plan years (in the individual market, policy years) beginning on or after January 1, 2026. These proposed rules, if finalized, would mandate the use of the currently optional therapeutic equivalence approach described in FAQs Part 64, where applicable, and newly require the coverage of OTC contraceptive items without a prescription. In the Departments' view, the proposed applicability dates appropriately balance the need for improved access to coverage of recommended preventive services with the time necessary for plans and issuers to make the systems and operational changes to implement these proposals.

Until any final rules are issued and applicable, the Departments would continue to consider plans and issuers that provide coverage consistent with the therapeutic equivalence approach and have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome as outlined in FAQs Part 64 to be in compliance with section 2713

of the PHS Act and its implementing regulations with respect to coverage of recommended contraceptives that are drugs and drug-led devices.

To align with applicability dates for the proposed requirements for OTC contraceptive items and therapeutic equivalents, the proposed requirements in 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2 and 45 CFR 147.211 that would direct plans and issuers to disclose information related to contraceptive coverage in the self-service tool would be applicable to plans and issuers for plan years (or in the individual market, policy years) beginning on or after January 1, 2026.

The Departments request comment on the proposed applicability dates. With respect to the proposed delayed applicability dates, the Departments request comment on whether an earlier applicability date (such as the effective date of any final rules) would be feasible.

III. Severability

In the event that any provision of these proposed rules, if finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, the Departments intend that these rules shall be construed so as to continue to give maximum effect to these rules as permitted by law, unless the holding shall be one of utter invalidity or unenforceability. In the event a provision is found to be utterly invalid or unenforceable, the provision shall be severable from these proposed rules as finalized, as well as the final rules they amend and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

In these rules, the Departments are proposing several amendments to reduce barriers to coverage and promote access to recommended preventive services, including OTC contraceptive items. The Departments' authority under section 9833 of the Code, section 734 of ERISA, sections 2713, 2715A, and 2792 of the PHS Act, and sections 1311(e)(3)(C) and 1321 of the ACA to propose these amendments is well-established in law and long-standing practice and should be upheld in any legal challenge. However, in the event that any portion of the final rules related to any of the proposals in these rules, if finalized, is declared invalid, the Departments intend that the other provisions would be severable, except as described in this section of the preamble. For example, if a court were to find unlawful (1) the requirement that plans and issuers utilizing medical management techniques provide an

exceptions process in order for such techniques to be considered reasonable; (2) the requirement to provide coverage for OTC contraceptive items without requiring a prescription or imposing cost sharing; or (3) the therapeutic equivalence approach to reasonable medical management for contraceptive items that are drugs and drug-led combination products, the Departments intend the remaining provisions of the rules to stand. Additionally, the Departments intend for the proposed amendments to the preventive services regulations to remain in place in the event that a court were to find unlawful any portion of the rules, if finalized, with respect to the proposals related to disclosing information related to contraceptive coverage through the self-service tool. However, the Departments do not intend for the disclosure through the self-service tool to remain in place in the event that a court were to find unlawful the requirement to provide coverage for OTC contraceptive items without requiring a prescription or imposing cost sharing, as the disclosure requirements would not provide meaningful information to consumers in the absence of these underlying coverage requirements.

IV. Regulatory Impact Analysis

A. Summary—Departments of Health and Human Services and Labor¹³³

These proposed rules would make several changes to the requirements for non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to provide coverage of certain recommended preventive services without cost sharing under section 2713 of the PHS Act and its implementing regulations. First, these proposed rules would provide that medical management techniques used by plans and issuers with respect to recommended preventive services, including contraceptive items, would not be considered reasonable unless the plan or issuer provides an easily accessible, transparent, and sufficiently expedient exceptions process that allows an individual to receive coverage without cost-sharing requirements for a recommended preventive service according to the frequency, method, treatment, or setting that is medically necessary with respect to the individual, as determined by the individual's attending provider. These proposed rules also would require plans and issuers to cover recommended OTC

contraceptive items without a prescription and without imposing cost-sharing requirements. These proposed rules would further require plans and issuers to cover all recommended contraceptive items that are drugs and drug-led combination products without imposing cost-sharing requirements, unless a therapeutic equivalent of the drug or drug-led combination product is covered without cost sharing. Lastly, these proposed rules would amend the Transparency in Coverage final rules implementing section 2715A of the PHS Act and section 1311(e)(3) of the ACA by requiring plans and issuers to provide information related to contraceptive coverage and cost-sharing requirements, including a statement explaining the coverage of OTC contraceptive items without cost sharing, in their Transparency in Coverage internet-based self-service tool or, if requested by the individual, on paper.

The Departments have examined the impacts of these proposed rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993),¹³⁴ Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011),¹³⁵ Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023),¹³⁶ the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).¹³⁷

B. Executive Orders 12866, 13563, and 14094—Departments of Health and Human Services and Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 (Modernizing Regulatory Review) amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a

“significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$200 million or more in any 1 year (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) for changes in gross domestic product), or adversely affecting in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, Territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in Executive Order 12866, as specifically authorized in a timely manner by the Administrator of OIRA in each case.¹³⁸

A regulatory impact analysis (RIA) must be prepared for rules deemed significant under section 3(f). Based on the Departments' estimates, OMB's OIRA has determined this rulemaking is significant under section 3(f)(1) as measured by the \$200 million or more in any 1 year threshold. Therefore, OMB has reviewed these proposed rules, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

As discussed in section II of this preamble, ongoing complaints and reports of noncompliance with section 2713 of the PHS Act and its implementing regulations indicate that participants, beneficiaries, and enrollees face barriers when attempting to use their coverage to access recommended preventive services without cost sharing. As a result of these concerns and other significant activity related to preventive services, the Departments are proposing to amend the regulations governing coverage of recommended preventive services in order to ensure that participants, beneficiaries, and enrollees would be able to access the full range of recommended preventive services to which they are entitled, with particular focus on strengthening coverage requirements with respect to recommended contraceptive items for women, as summarized in section IV.A

¹³³ In sections IV.A, IV.B, and IV.C of this preamble, “the Departments” refers to the Departments of HHS and Labor.

¹³⁴ Executive Order 12866 of September 30, 1993, 58 FR 51735 (October 4, 1993).

¹³⁵ Executive Order 13563 of January 18, 2011, 76 FR 3821 (January 21, 2011).

¹³⁶ Executive Order 14094 of April 6, 2023, 88 FR 21879 (April 11, 2023).

¹³⁷ Executive Order 13132 of August 4, 1999, 64 FR 43255 (August 10, 1999).

¹³⁸ Executive Order 14094 of April 6, 2023, 88 FR 21879 at 21879 (April 11, 2023).

of this preamble. The Departments consider these provisions to be timely and necessary given the ongoing documented challenges faced by consumers in accessing recommended preventive services, as discussed further in section IV.B.2.a of this preamble.

2. Summary of Impacts

In accordance with Executive Order 12866 and OMB Circular A–4, table 1 depicts an accounting statement summarizing the Departments’ assessment of the benefits, costs, and

transfers associated with these regulatory actions. The Departments are unable to quantify all benefits, costs, and transfers associated with these proposed rules, but have sought, where possible, to describe these non-quantified impacts.

TABLE 1—ACCOUNTING TABLE

Benefits				
Non-Quantified:				
<ul style="list-style-type: none"> • Potential reduction in unintended pregnancies and improved health outcomes for covered individuals. • Increased convenience and decreased costs for covered individuals who no longer need to obtain a prescription to obtain recommended OTC contraceptive items without cost sharing. • Decreased costs to plans and issuers due to improved health outcomes associated with increased coverage of recommended preventive services without cost sharing and avoided unintended pregnancies. • Potential benefits associated with increased awareness of coverage of OTC contraceptive items without a prescription and without cost sharing. 				
Costs	Estimate	Year dollar	Discount rate	Period covered
Annualized Monetized (\$/year)	\$9.9 million	2024	2 percent	2026–2035
Quantified:				
<ul style="list-style-type: none"> • Costs to issuers and TPAs, on behalf of self-insured group health plans, associated with the disclosure of coverage and cost-sharing requirements for OTC contraceptive items, including one-time costs of approximately \$35.1 million for integrating the contraception statement language into the existing Transparency in Coverage internet-based self-service tool and creating or updating a webpage to provide information about coverage benefits, and annual costs of approximately \$6.1 million for programming updates, webpage maintenance, training customer service representatives, and responding to calls to provide assistance; these costs would ultimately be incurred by plans and issuers.¹³⁹ 				
Non-Quantified:				
<ul style="list-style-type: none"> • Increased costs to plans and issuers due to changes in utilization of recommended preventive services. • Potential administrative costs to plans and issuers associated with the establishment of or use of an existing exceptions process that allows an individual to receive coverage without cost-sharing requirements for a medically necessary recommended preventive service. • Cost to pharmacies, plans, and issuers to update billing processes and systems for covered OTC products. 				
Transfers	Estimate	Year dollar	Discount rate	Period covered
Annualized Monetized (Excluding Federal Budgetary) (\$/year)	\$468.6 million	2024	2 percent	2026–2035
Annualized Monetized Federal Budgetary (\$/year)	\$300.1 million	2024	2 percent	2026–2035
Quantified:				
<ul style="list-style-type: none"> • Transfers totaling approximately \$768.7 million per year from plans and issuers to covered individuals caused by reduced out-of-pocket costs for contraceptive items, which plans and issuers would recoup in the form of higher premiums. <ul style="list-style-type: none"> ○ The increase in premiums could increase the cost of employer-sponsored insurance and reduce the share of total employee compensation subject to taxation, reducing Federal tax revenue by approximately \$217 million per year. ○ Net Federal spending on premium tax credits for Exchange plans could increase by approximately \$83.1 million per year. ○ Premiums paid (directly or indirectly, through declines in after-tax wages) by covered individuals could increase by approximately \$468.6 million per year. 				
Non-Quantified:				
<ul style="list-style-type: none"> • Transfers from plans and issuers to covered individuals caused by reduced out-of-pocket costs for other recommended preventive services for which coverage without cost sharing would be accessible through an exceptions process, which plans and issuers would recoup in the form of higher premiums. This could result in an increase in premiums paid by covered individuals and an increase in net Federal spending on premium tax credits for Exchange plans. • Potential transfers from plans and issuers to firms in the medicine and medical device supply chain due to decreased bargaining leverage on prices for contraceptive items. 				

a. Background

Nine in ten women report using contraception at some point in their lifetime.¹⁴⁰ Estimates from the CDC indicate that 65.3 percent of women ages 15–49 used some form of contraception between 2017 and 2019, including permanent or one or more forms of reversible contraception listed in the FDA’s Birth Control Guide.¹⁴¹ The majority of women used reversible

contraception such as oral contraceptive pills (14 percent), long-acting reversible contraceptives (LARCs) such as intrauterine device (IUDs) (10.4 percent), or the male condom (8.4 percent). The most common form of contraception is female sterilization (18.1 percent), a nonreversible method.¹⁴²

The 2022 KFF Women’s Health Survey (of U.S. women ages 18–49)

found that nearly two-thirds of survey respondents who were not currently trying to get pregnant reported avoiding a pregnancy in the next month as being “very important.”¹⁴³ The same survey found that among women who use contraception, 61 percent use it only to prevent pregnancy, 24 percent use it both to prevent pregnancy and for some other reason, and 15 percent use it solely for a reason not related to

¹³⁹ The Departments expect self-insured group health plans to rely on TPAs to implement the proposed requirements and compensate them accordingly and thereby bear any implementation costs.

¹⁴⁰ Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). “Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage,” available at <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/>.

www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/.

¹⁴¹ Daniels, K. and Abma, J.C., CDC (2020). “Current Contraceptive Status Among Women Aged 15–49: United States, 2017–2019,” NCHS Data Brief No. 388, available at <https://www.cdc.gov/nchs/products/databriefs/db388.htm>.

¹⁴² *Id.*

¹⁴³ Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). “Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage,” available at <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/>.

preventing pregnancy (for example, managing a medical condition or preventing a sexually transmitted infection).¹⁴⁴ Individuals' contraceptive needs, including because of side effects, can vary depending on their health history, medical needs, allergies, and other factors. A recent study that reviewed two decades of literature on contraception found that hormonal contraceptives can impact medical conditions associated with hormonal fluctuations, including acne, endometriosis, and premenstrual dysphoric disorder.¹⁴⁵ This and other studies detail that combined hormonal contraceptives and progestin-only pills often have different side effects for women with varying backgrounds or medical conditions.¹⁴⁶ Studies emphasize that it is difficult to predict how individuals will react to oral contraceptives, with one noting that "certain side effects . . . may be considered beneficial by some people but unacceptable by others," and that "different formulations have different side effect profiles, so patients may need to try another formulation if an undesirable side effect occurs."¹⁴⁷ Studies point to the fact that optimal contraception selection depends on a person's health needs and personal factors and preferences.¹⁴⁸

A growing body of research finds there is a mismatch between preferred and commonly used contraception methods.¹⁴⁹ These studies find that LARCs and hormonal methods generally have higher rates of satisfaction than condoms, withdrawal, and no method of contraception. Nearly 25 percent of all people, and nearly 30 percent of people earning under 200 percent of the Federal Poverty Line, are not using their preferred method. People report using less preferred methods due to issues with side effects, cost and affordability, inadequate counseling, and other access barriers such as facilities not offering the preferred method.¹⁵⁰ The mismatch

between preferred and used method was found to be less common among those with higher incomes, those with insurance coverage, and those that have a usual source of care.¹⁵¹ The literature also finds that unsatisfied preferences were associated with discontinuation of contraception method and subsequently higher rates of pregnancy, indicating that reducing barriers that contribute to this satisfaction mismatch has the potential to reduce unwanted pregnancies, especially among underserved communities such as women of color and low-income communities.¹⁵²

The 2022 KFF Women's Health Survey found that 77 percent of respondents (and 79 percent of respondents with private health insurance coverage) favored making oral contraceptive pills available OTC without a prescription if research showed they are safe and effective, and 39 percent of respondents indicated they would be likely to use oral contraceptive pills available OTC without a prescription.¹⁵³ The survey further found that 29 percent of respondents currently using oral contraceptive pills would be "very likely" to use OTC oral contraceptive pills that do not require a prescription, as would 19 percent of respondents currently using other contraceptive methods and 15 percent of respondents currently not using any contraceptive method.¹⁵⁴ These figures indicate that take-up of OTC contraceptive items available without a prescription and without cost sharing might be fairly high. When asked why they would be likely to use OTC oral contraceptive pills, most respondents reported that it is because they are more convenient (59 percent) or faster (15 percent), while 8

Preferences, and Coverage," available at <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings> and Burke, K. and Potter, J. (2023). "Meeting Preferences for Specific Contraceptive Methods: An Overdue Indicator," *Studies in Family Planning*, available at <https://onlinelibrary.wiley.com/doi/full/10.1111/sifp.12218>.

¹⁵¹ Burke, K. and Potter, J. (2023). "Meeting Preferences for Specific Contraceptive Methods: An Overdue Indicator," *Studies in Family Planning*, available at <https://onlinelibrary.wiley.com/doi/full/10.1111/sifp.12218>.

¹⁵² *Id.*

¹⁵³ This figure was the same (39 percent) among the subset of respondents with private health insurance coverage. See Long, M., Frederiksen, B., Ranji, U., Diep, K., and Salganicoff, A., KFF (2022). "Interest in Using Over-the-Counter Oral Contraceptive Pills: Findings from the 2022 KFF Women's Health Survey," available at <https://www.kff.org/womens-health-policy/issue-brief/interest-using-over-the-counter-oral-contraceptive-pills-findings-2022-kff-womens-health-survey>.

¹⁵⁴ *Id.*

percent reported that they do not want a physical or pelvic exam, 7 percent reported that OTC oral contraceptive pills are more confidential, 6 percent reported that they think it would save money, and 3 percent reported that they do not want to have to use health insurance.¹⁵⁵ Coverage of OTC contraceptive items without cost sharing or a prescription requirement would be particularly beneficial for certain contraceptive users considering that 33 percent of hormonal contraceptive users indicated that they missed taking their birth control on time because they were not able to get their next supply on time¹⁵⁶ and 36 percent of oral contraceptive users have missed taking it on time for the same reason.¹⁵⁷

More generally, as discussed in section II of this preamble, cost sharing reduces the use of preventive care, and some individuals may forego a preventive service entirely rather than being forced to choose between a form of care that their provider has determined would not be medically appropriate for them or to pay out-of-pocket for the care they need.

b. Number of Affected Entities

This section addresses entities that would be directly affected by these proposed rules. These proposed rules would apply to non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage.¹⁵⁸ For the purposes of this RIA, the term *covered plans* refers to these plan and coverage types. *Health insurance company* refers to a single entity that offers health insurance coverage in one or multiple States, which might own or be affiliated with one or multiple entities that are separately required to be licensed to engage in the business of insurance in each such State. *Health insurance issuer* or *issuer* means an insurance company, insurance service, or insurance organization (including a health maintenance organization (HMO)) that is required to be licensed to engage in

¹⁵⁵ *Id.*

¹⁵⁶ Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," available at <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings>.

¹⁵⁷ Long, M., Diep, K., Sobel, L. and Salganicoff, A., KFF (2023). "Over-the-Counter Oral Contraceptive Pills," available at <https://www.kff.org/womens-health-policy/issue-brief/over-the-counter-oral-contraceptive-pills>.

¹⁵⁸ As noted in section I.A, these proposed rules would not modify Federal conscience protections related to contraceptive coverage for employers, plans and issuers. See fn. 24.

¹⁴⁴ *Id.*

¹⁴⁵ Teal, S. and Edelman, A. (2021). "Contraception Selection, Effectiveness, and Adverse Effects: A Review," *JAMA*, available at <https://pubmed.ncbi.nlm.nih.gov/34962522>.

¹⁴⁶ Britton, L.E., Alspaugh, A., Greene, M.Z., and McLemore, M.R. (2020). "An Evidence-Based Update on Contraception," *American Journal of Nursing*, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7533104>.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ Burke, K. and Potter, J. (2023). "Meeting Preferences for Specific Contraceptive Methods: An Overdue Indicator," *Studies in Family Planning*, available at <https://onlinelibrary.wiley.com/doi/full/10.1111/sifp.12218>.

¹⁵⁰ Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences,

the business of insurance in a State and that is subject to State law that regulates insurance.

The Departments estimate that there are 499,299 ERISA-covered self-insured, non-grandfathered group health plans¹⁵⁹ and 1,844,520 ERISA-covered fully-insured, non-grandfathered group health plans.¹⁶⁰ The Departments further estimate that there are 76,345 non-grandfathered non-Federal governmental plans sponsored by State and local governmental entities.¹⁶¹

Issuers and third-party administrators (TPAs) provide key support for plan compliance with laws and regulations. Plans often have TPAs provide expertise in plan design, establish networks, and administer claims. For medications, issuers and TPAs often provide these services via contracted or affiliated PBMs.

The Departments assume that issuers and TPAs would be the organizations performing the work of redesigning

¹⁵⁹ The Departments estimate that there are 594,404 ERISA-covered self-insured group health plans based on data from the 2022 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2020 County Business Patterns from the Census Bureau. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan (see KFF, 2020 Kaiser Employer Health Benefits Survey, available at <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>). Thus, the Departments have calculated the number of self-insured, non-grandfathered plans in the following manner: 594,404 ERISA-covered self-insured group health plans \times (100 percent minus 16 percent) = 499,299.

¹⁶⁰ The Departments estimate that there are 2,195,857 ERISA-covered fully-insured group health plans based on data from the 2022 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2020 County Business Patterns from the Census Bureau. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan (see KFF, 2020 Kaiser Employer Health Benefits Survey, available at <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>). Thus, the Departments have calculated the number of fully-insured, non-grandfathered plans in the following manner: 2,195,857 ERISA-covered fully-insured group health plans \times (100 percent minus 16 percent) = 1,844,520.

¹⁶¹ According to data from the 2022 Census of Governments, there are 90,887 State and local governmental entities (see U.S. Census Bureau, 2022 Census of Governments, available at <https://www.census.gov/data/tables/2022/econ/gus/2022-governments.html>). The Departments assume that each State and local governmental entity sponsors one health plan on average. Therefore, the Departments estimate that there are 90,887 non-Federal governmental health plans. The 2020 KFF Employer Health Benefits Survey reported that 16 percent of employers offer at least one grandfathered plan (see KFF, 2020 Kaiser Employer Health Benefits Survey, available at <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>). The Departments therefore estimate there are approximately 76,345 non-grandfathered non-Federal governmental plans.

prescription drug formularies, negotiating new or amended network arrangements with pharmacies, and developing any necessary amendments and changes to billing systems and procedures.

The Departments estimate that these proposed rules would affect 479 health insurance companies nationwide that provide coverage in the group and individual health insurance markets, with 1,467 issuers (health insurance company/State combinations).¹⁶²

These proposed rules would also affect pharmacies, given the coverage requirements for OTC contraceptives proposed in these proposed rules. According to the Census Bureau's Statistics of U.S. Businesses, there are 19,234 firms in the pharmacies and drug stores sector in the U.S. as of 2017.¹⁶³

Because these proposed rules have the potential to impact the gross premiums of covered plans—either directly as paid by plan participants and enrollees and/or indirectly by their employers in lieu of salary or other benefits—all participants, beneficiaries, and enrollees in affected plans may potentially be affected by these proposed rules, regardless of their use of contraceptive items. For purposes of this RIA, *covered individuals* refers to participants, beneficiaries, and enrollees in covered plans that are subject to the proposed rules.

There are an estimated 181.4 million individuals in plans that would be affected by these proposed rules.¹⁶⁴

¹⁶² The Departments' estimate of the number of health insurance companies and the number of issuers (issuer/State combinations) is based on medical loss ratio reports submitted by issuers for the 2022 reporting year (see Centers for Medicare & Medicaid Services, "Medical Loss Ratio Data and System Resources (2022)," available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>).

¹⁶³ U.S. Census Bureau (2017). 2017 SUSB Annual Data Tables by Establishment Industry (Data by Enterprise Receipts Size), available at <https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html>.

¹⁶⁴ The calculation (approximately 181,412,000 individuals) is based on reports of private insurance coverage in the 2023 Current Population Survey Annual Social and Economic Supplement (CPS-ASEC). Private coverage in that survey includes employment-based (including non-government, non-Federal government, and Federal government employment), directly purchased (Exchange and non-Exchange), and TRICARE coverage. To arrive at the number of covered individuals (which excludes TRICARE enrollees), the Departments remove from the count respondent households for which the respondent is a member of the military. It also removes respondents who are over 65 or who report government insurance (such as Medicare, Medicaid, or VA) in addition to private insurance. The Departments view this calculation as an upper bound because the data are not sufficient to identify and exclude enrollees in grandfathered plans or individuals in non-ACA compliant individually purchased plans. The Departments do not have an

Within this total, there are an estimated 21 million covered individuals enrolled in coverage provided through an Exchange (with approximately 16 million policyholders).¹⁶⁵ This separate tally of Exchange enrollees is used as an input to the estimation of the net Federal spending impact of these proposed rules in the transfers section IV.B.2.e of this preamble.

Among individuals in covered plans, the Departments estimate that 51.71 million individuals (28.5 percent) are women of reproductive age (15–49).¹⁶⁶ The Departments calculate, based on data from the 2017–2019 National Survey of Family Growth (NSFG),¹⁶⁷ that 29.4 percent of women of reproductive age who have private health insurance are using contraceptive items that are (only now, in the case of oral contraceptive pills) available OTC (oral contraception pills, condoms, and/or emergency contraception) in a given enrollment month. This estimate is somewhat higher than the 2020 estimate by the National Center for Health Statistics (approximately 22.4 percent), given that the Departments' analysis restricts its calculations to women who

estimate of the relevant number of enrollees in either of these plan types; the latest available data on percentage of enrollees in grandfathered plans is from the 2020 KFF Employer Health Benefits Survey. See KFF, 2020 Kaiser Employer Health Benefits Survey, available at <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>, reporting that 14 percent of individuals were enrolled in grandfathered plans. However, the number has been declining since 2011, falling from 56 percent in 2011. See KFF, 2018 Kaiser Employer Health Benefits Survey, Figure 13.3, available at <https://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018>. In the absence of more recent data, the Departments cannot rule out that the rate has continued to fall.

¹⁶⁵ See CMS, "Open Enrollment Period Report: Final National Snapshot," available at <https://www.cms.gov/newsroom/fact-sheets/marketplace-2024-open-enrollment-period-report-final-national-snapshot> (reporting 21,310,538 Exchange enrollees). The estimated conversion between total enrollees and policyholders—15 enrollees per 11 policyholders—is based on medical loss ratio reports submitted by issuers for the 2021 reporting year, in which the number of policyholders in individual health insurance coverage offered in the individual market was approximately 11 million, and the number of enrollees was approximately 15,000,000. See CMS (2022), "Medical Loss Ratio Data and System Resources," <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

¹⁶⁶ The calculation is based on the reports of private insurance coverage in the 2023 CPS-ASEC. The calculation specifically includes all individuals who report their sex as female and are of age 15 to 49 years. Private insurance coverage includes those covered by directly purchased (Exchange and non-Exchange) and employment-based health insurance. Those in the armed services are excluded from the calculation.

¹⁶⁷ See CDC, "2017–2019 NSFG: Public-Use Data Files, Codebooks, and Documentation," available at https://www.cdc.gov/nchs/nsfg/nsfg_2017_2019_puf.htm.

report enrollment in private health insurance coverage.¹⁶⁸ Thus, the Departments estimate that 15.2 million individuals (8.4 percent of all individuals in covered plans) are

women of reproductive age using these forms of contraceptives.¹⁶⁹ The Departments request comment on this analysis.

Table 2 summarizes the number of entities that would be affected by these proposed rules.

TABLE 2—NUMBER OF AFFECTED ENTITIES

Affected entity	Number of entities
ERISA-covered non-grandfathered group health plans	2,343,819
ERISA-covered self-insured, non-grandfathered group health plans	499,299
ERISA-covered fully-insured, non-grandfathered group health plans	1,844,520
Non-grandfathered non-Federal governmental plans	76,345
Issuers (health insurance company/State combinations)	1,467
Pharmacies and drug stores	19,234
Covered individuals	181,412,000

c. Benefits

This analysis provides a qualitative discussion of the benefits associated with these proposed rules, as the Departments do not have the data necessary to quantify these benefits. The Departments request comment and data on how to quantify these benefits.

(1) Enhanced Coverage of a Wider Range of Preventive Services Without Cost Sharing for Eligible Individuals Leading to a Potential Reduction in Unintended Pregnancies and Improved Health Outcomes for Individuals

The potential for these proposed rules to facilitate greater coverage of a wider range of preventive services without cost sharing for eligible individuals could lead to important benefits to health and satisfaction (for example, in the form of better matches between chosen contraceptive items and individuals’ medical needs and preferences). There is clear evidence that many contraceptive users are not using their preferred form of contraception because of concerns about side effects, cost, or availability, for example.¹⁷⁰ Greater flexibility in contraceptive choice could directly improve quality of life, including by minimizing side effects and facilitating covered individuals in optimizing contraceptive use according to their

unique needs and preferences. Improved satisfaction with one’s contraceptive method, including by reducing unwanted side effects, would be an important benefit of these proposed rules. Given the many variations of contraceptive drugs or drug-led combination products, each with different hormonal properties, dosage levels, physical properties, delivery mechanisms, side effects, and benefits, there is significant need for individual tailoring and choice. Better aligning contraceptive use with a method or product with preferred health outcomes could be a source of major health improvements for covered individuals, as discussed further in this section. The ability to select among more contraceptive options at zero cost may facilitate such alignment, helping more women find a contraceptive that works best for their medical needs.

Increased coverage of medically necessary preventive services without cost-sharing requirements through the use of an exceptions process would have a similar effect of expanding covered individuals’ ability to access and use appropriate recommended preventive services by eliminating a financial barrier to receiving medically necessary care.

The Departments recognize the potential for a reduction in unintended

pregnancies and improved health outcomes as a result of these proposed rules. First, a reduction in unintended pregnancies and improved health outcomes could result from increases in the share of covered women who use contraception.¹⁷¹ Second, these proposed rules could induce some contraceptive switching among covered women already using reversible contraception that could create a closer match between the contraceptive method or product with the best medical outcomes for the individual and the method or product they currently use. In such cases, individuals able to switch to a method or product with the best medical outcome for them may more reliably adhere to the relevant usage recommendations.¹⁷²

Any benefit of reducing unintended or unplanned pregnancies would scale in proportion to the extent of new (or more reliable) use of contraception. The Departments do not have the data necessary to precisely estimate the extent of such an expansion in contraception use along both the extensive (new use) and intensive (more reliable use) margins, but anticipate relatively small effects on the number of women newly using any contraceptives as a result of the proposed rules, as discussed later in this section.

¹⁶⁸ See CDC, “Current Contraceptive Status Among Women Aged 15–49: United States, 2017–2019,” available at <https://www.cdc.gov/nchs/data/databriefs/db388-H.pdf> (estimating that approximately 65 percent of women ages 15–49 were currently using contraception. By method, these included female sterilization (18.1 percent), oral contraceptive pills (14.0 percent), LARCs (10.4 percent), male condoms (8.4 percent), male sterilization (5.6 percent), Depo-Provera, contraceptive ring, or patch (3.1 percent), and 5.7 percent across all other methods (includes diaphragm, withdrawal, periodic abstinence with

safe period assessed via calendar rhythm, temperature, or cervical mucus test)).
¹⁶⁹ Approximately 181.4 million individuals in covered plans, times 28.5 percent who are women of reproductive age, times 29.4 percent of these who are assumed to use recommended OTC contraceptives, per the NSFG analysis (see https://www.cdc.gov/nchs/nsfg/nsfg_2017_2019_puf.htm).
¹⁷⁰ Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). “Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage,” available at [\[united-states-a-closer-look-at-experiences-preferences-and-coverage-findings\]\(https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings\).
¹⁷¹ See CDC, “Reproductive Health, Unintended Pregnancy,” available at <https://www.cdc.gov/reproductive-health/hcp/unintended-pregnancy/index.html> \(finding that 41.6 percent of pregnancies were unintended\).
¹⁷² Fiffick, A.N., Iyer, T.K., Cochran, T., and Batur, P. \(2023\). “Update on Current Contraceptive Options: A Case-based Discussion of Efficacy, Eligibility, and Use.” *Cleveland Clinic Journal of Medicine*, available at: <https://www.ccmj.org/content/ccjom/90/3/181.full.pdf>.](https://www.kff.org/report-section/contraception-in-the-</p>
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Studies have consistently shown that approximately 70 percent of privately insured women who use contraception have the cost of their method covered in full by private health insurance.¹⁷³ These studies include evidence on the share of privately-insured women who do not pay cost sharing for oral contraceptives after passage of the ACA.¹⁷⁴ That these proposed rules would apply to a population of privately-insured women who already have coverage of certain contraceptives without cost sharing suggests the possibility of a small net effect on any contraception use for covered individuals. For example, in the 2022 KFF Women's Health Survey, only 4 percent of respondents reported cost as a reason for not using birth control, and this figure included individuals who did not have health insurance.¹⁷⁵

Nonetheless, it is plausible that by providing coverage without cost sharing for a wider variety of contraceptive items, these proposed rules could induce new take-up among covered individuals who were previously dissuaded from contraceptive use because of cost and accessibility considerations related to their preferred method, as discussed in section IV.B.2.a of this RIA. Further, medication adherence and consistent use of contraception could be improved if more covered individuals have coverage of their preferred method without cost sharing. In the 2022 KFF Women's Health Survey, among female contraceptive users ages 18–49 who were not using their preferred contraceptive method, 12 percent of survey respondents indicated that the primary reason for not doing so was because they could not afford it.¹⁷⁶ A third of women report not using contraception due to concerns over side effects,¹⁷⁷ the burden of which could be

lessened by expanding the selection of covered contraceptive product choice available without cost sharing. Such considerations could be important given that women using contraception—especially women with low incomes and women using less effective contraceptive methods—often report a mismatch between their most preferred contraceptive method and the method they usually use.¹⁷⁸

Historically, more comprehensive coverage of contraceptive services has been shown to improve the consistent use of the most effective short-acting methods of contraception, and the removal of cost sharing also increases the use of more effective LARC methods.¹⁷⁹ One study found that following the implementation of the ACA contraceptive coverage requirement, the discontinuation of use of oral contraceptive pills fell and nonadherence to brand-name oral contraceptive pills also declined.¹⁸⁰

Therefore, beyond the direct benefits of improved satisfaction with contraceptive method—due to, for example, reductions in side effects—remediating the misalignment between contraceptive preference and contraceptive use could lead to fewer unplanned pregnancies because of lower rates of discontinuation.¹⁸¹

While the Departments do not anticipate that the proposed requirement in these proposed rules to cover OTC contraception without cost sharing would substantially affect the overall rate of birth control use, to the extent that access to and use of OTC and

become pregnant who are not using contraception, four in ten say it is because they did not want to use birth control (42 [percent]). One in three females who are not currently using contraception report concern about side effects (32 [percent]), and one in five (22 [percent]) say they don't really mind if they become pregnant.”)

¹⁷⁸ He, K., Dalton, V.K., Zochowski, M.K., and Hall, K.S. (2017). “Women's Contraceptive Preference-Use Mismatch,” *Journal of Women's Health*, available at <https://pubmed.ncbi.nlm.nih.gov/27710196> and Burke, K. and Potter, J. (2023). “Meeting Preferences for Specific Contraceptive Methods: An Overdue Indicator,” *Studies in Family Planning*, available at <https://pubmed.ncbi.nlm.nih.gov/36705876>.

¹⁷⁹ Behn, M., Pace L.E., and Leighton, K. (2019). “The Trump Administration's Final Regulations Limit Insurance Coverage of Contraception,” *Women's Health Issues*, available at [https://www.whjournal.com/article/S1049-3867\(18\)30751-5/fulltext](https://www.whjournal.com/article/S1049-3867(18)30751-5/fulltext).

¹⁸⁰ Pace, L., Dusetzina, S., and Keating, N. (2016). “Early Impact of the Affordable Care Act on Oral Contraceptive Cost Sharing, Discontinuation, and Nonadherence,” *Health Affairs*, available at <https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1624>.

¹⁸¹ Burke, K. and Potter, J. (2023). “Meeting Preferences for Specific Contraceptive Methods: An Overdue Indicator,” *Studies in Family Planning*, available at <https://pubmed.ncbi.nlm.nih.gov/36705876>.

other contraceptive items, without cost sharing, is increased, it is expected to provide better matching of preferred contraceptive items and thus may ultimately improve health outcomes.

The Departments also anticipate that improved health outcomes would result from enhanced coverage of a wider range of recommended preventive services without cost sharing through the use of an exceptions process for recommended preventive services offered by plans and issuers. Covered individuals would have coverage of medically necessary preventive services because of this provision, whereas under current regulations they might be more likely to pay for such services out-of-pocket or forgo such services.

The Departments request comment on this analysis.

(2) Increased Convenience and Decreased Costs for Covered Individuals Who No Longer Need a Prescription To Obtain Recommended OTC Contraceptive Items

The Departments anticipate that some covered individuals would benefit from the provision of these proposed rules that would require plans to cover recommended OTC contraceptive items without a prescription and without cost sharing because these individuals would face reduced transportation costs, childcare costs, and/or time costs that would otherwise be incurred due to scheduling, travelling to, and attending health care provider visits in order to obtain prescriptions for contraceptives. Some covered individuals would also benefit from this provision if they cannot secure timely access to appointments to obtain a prescription, particularly if the individuals are in areas with primary care shortages. Out-of-pocket visit costs, if any, would also be avoided. Any such effects would be proportional to the number of covered individuals forgoing such provider visits as a result of this proposed provision, and therefore dependent on both the share of contraceptive users who switch methods from a prescription contraceptive to an OTC product and on the subset of these switchers who forgo provider visits that would otherwise have been needed for a contraceptive prescription.

As discussed further in section IV.B.2.f of this preamble, the Departments do not anticipate a significant share of covered individuals to both switch methods from prescription contraceptives to OTC contraceptives and make fewer preventive health care visits. The Departments assume that even among covered women who would avail

¹⁷³ Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). “Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage,” available at <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/#Contraceptive-Coverage>.

¹⁷⁴ Sonfield, A., Tapales, A., Jones, R.K., and Finer, L.B. (2015). “Impact of the Federal Contraceptive Coverage Guarantee on Out-of-Pocket Payments for Contraceptives: 2014 Update,” *Contraception*, available at <https://pubmed.ncbi.nlm.nih.gov/25288034/>.

¹⁷⁵ Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). “Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage,” available at <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings>.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.* (“Among reproductive age females who are able to conceive and are not pregnant or trying to

themselves of the new OTC benefit in these proposed rules, nearly all would continue to utilize preventive care visits. Therefore, while the benefits of reduced burdens associated with reduced health care visits could be significant for any individuals who see providers less frequently as a result of this proposed provision, the Departments do not anticipate such averted benefits (or costs) would accrue to a significant fraction of covered individuals. The Departments request comment on this analysis.

(3) Potential Benefits of Increased Transparency by Expanding Awareness of Coverage of OTC Contraceptive Items Without a Prescription and Without Cost Sharing

Studies have found that increased transparency about contraceptive care options and service costs are essential for improving contraceptive access by increasing public awareness and understanding about current health care policy and opportunities, and when women are fully informed about available contraceptive methods and find them affordable, they are more likely to use them consistently.¹⁸²

Overall, making information about OTC contraceptive coverage without a prescription and without cost sharing available to participants, beneficiaries, and enrollees can result in better health outcomes, as discussed in more detail in this section IV.B.2.c of this preamble.

The Departments request comment on this analysis.

d. Costs

This section provides a qualitative and quantitative discussion of the costs associated with these proposed rules. The Department request comment and data on how to better quantify these costs.

(1) Increased Costs to Plans and Issuers Due to a Change in Utilization of Preventive Services, and Decreased Costs Due to Improved Health Outcomes and Avoided Unintended Pregnancies

Previous analysis by the Office of the Assistant Secretary for Planning and Evaluation (ASPE), which evaluated the

impacts of the ACA's original contraceptive coverage requirements, found no likely net impact on gross costs of expanding utilization for contraception: "While the costs of contraceptives for individual women can be substantial and can influence choice of contraceptive methods, available data indicate that providing contraceptive coverage as part of a health insurance benefit does not add to the cost of providing insurance coverage."¹⁸³ This conclusion was reached based on a review of the literature and of case studies on how expanding access to reproductive care affected insurance costs and gross premiums. For example, in 1999, Congress required the health plans in the Federal Employees Health Benefits (FEHB) program to cover the full range of FDA-approved contraceptive methods. ASPE concluded: "When medical costs associated with unintended pregnancies are taken into account, including costs of prenatal care, pregnancy complications, and deliveries, the net effect on premiums is close to zero."¹⁸⁴ This conclusion echoes the conclusion of earlier studies.¹⁸⁵ The Departments are aware that the health insurance market has evolved since the publication of this study but are of the view that the general results of this analysis are still relevant today.

The Departments assume that, unlike the initial introduction of contraceptive coverage requirements under the ACA, these proposed rules would have small impacts on the fraction of covered women using contraception, as approximately 70 percent of this population of covered women that uses contraception already has coverage for contraception through private insurance without cost sharing.

Nonetheless, in line with the findings of ASPE and others, the Departments assume that any increase in contraception utilization, however small, induced by these proposed rules would not increase net insurer claims costs and thus not increase gross premiums. This effect is separate from the transfers created by shifting the out-

of-pocket cost burden from the covered individual to the plan, which are accounted for separately. The Departments request comment on this analysis.

The Departments also anticipate that the establishment or use of an existing exceptions process by plans and issuers that would allow covered individuals to access coverage of certain recommended preventive services without cost sharing would also lead to a decrease in out-of-pocket costs for these preventive services and a corresponding increase in utilization or switching from other preventive services. The Departments expect that this change would increase net claims costs initially and potentially over time. Plans and issuers could experience claims cost savings that at least partially offset these new costs, due to improved health outcomes associated with increased utilization of certain recommended preventive services.

The Departments request comment and data on how the costs to plans and issuers would change due to a change in utilization of preventive services associated with these proposed rules.

(2) Costs to Pharmacies and Plans and Issuers To Update Billing Processes and Systems for Covered OTC Products

The Departments anticipate that pharmacies, as well as plans and issuers, would incur some upfront and annual operational and administrative costs in order to comply with the coverage requirements for OTC contraceptives in these proposed rules, but do not have information necessary to estimate such costs.

For pharmacies, the Departments anticipate costs would include updating real-time claims adjudication systems and processes for their point-of-sale systems. The Departments are aware that there are uncertainties regarding how pharmacies could adapt existing systems, including the requirements in some point-of-sale systems to fill in a "prescriber NPI," which would not exist in its usual form for OTC products. The Departments are aware of at least one large pharmacy chain that has already implemented insurance coverage for an OTC oral contraceptive pill at the pharmacy counter by setting up codes for insurance reimbursement with real-time claim adjudication. The Departments lack information regarding how widespread such existing capabilities are among pharmacies and thus the costs of transitioning systems and processes that do not yet have these

¹⁸² Swan, L.E.T. (2021). "The Impact of US Policy on Contraceptive Access: A Policy Analysis," *Reproductive Health*, available at <https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-021-01289-3> and Planned Parenthood Federation of America (2014). "New Study on Birth Control Use Shows That, When Fully Implemented, the Affordable Care Act Could Dramatically Reduce Unintended Pregnancy in the U.S.," available at <https://www.plannedparenthood.org/about-us/newsroom/press-releases/new-study-birth-control-use-shows-when-fully-implemented-affordable-care-act-could-dramatically>.

¹⁸³ Bertko, J., Glied, S., Miller, E., Simmons, A., and Wilson, L., ASPE (2012). "The Cost of Covering Contraceptives through Health Insurance," available at <https://aspe.hhs.gov/reports/cost-covering-contraceptives-through-health-insurance>.

¹⁸⁴ *Id.*

¹⁸⁵ Trussell, J., Leveque, J.A., Koenig, J.D., London, R., Borden, S., Henneberry, J., LaGuardia, K., Stewart, F., Wilson, G., Wysocki, S., and Strauss, M. (1995). "The Economic Value of Contraception: A Comparison of 15 Methods," *American Journal of Public Health*, available at <http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.85.4.494>.

capabilities.¹⁸⁶ The Departments request comment on the potential changes that pharmacies would have to make to their systems and processes and the corresponding burden and costs.

The Departments anticipate that plans and issuers would incur costs associated with updating IT systems and processes to process claims. Plans and issuers would also have to develop, if they have not already, processes aimed at preventing fraud, waste, and abuse for OTC products, which could include processes to monitor utilization. Plans and issuers routinely do such monitoring for prescription products in order to, for example, enforce reasonable quantity limits. The Departments request comment on the costs and any associated burden that would be borne by plans and issuers to update their systems and processes.

The Departments do not anticipate significant costs associated with formulary redesign to accommodate OTC products, as formularies are regularly updated even in the absence of any relevant policy changes and plans and issuers are already required to cover OTC products without cost sharing when the patient has a prescription. For the same reason, the Departments do not anticipate significant costs associated with formulary redesign to comply with the provision of the proposed rules requiring coverage of every recommended contraceptive drug and drug-led combination product without cost sharing unless a therapeutic equivalent is covered without cost sharing.

The Departments also anticipate some costs to pharmacies, as well as plans and issuers, associated with negotiating new contract terms for OTC coverage.

Despite the costs to pharmacies identified in this section, the Departments anticipate that pharmacies would see increased revenues from sales of covered OTC contraceptives, and that associated profit increases (if they occur) might offset these costs from the pharmacies' perspective.

The Departments request comment on the potential costs (and revenues) to

¹⁸⁶ One analogous example of widespread implementation of over-the-counter insurance coverage is the recent COVID-19 pandemic when COVID tests were available over-the-counter at no cost sharing. See Huber, K., T. Roades, A. Higgins, M. Aspinall, C. Silcox, and M. McClellan, Duke University Margolis Center for Health Policy, (2022). "Over the Counter COVID-19 Testing: Insurance Coverage Strategies to Support Equitable Access," available at <https://healthpolicy.duke.edu/sites/default/files/2022-05/Margolis%20OTC%20Testing.pdf>. It remains unclear how these preparations might affect the cost of implementation of these proposed rules, but it is likely that this prior work may—to some extent—mitigate costs.

pharmacies and costs to plans and issuers associated With the changes in these proposed rules.

(3) Potential Administrative Costs to Plans and Issuers Associated With the Establishment or Use of an Existing Exceptions Process

Plans and issuers could incur administrative costs associated with the establishment or use of an existing exceptions process that allows an individual to receive coverage without cost-sharing requirements for a medically necessary recommended preventive service. The Departments assume that most plans and issuers have an exceptions process in place that they would be able to adapt for the provision in these proposed rules. However, those that do not would incur costs to develop one. The Departments do not have information about the percentage of plans and issuers that currently have an exceptions process in place that could be adapted for the provision in these proposed rules or the upfront and recurring costs that plans and issuers would incur to establish one. The Departments request comment on the potential costs to plans and issuers associated with this provision.

(4) Costs to Issuers and TPAs (on Behalf of Self-Insured Group Health Plans) Associated With the Disclosure of Coverage and Cost-Sharing Requirements for OTC Contraceptive Items

As detailed in section IV.D of this preamble, issuers and TPAs,¹⁸⁷ on behalf of self-insured group health plans, would incur costs associated with the disclosure of coverage and cost-sharing requirements for OTC contraceptive items. Specifically, issuers and TPAs would incur one-time costs of \$35,089,261 to integrate the contraception statement language into the existing Transparency in Coverage internet-based self-service tool,¹⁸⁸ and to create or update a web page to

¹⁸⁷ The Departments assume that fully-insured group health plans would depend on health insurance issuers and self-insured group health plans would rely on TPAs to implement the proposed requirements. The Departments expect self-insured group health plans would compensate TPAs accordingly and thereby bear any implementation costs.

¹⁸⁸ The Departments expect that while participants, beneficiaries, and enrollees will continue to request cost-sharing information on paper in certain circumstances, the proposed additional disclosure would impose negligible additional burden on plans and issuers as the disclosure will likely be no more than one or two sentences and would only be required when a participant, beneficiary, or enrollee requests cost-sharing information for a subset of covered items and services, covered contraceptive items and services.

provide information about coverage of contraceptive items and services. Additionally, issuers and TPAs would incur annual costs of \$6,091,096 for programming updates, web page maintenance, training customer service representatives, and responding to calls to provide assistance. These costs would ultimately be incurred by plans and issuers and, in turn, by covered individuals through a minimal impact on premiums. The Departments request comment on the costs to issuers and TPAs associated with this provision.

e. Transfers

Eliminating cost sharing for some contraceptive items has the potential to affect transfers associated with contraceptive items and insurance coverage. Specifically, the Departments expect these proposed rules would result in transfers from plans and issuers to covered individuals resulting from reduced out-of-pocket costs for contraceptive items, which are estimated to be mostly paid by covered individuals experiencing higher premiums, with a smaller portion paid by the Federal government through premium tax credit (PTC) spending. The Departments also expect these proposed rules would result in transfers from plans and issuers (and potentially premium-payers and the Federal government) to pharmacies, drug wholesalers, and drug manufacturers resulting from anticipated shifts in formulary design and utilization management that could affect plan-paid prices for some contraceptive items. Lastly, the Departments expect these proposed rules would result in transfers associated with the use of an exceptions process for covered individuals to access coverage without cost sharing of certain recommended preventive services but are unable to quantify the magnitudes of these transfers due to a lack of data, as discussed later in this section.

(1a) Transfers From Plans and Issuers to Covered Individuals Resulting From Reduced Out-of-Pocket Costs for Contraceptive Items

The Departments expect that the proposed elimination of cost sharing for a wider variety of contraceptive items would lead to transfers from plans and issuers to covered individuals due to reduced out-of-pocket spending on contraceptive services. (Analysis of who ultimately pays these transfers is presented in the next sub-section.) These transfers would accrue to covered individuals who are women of reproductive age, who use a contraceptive method, who—in the

absence of the proposed changes—would otherwise pay some non-zero cost-sharing amount for contraceptives, and whose out-of-pocket costs would be reduced by these proposed rules. As per the calculation in section IV.B.2.b of this preamble, approximately 15.2 million individuals (8.4 percent of individuals in covered plans) are women of reproductive age using those noted forms of contraceptives. The 2022 KFF Women’s Health Survey showed that among privately-insured women using contraception, 70 percent reported that insurance covered their contraceptive method with no cost sharing, and 16 percent reported that insurance paid some but not all of the cost.¹⁸⁹ The remaining 13 percent of respondents paid out-of-pocket despite being insured, believed contraception not to be covered by insurance, or replied in some other way.¹⁹⁰

In terms of consumer response, lack of knowledge about plan benefits and features as well as preference for non-covered contraceptive items (for example, a branded drug in the presence of a generic drug with no cost sharing) may explain some of the incomplete take-up of zero cost-sharing options under the status quo, and such frictions and preferences might persist to some degree under the proposed rules.

Therefore, the Departments assume that—as under the status quo—some covered women would continue to pay out-of-pocket for contraceptives, including by not using insurance when insurance could cover some or all of the out-of-pocket costs. The Departments operationalize this assumption by assuming that the 16 percent of women who currently use insurance but face non-zero cost sharing due to partial insurance coverage would instead face zero cost sharing under these proposed rules, while the 13 percent¹⁹¹ of contraceptive users who are insured but do not use insurance coverage for their contraceptive items would continue to

not use insurance coverage.¹⁹² The Departments estimate that among the subset of covered individuals for whom contraceptives are covered with non-zero cost sharing (16 percent of contraceptive users and therefore estimated to be approximately 1.3 percent of the total covered population)¹⁹³ these proposed rules would decrease average cost sharing by a maximum of \$316 per year.¹⁹⁴ Therefore, the Departments estimate a total transfer of approximately \$768.7 million per year to contraceptive users in the form of reduced out-of-pocket payments.¹⁹⁵

(1b) Transfers From Covered Individuals and From the Federal Government to Plans and Issuers in the Form of Higher Premiums (Analysis of Who Pays for the Transfers Estimated Above)

The Departments assume these proposed provisions would cause plans and issuers to increase premiums to approximately offset the new net costs incurred by lower cost sharing. In other words, the Departments assume the cost of decreased cost sharing would be passed on to premium payers. From a total decline in out-of-pocket payments of \$768.7 million per year, the Departments estimate that these proposed rules would increase annual gross premiums by about \$4.24 per covered individual or less than 0.1

percent.¹⁹⁶ Premium payers include employer plan participants—both directly through employee contributions to premiums and indirectly by reductions in salary compensation or other benefits—and individuals purchasing plans outside of the employment context (on or off an Exchange). Because these proposed provisions would increase the cost of employer-sponsored insurance and reduce the share of total compensation subject to taxation, the Departments estimate these changes would reduce Federal tax revenue by \$217 million annually. Because these proposed provisions are expected to increase gross premiums for individual health insurance coverage purchased on the Exchanges, the Departments estimate and anticipate an \$83.1 million increase in net Federal premium tax credit (PTC) spending.¹⁹⁷ The annual Federal budgetary transfers would therefore amount to an estimated \$300.1 million (\$217 million reduction in Federal tax revenue plus \$83.1 million increase in net Federal PTC spending).

¹⁹⁶ Approximately \$768.7 million in new plan costs divided across 181.4 million covered individuals = \$4.24 in annual premiums. Of the 181.4 million covered individuals, the CMS 2023 Open Enrollment Report indicates there are 16.4 million consumers enrolled in health insurance plans purchased through an Exchange and that the average annual premium for single coverage for Exchange coverage is \$7,260 (\$605 per individual per month). The Departments assume that the average annual premium for off-Exchange single coverage would be comparable to this figure. 2023 KFF data indicate that the average annual premium for (single) group comprehensive insurance is \$8,435. The Departments assume that the average annual premium for (single) non-Federal government plan coverage would be comparable to this figure. Based on these figures and assumptions, the weighted average annual premium would be expected to increase by about 0.05 percent. See CMS, “Health Insurance Marketplaces 2023 Open Enrollment Report,” available at <https://www.cms.gov/files/document/health-insurance-exchanges-2023-open-enrollment-report-final.pdf> and KFF, “2023 Employer Health Benefits Survey,” available at <https://www.kff.org/health-costs/report/2023-employer-health-benefits-survey/>.

¹⁹⁷ The Departments have estimated this net Federal spending transfer effect by assuming that the expected \$4.24 increase in annual gross premiums will apply to the second-lowest-cost silver plans in each market, and that each dollar of increased silver plan premiums generates exactly a dollar of additional net Federal PTC spending for individuals receiving PTCs. A \$4.24 increase in per capita annual gross premiums, times 21,310,538 Exchange annual enrollees (as reported above), times 92 percent of enrollees receiving PTCs, equals approximately \$83.1 million. This estimate does not account for the expiration of the enhanced PTC subsidies at the end of 2025, which would likely reduce the level of Exchange enrollment (or at least reduce enrollment growth), reduce the share of enrollees receiving PTCs, and therefore reduce net Federal PTC spending. Source of fraction receiving PTCs: Effectuated Enrollment: Early 2024 Snapshot and Full Year 2023 Average, available at <https://www.cms.gov/files/document/early-2024-and-full-year-2023-effectuated-enrollment-report.pdf>.

¹⁸⁹ Frederiksen, B, Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). “Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage,” available at <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/>.

¹⁹⁰ The Departments note that studies of out-of-pocket spending for contraception based on examination of health care claims cannot speak to the issue of an insured woman not making use of insurance for a contraceptive purchase—a case that would not generate an insurance claim.

¹⁹¹ This is the sum of the 6 percent of users whose plan does not cover contraception, the 4 percent of users who reported “Other,” and the 3 percent of users who had coverage but did not use it. The Departments note that these proposed rules could induce this final category of users to switch to a covered OTC method, but the Departments do not assume this is the case.

¹⁹² Frederiksen, B, Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). “Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage,” Fig. 14, available at <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/>.

¹⁹³ 8.4 percent of covered individuals are women of reproductive age who are currently using contraception, and 16 percent of these women face some out-of-pocket costs for contraception = 1.3 percent.

¹⁹⁴ The Departments calculate the typical monthly out-of-pocket costs for those individuals who use insurance but pay a non-zero amount by estimating a weighted average of out-of-pocket amounts as reported in the KFF survey: 24 percent reporting \$50 or more, 13 percent reporting \$25–\$49, 19 percent reporting \$15–\$24, 26 percent reporting \$5–\$14, and 6 percent reporting \$1–\$4, and 12 percent reporting “Don’t know.” Taking midpoints of these ranges, assuming a \$50 monthly payment for the top category, and excluding individuals who report “don’t know” yields \$26.29 per month $= ((.24*50) + (.13*37) + (0.19*19.5) + (.26*9.5) + (.06*2.5)) / (1 - .12)$ or \$315.50 annually. The Departments assume that the estimated 16 percent of covered women with partial coverage would face zero cost sharing under these proposed rules, while the remaining 14 percent of covered women, who currently do not report using insurance for contraceptives, would not experience a significant decline in out-of-pocket costs.

¹⁹⁵ Approximately 1.3 percent of the covered population (approximately 181.4 million individuals) times a \$316 reduction in out-of-pocket costs = \$768.7 million.

The remainder of the estimated \$768.7 million in annual transfers, or approximately \$468.6 million (\$768.7 million minus \$300.1 million), is expected to be paid by covered participants and enrollees (directly or indirectly, as discussed earlier in this section) through increased premiums paid to plans and issuers and subsequent reductions to employees' taxable wages. However, the Departments acknowledge that employers could also offset plan or coverage cost increases through increased prices for consumers, reduced production costs (for example, layoffs, other reductions to labor costs, or other production cost reductions), or lower profits, for example. The Departments request comment on and evidence regarding the extent to which new net costs incurred by lower cost sharing for contraceptive items would be passed along to covered individuals through increases in premiums.

(2) Transfers Associated With the Use of an Exceptions Process

The Departments anticipate that the increased access to coverage without cost sharing of other recommended preventive services through the use of an exceptions process would generate transfers caused by reduced out-of-pocket costs for other recommended preventive services for which coverage without cost sharing would be accessible through an exceptions process.

More specifically, the Departments anticipate that the increased access to coverage without cost sharing of other preventive services through the use of an exceptions process would generate transfers; on an intermediate basis, they would flow from plans and issuers to covered individuals, but these transfers are expected to be ultimately paid by a combination of other covered individuals, experiencing higher premiums, and by the Federal government in the form of higher net Federal PTC spending for Exchange plans caused by higher premiums (approximately equal in size to the total reduction in out-of-pocket costs for other preventive services for which coverage without cost sharing would be accessible through the use of an exceptions process).

It is uncertain how plan and issuer expenditure would change due to use of an exceptions process to allow covered individuals to access coverage of recommended preventive services without cost sharing. The Departments do not have data that would allow for a quantification of these effects. The Departments request comment on the

transfers associated with the exceptions process and their likely magnitudes.

(3) Potential Transfers From Plans and Issuers to Pharmacies, Drug Wholesalers, and Drug Manufacturers Resulting From Anticipated Shifts in Formulary Design That Could Affect Plan-Paid Prices for Some Contraceptive Items

These proposed rules would require plans and issuers to cover a wider range of recommended contraceptive items without cost sharing. This is likely to affect the relative price negotiating power between entities in the drug supply chain (manufacturers, wholesalers, and pharmacies) and plans and issuers, including their affiliated or subcontracted PBMs. This could lead to higher negotiated prices to plans, issuers, and their PBMs. If so, it would increase total plan costs for recommended contraceptive items and would ultimately cause increases in plan premiums.

Plans and issuers place downward pressure on negotiated prices for drugs and devices and limit spending in several ways:¹⁹⁸ through the threat of exclusion of a product from a drug formulary; through the threat of setting high consumer cost sharing that would steer covered individuals away from high cost or ineffective products; and through the threat of erecting non-price barriers to access, such as prior authorization, step-therapy, or requirements for a provider-requested exception to access a product.¹⁹⁹ Plans and issuers also place downward pressure on negotiated prices for drugs and devices and limit spending by contracting with providers whose prescribing patterns align with the cost-control goals of the plans and issuers.

Because drug and device suppliers desire favorable coverage and favorable provider prescribing behavior in order to attract higher volumes of covered individuals to use their products, these tools place powerful downward pressures on negotiated (net-of-rebate) prices paid by plans. Research has shown that when plans and issuers are unable to use cost sharing, they rely on

non-price barriers to access, such as prior authorization and step therapy, to steer consumers across medication options, and ultimately constrain overall plan costs.²⁰⁰

The provisions of these proposed rules would clarify the use of reasonable medical management that plans and issuers can use with respect to covering recommended preventive services, including contraceptive items, without cost sharing under the ACA. This clarification could impact their bargaining power against drug suppliers, removing some sources of downward pressure on prices. The Departments do not have sufficient data to estimate the magnitude of these effects. The Departments anticipate that they are unlikely to be significant for contraceptive products for which there are available therapeutic equivalents. For such products, competition across two or more therapeutic equivalents is a key constraint on prices even in the absence of cost sharing and other plan and issuer tools. The Departments anticipate that price effects could be larger for products for which there is no therapeutic equivalent. The Departments request comment and data regarding these potential transfers.

f. Uncertainty

As noted throughout this RIA, due to a lack of data and information, there are several areas of uncertainty regarding the potential impacts of these proposed rules. The Departments are unable to forecast with high confidence how the provisions of these proposed rules would affect the choice of contraceptive method or product among covered women or how many covered women would continue to use contraceptives with non-zero cost sharing. Further, the Departments are unable to forecast with high confidence whether or the extent to which the pharmaceutical and medical device supply chain entities (including manufacturers, wholesalers, and pharmacies) might respond in pricing negotiations with PBMs and issuers to both the new patterns of consumer take-up of contraceptive items—as the set of options without cost sharing would expand under these proposed rules—and to the provisions of these proposed

¹⁹⁸ For a useful overview of the management tools employed by managed care organizations, see Glied, S., National Bureau of Economic Research (1999), "Managed Care," available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=202746.

¹⁹⁹ Lakdawalla, D. and Yin, W., National Bureau of Economic Research (2009). "Insurer Bargaining and Negotiated Drug Prices in Medicare Part D," available at <https://www.nber.org/papers/w15330>; Lakdawalla, D.N. (2018). "Economics of the Pharmaceutical Industry," *Journal of Economic Literature*, available at <https://www.aeaweb.org/articles?id=10.1257/jel.20161327>.

²⁰⁰ See Geruso, M., Layton, T., and Prinz, D. (2019). "Screening in Contract Design: Evidence from the ACA Health Insurance Exchanges," *American Economic Journal: Economic Policy*, available at <https://www.aeaweb.org/articles/pdf/doi/10.1257/pol.20170014> (finding that when plans are limited in their ability to expose their enrollees to cost-sharing, as with cost-sharing-reduction enrollees in Exchange plans, plans may respond by relying more heavily on non-price barriers to access, such as step-therapy and prior authorization).

rules that would clarify plans' and issuers' ability to use reasonable medical management. As a result, there is some uncertainty about the potential impact on premiums.

The Departments expect that the administrative and operational costs associated with these proposed rules would primarily fall on plans, issuers, and pharmacies. As discussed in section IV.B.2.d of this preamble and discussed in comments in response to the OTC Preventive Products RFI, these entities would incur costs associated with updating IT systems and processes to accommodate insurance coverage of OTC contraceptives. Commenters noted that various systems would likely need to be updated or created, such as to accommodate new information requirements for claims, but provided no further information related to any associated burdens or costs. Therefore, the Departments lack information on the scope and size of such activities and costs.

The Departments are uncertain about the number of women who would switch contraceptive methods to OTC contraceptives as a result of these proposed rules. Since the first FDA-approved daily OTC oral contraceptive pill was approved in July 2023 and became widely available for purchase (including by being carried by major pharmacy chains and online retailers) beginning in March 2024, it is too soon to predict with confidence the extent of switching to an OTC contraceptive from other prescription products.

A reasonable analog to daily OTC oral contraception is the increased use of emergency contraception since its approval for OTC use in the early 2000s. The FDA approved nonprescription availability of emergency contraception (Plan B) for women 18 years or older in August 2006.²⁰¹ This was expanded to women 17 years and older in 2009 and without age restrictions in 2013. The Guttmacher Institute reports that between 2008 and 2015, the use of emergency contraceptive pills increased significantly across nearly all social and demographic groups.²⁰² For example, the report shows that use among 25–29-year-olds more than doubled during this time, increasing from 16 percent of women ever having used emergency contraception to 36 percent. While these

data do not allow us to forecast switching from prescription to OTC birth control, they do suggest that take-up of OTC contraceptive items may increase.

There is also insufficient data to forecast the extent to which take-up of OTC oral contraception would result in fewer visits to health care providers and the scope for potential negative health consequences due to this reduction in contact with health care providers. Research finds that fewer primary care visits may lead to less interaction with preventive care services such as mammograms, vaccinations, and colonoscopies, and may result in more emergency room visits and hospitalizations, all of which could lead to greater health care expenditures in the future.²⁰³ However, the same work finds that the likelihood of preventive services uptake does not increase with respect to the number of visits, suggesting that while increased engagement with primary care improves compliance with these preventive interventions, the benefits of visits may diminish in value past a certain frequency.²⁰⁴ Applied to this uncertain setting, this body of research suggests a possibility that covering recommended OTC contraceptive items without cost sharing and without a prescription could be associated with negative health consequences if it leads to a reduction in provider visits that specifically reduces interaction with preventive services. However, there is no evidence to suggest that such a policy to increase coverage of recommended OTC contraceptive items would affect the strong incentives for women to continue to seek preventive care, via a provider visit, outside of their need to obtain a prescription for contraception. Among these incentives, the ACA requires plans and issuers to cover, without cost

sharing, an annual well-woman visit as well as other recommended preventive services.

Further, there is significant uncertainty about the potential changes in take-up of OTC contraceptives that would be caused by these proposed rules and the impact of any such change on the frequency of provider visits. In a survey about hypothetical use that predated the introduction of an FDA-approved daily OTC oral contraceptive pill, many female respondents indicated they would be likely to switch to an OTC contraceptive if it was available to them.²⁰⁵ Women may be motivated to make such a switch by the potential reduction in required provider visits to maintain a prescription. The costs of seeing a provider include costs such as transportation and childcare during the appointment time, or the opportunity costs of time associated with the visit. If these proposed rules reduce the frequency or likelihood of health care provider visits among women, the revenue of providers who otherwise would have performed and billed for services would be impacted, representing a cost of at least \$100 per visit, on average.²⁰⁶

Nonetheless, practical considerations surrounding OTC contraceptive items may limit the number of covered individuals who take up this option in practice. First, contraceptives have numerous side effects, which vary by person and product.²⁰⁷ Women are likely to have a preference for a given contraceptive they have already become accustomed to; in this case, they may perceive switching as involving some risk of generating a worse match.²⁰⁸ A

²⁰⁵ Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," available at <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings> (finding that 60 percent of reproductive age females who have used birth control pills in the past 12 months said they would be likely or very likely to use over-the-counter birth control pills).

²⁰⁶ In 2016, the average cost per visit to a primary care physician was \$106 compared to \$103 for an office visit to a NP or PA. See Hargraves, J., Frost A. (2018). "HCCI Brief: Trends in Primary Care Visits," available at <https://healthcostinstitute.org/hcci-originals-dropdown/all-hcci-reports/trends-in-primary-care-visits>.

²⁰⁷ Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," available at <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings>.

²⁰⁸ Switching oral contraceptives can increase the chance of pregnancy and can often cause side effects. See Lesnewski, R., Prine, L., and Ginzburg, R. (2011). "Preventing Gaps When Switching Contraceptives," *American Family Physician*

²⁰¹ FDA, Center for Drug Evaluation and Research, "Plan B One-Step Information," available at <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/plan-b-one-step-15-mg-levonorgestrel-information>.

²⁰² Guttmacher Institute (2021). "Use of Emergency Contraception in the United States," available at <https://www.guttmacher.org/fact-sheet/use-emergency-contraception-united-states>.

²⁰³ Rose, A.J., Timble, J.W., Setoldji, C., Friedberg, M.W., Malsberger, R., and Kahn, K.L. (2019). "Primary Care Visit Regularity and Patient Outcomes: An Observational Study," *Journal of General Internal Medicine*, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6318173> and Hostetter, J., Schwarz, N., Klug, M., Wynne, J., and Basson, M.D. (2020). "Primary Care Visits Increase Utilization of Evidence-Based Preventative Health Measures," *BMC Family Practice*, available at <https://bmcpimcare.biomedcentral.com/articles/10.1186/s12875-020-01216-8>.

²⁰⁴ Gao, J., Moran, E., Grimm, R., Toporek, A., Ruser, C. (2022). "The Effect of Primary Care Visits on Total Patient Care Cost: Evidence from the Veterans Health Administration," *Journal of Primary Care Community Health*, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9793026> (examining the correlation between additional in-person primary care visits and total health care costs among Veterans Health Administration patients and finding that the first visit was associated with the largest savings, with diminishing returns for subsequent visits).

commenter to the OTC Preventive Products RFI noted these considerations in explaining why the extent of switching to OTC products would likely be moderate.

One way to understand how important such factors may be is to examine the experience with pharmacist-prescribed contraceptives. As of 2023, 28 states and the District of Columbia allowed pharmacists to provide contraceptives, 21 of which do not require any physician follow-up.²⁰⁹ However, less than 10 percent of women currently opt to take advantage of pharmacist provision.²¹⁰ Some women may be unaware of this option, while others might find that the added convenience may not be enough to offset a significant preference towards consulting with a physician and obtaining a prescription for contraception. There are several considerations that may explain this preference: first, most women (73 percent) see a family or internal medicine doctor as their usual source of care.²¹¹ Thus, it is likely that many women are prescribed birth control through their primary care physician (PCP), and that these visits are likely to continue on a semi-regular basis regardless of how birth control is obtained.²¹² Next, practitioners are able to renew birth control pills over the phone or via telemedicine applications, eliminating the net potential benefit of reducing follow-up visits by switching

to an OTC pill. Finally, some women currently procure contraception from a clinical visit that does not include a significant medical exam, thus lowering the health benefit of such a provider interaction (other than its prescribing function)—in contrast to other visit types with PCPs. Therefore, despite the potential time and money savings of forgone visits that would be enabled by wider OTC contraceptive coverage without cost sharing, this evidence suggests these factors may not significantly impact the use of recommended preventive services.

Informed by the existing research discussed in this section, the Departments anticipate approximately no impact of the proposed rules on the frequency of recommended preventive services visits with PCPs, nurse practitioners, or physician assistants, and thus approximately no impact on health outcomes of covered women through this channel. Similarly, the Departments anticipate approximately no impact of the proposed rules on revenues of these health care providers. The Departments note that although the option of switching to OTC contraception may not provide significant value to all contraceptive users, the option may provide particularly high value for the subset of covered women in contraception deserts. The Departments request comment on this analysis.

Finally, the Departments acknowledge the potential for long-term economic effects of increased coverage of certain recommended preventive services. Research suggests that access to contraception can increase educational attainment and labor force participation, for example, with follow-on potential to improve career outcomes and lifetime earnings.²¹³ It is also possible that overall health outcomes might improve because of increased coverage of certain recommended preventive services, which, in turn, could reduce health care expenditures and therefore premiums in the future. Further long-term economic effects could be seen by entities and individuals directly or indirectly (public health insurance programs, uninsured or self-pay individuals, and suppliers in the pharmaceutical industry, for example) affected by these proposed rules, to the extent that prices for different recommended preventive services change as a result of these proposed rules. However, due to a lack

of data and clear understanding of how preventive services utilization will evolve given these proposed rules, the Departments are unable to develop monetized estimates of these potential benefits, costs, and transfers.

Due to the lack of data, the Departments are unable to develop monetized estimates of the benefits to covered individuals anticipated to arise from these proposed rules, including a potential reduction in unintended pregnancies and improved health outcomes for individuals and greater flexibility in utilizing a wider range of recommended preventive services without cost sharing for eligible individuals.

g. Regulatory Review Cost Estimation

Due to the uncertainty involved with quantifying the number of entities that will review these proposed rules, the Departments assume that the total number of unique entities that may review these proposed rules will equal the number of health insurance companies (479) plus the number of TPAs (205) (on behalf of self-insured group health plans) plus the States, Territories, and Washington DC (56) plus the number of unique commenters (364) to the OTC Preventive Products RFI.²¹⁴ That sum yields 1,104 unique entities. The Departments acknowledge that this assumption may understate or overstate the number of reviewers and therefore the costs of reviewing these proposed rules. The Departments request comment on the approach in estimating the number of entities which will review these proposed rules.

Using the median wage information from the BLS for business operations specialist (13–1199) to account for labor costs (including a 100 percent increase to account for the cost of fringe benefits and other indirect costs), the Departments estimate that the cost of reviewing this rule is \$76.52 per hour, including overhead and fringe benefits.²¹⁵ Assuming an average reading speed of 200 words per minute, the Departments estimate that it would take approximately 3.25 hours for the staff to review these proposed rules. For each entity that reviews the rule, the estimated cost is \$248.69 (3.25 hours × \$76.52). Therefore, the Departments estimate that the total cost of reviewing this regulation is approximately \$274,554 (\$248.69 × 1,104).

Journal, available at <https://www.aafp.org/pubs/afp/issues/2011/0301/p567.html> and Burgess, L. (2023). "How to Switch Birth Control Pills Properly," Medical News Today, available at <https://www.medicalnewstoday.com/articles/322356>.

²⁰⁹ Guttmacher Institute (2023). "Pharmacist-Prescribed Contraceptives," available at <https://www.guttmacher.org/state-policy/explore/pharmacist-prescribed-contraceptives>.

²¹⁰ The 2022 KFF Women's Health Survey finds that 8 percent of women ages 18–49 get their birth control from places other than the doctor's office, a clinic, or online, where "other" includes pharmacies. When asked about where women would prefer to get their birth control, only 12 percent said "other". See Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," available at <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings>.

²¹¹ Long, M., Frederickson, B., Ranji, U., and Salganicoff, A., KFF (2020). "Women's Health Care Utilization and Costs: Findings from the 2020 KFF Women's Health Survey," available at <https://www.kff.org/womens-health-policy/issue-brief/womens-health-care-utilization-and-costs-findings-from-the-2020-kff-womens-health-survey/>.

²¹² Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," available at <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings>.

²¹³ See, e.g., Bernstein, A. and Jones, K.M. (2019). "The Economic Effects of Contraceptive Access: A Review of the Evidence," Institute for Women's Policy Research, available at https://iwpr.org/wp-content/uploads/2020/07/B381_Contraception-Access_Final.pdf.

²¹⁴ See 88 FR 68519 (Oct. 4, 2023).

²¹⁵ BLS, "May 2023 National Occupational Employment and Wage Estimates, United States," available at https://www.bls.gov/oes/current/oes_nat.htm.

*C. Regulatory Alternatives—
Departments of Health and Human
Services and Labor*

In developing these proposed rules, the Departments considered various alternative approaches.

The Departments considered proposing to require plans and issuers to cover all recommended preventive services, with no cost sharing and without applying reasonable medical management techniques. However, as discussed in section II.A of this preamble, the Departments have determined that allowing plans and issuers to utilize reasonable medical management techniques, when paired with requirements to provide an exceptions process, as proposed in these rules, strikes an appropriate balance between the statutory requirement that plans and issuers cover recommended preventive services at no cost and the importance of allowing plans and issuers to impose reasonable limitations in order to contain costs (including costs that would be passed on to consumers in the form of increased premiums) and promote efficient delivery of care. The provision of an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other person acting as the individual's authorized representative) would ensure that covered individuals can access coverage of medically necessary recommended preventive services without cost sharing even if such services are typically not covered or are otherwise subject to reasonable medical management techniques.

With respect to the proposal to require plans and issuers utilizing reasonable medical management techniques to provide an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome, the Departments considered limiting this proposal to contraceptive items only or to a subset of recommended preventive services rather than to all preventive services. However, the Departments concluded that an exceptions process should be required for all recommended preventive services in order to fully implement the requirements under section 2713 of the PHS Act to ensure that plans and issuers provide coverage of recommended preventive services without cost-sharing requirements, consistent with prior guidance. Without such a process, individuals could be forced to pay out-of-pocket or forego the medically necessary form of a recommended preventive service if it

differs from the form covered by their plan or issuer. While prior guidance has generally focused on the use of an exceptions process in the context of contraceptive coverage, it has not been exclusively limited to that context, nor are the Departments aware of any legal or policy reason for limiting applicability of an exceptions process to one or a subset of recommended preventive services. Therefore, the Departments determined it was appropriate to propose that a plan or issuer would be required to provide an exceptions process with respect to any recommended preventive service for which it utilizes medical management techniques in order for such techniques to be considered reasonable.

The Departments considered whether to propose to require plans and issuers to provide coverage without cost sharing of all or a subset of recommended OTC preventive products. The Departments similarly considered whether to propose that the therapeutic equivalence approach be applicable to all or some broader subset of recommended preventive services that are drugs and drug-led combination products, rather than only to contraceptive drugs and drug-led combination products. However, the Departments decided to take an incremental approach, beginning first with recommended contraceptive items. As discussed in section II.A.2 of this preamble, section 2713 of the PHS Act and its implementing regulations do not exclude from their coverage requirement coverage of OTC recommended preventive services. However, in consideration of comments in response to the OTC Preventive Products RFI cautioning against swift implementation of a coverage requirement for all OTC preventive products, the Departments determined it would be advisable to propose an initial implementation of such a requirement, applicable only to recommended OTC contraceptive items. Similarly, the Departments are of the view that it is advisable to initially propose to require the use of a therapeutic equivalence approach for the same set of recommended preventive services—that is, to contraceptive drugs and drug-led combination products—as in prior guidance. This incremental approach to coverage, with respect to recommended OTC contraceptive items and therapeutic equivalence, would provide plans and issuers, providers, retailers, and other interested parties with the opportunity to gather implementation data before the Departments determine whether additional guidance or

rulemaking is appropriate. Further, for the reasons outlined in sections I and II.A of this preamble, it is particularly necessary to support access to contraceptive items at this time.

With respect to the Departments' effort to ensure individuals are made aware that OTC contraceptive items are covered without cost sharing and without a prescription, the Departments also considered proposing to require plans and issuers to create a public-facing web page with comprehensive information about their contraceptive coverage policy, including related to therapeutic equivalents, exceptions processes, network information, and OTC coverage. However, the Departments understand that at least some group health plans do not maintain a website for employee health benefit plans, and the Departments believe more information is needed to assess whether it would be feasible for plans and issuers to provide information about contraceptive coverage on a public website in cases where they do not maintain such a website, such as by entering into a written agreement under which a plan's health insurance issuer or TPA, as applicable, posts the information on its public website where information is normally made available to participants, beneficiaries, and enrollees, on the plan's behalf. The Departments also considered proposing to require the statement to include more information about coverage of therapeutic equivalents and requested comment on this approach, given the Departments' desire to maximize the statement's effectiveness by keeping it brief, and that therapeutic equivalent coverage policies will not differ between plans and thus a plan-specific disclosure may be less essential.

The Departments also considered proposing to require that information about coverage of OTC contraceptive items without cost sharing and without a prescription be included on SBCs. However, due to the space limitations, the Departments are concerned that the SBC would not provide a sufficiently robust disclosure. The Departments decided to seek comment on the SBC's utility for informing participants, beneficiaries, and enrollees of coverage of OTC contraceptive items without cost sharing and without a prescription.

D. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA), the Departments are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. To fairly

evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that the Departments solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of an agency.
- The accuracy of the Departments' estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

As part of the continuing effort to reduce paperwork and respondent burden, the Departments conduct a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing

collections of information in accordance with the PRA. This helps to ensure that the public understands the Departments' collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Departments can properly assess the impact of collection requirements on respondents. Under the PRA, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number.

The Departments have submitted a copy of these proposed rules to OMB in accordance with 44 U.S.C. 3507(d) for review of the proposed (revised) information collections described in this section. The Departments request public comment on these information collections. Commenters may submit

their comments on the Departments' PRA analysis in the same way they send comments in response to this NPRM as a whole (for example, through the <https://www.regulations.gov> website), including as part of a comment responding to the broader NPRM. To obtain copies of the supporting statements and any related forms for the proposed collections, please visit <https://www.reginfo.gov>.

1. Wage Estimates

The Departments generally used data from the Contract Awarded Labor Category (CALC) database tool²¹⁶ to derive average labor costs for estimating the burden and equivalent costs associated with the information collection requirements (ICRs). Table 3 presents the estimated mean hourly wages, which include both base pay and benefits, used in the burden and equivalent cost estimates.

TABLE 3—HOURLY WAGES USED IN BURDEN AND EQUIVALENT COST ESTIMATES

CALC occupation title	Mean hourly wage (\$/hour)
Project Manager/Team Lead	\$146.15
Sr. Developer/Lead	197.27
Designer	107.10
Training Specialist	99.95
Customer Service Representative	45.83
Web Database/Application Developer IV	170.35

2. ICR Regarding Requirements for Contraceptive Disclosure to Participants, Beneficiaries, or Enrollees on the Internet-Based Self-Service Tool (26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211)

The Departments propose in new 26 CFR 54.9815–2715A2(b)(1)(vi), 29 CFR 2590.715–2715A2(b)(1)(vi), and 45 CFR 147.211(b)(1)(vi) that if a participant, beneficiary, or enrollee requests cost-sharing information for any covered contraceptive item or service using a plan's or issuer's internet-based self-service tool or requests such information be provided on paper, a plan or issuer would be required to provide a statement explaining the availability of OTC contraceptive items without a prescription and without cost

sharing, along with a phone number and internet link to where a participant, beneficiary, or enrollee can learn more information about the plan's or policy's contraception coverage. The Departments propose to require plans and issuers to incorporate this disclosure into their existing self-service tool for plan years (in the individual market, policy years) beginning on or after January 1, 2026.

The Departments assume that fully-insured group health plans would depend on health insurance issuers and self-insured group health plans would rely on TPAs to implement the proposed requirements. Based on recent data, the Departments estimate that approximately 1,467 issuers²¹⁷ and 205 TPAs²¹⁸ would implement the

proposed requirements on behalf of plans and issuers.

The Departments assume that issuers and TPAs have already built self-service tools (first applicable for plan years (or policy years) beginning on or after January 1, 2023) and would only be required to modify their existing tools to incorporate the proposed new contraceptive statement. This statement would explain that OTC contraceptive items are covered without a prescription and without cost sharing and would provide a customer service phone number and internet link for a participant, beneficiary, or enrollee that wishes to speak with a customer service representative or gain additional information about the plan's or policy's contraception coverage. The

²¹⁶ The CALC tool was built to assist acquisition professionals with market research and price analysis for labor categories on multiple U.S. General Services Administration (GSA) & Veterans Administration (VA) contracts. The Departments chose to use wages derived from the CALC database because, even though the Bureau of Labor Statistics (BLS) data set is valuable to economists, researchers, and others that would be interested in larger, more macro-trends in parts of the economy, the CALC data set is meant to help market research based on existing government contracts in

determining how much a project/product will cost based on the required skill sets needed. The CALC data set factors the fully burdened hourly rates (base pay + benefits) into the wages whereas BLS does not. CALC occupations and wages provide the Departments with data that aligns more with, and provides more detail related to, the occupations required for the implementation of the requirements in these proposed rules. CALC information and wage rates are available at <https://buy.gsa.gov/pricing/>.

²¹⁷ The Departments' estimate of the number of health insurance companies and the number of issuers (issuer/State combinations) is based on medical loss ratio reports submitted by issuers for the 2022 reporting year. See CMS (2022), "Medical Loss Ratio Data and System Resources," available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

²¹⁸ Non-issuer TPAs estimate is based on data derived from the 2016 benefit year reinsurance program contributions.

introduction of the new contraception statement would impose the following additional burden on issuers and TPAs: ²¹⁹ (1) first-year one-time development costs needed to integrate the contraception statement language into the existing self-service tool. This would involve design changes to the existing web user interface to enable identification of services that would trigger the static statement to the consumer. Additionally, the statement would be required to include a link to information about the participant's, beneficiary's, or enrollee's contraception coverage benefits. Issuers and TPAs would incur one-time costs to create or update a web page to provide this

information; (2) annual costs of programming updates, web page maintenance, and maintaining the list of contraceptive items and services required to be coded to trigger the statement; (3) annual costs associated with training customer service representatives to assist consumers with inquiries related to the new contraceptive statement, and (4) annual costs for customer service representatives to respond to calls. The Departments estimate that for each issuer or TPA, on average, it would take a Project Manager/Team Lead 40 hours (at \$146.15 per hour), a Senior Developer/lead 20 hours (at \$197.27 per hour), a Designer 25 hours (at \$107.10 per hour), and a Web Database/

Application Developer IV 50 hours (at \$170.35 per hour) to integrate the contraception statement language into the existing self-service tool, make design changes, and create or update a web page to provide further details regarding the plan's or policy's contraceptive coverage. The Departments estimate the total hour burden per issuer or TPA would be approximately 135 hours, with an equivalent cost of approximately \$20,986 per issuer or TPA. For all 1,672 issuers and TPAs, the total first-year one-time total hour burden is estimated to be 225,720 hours, with an equivalent total cost of approximately \$35,089,261 as shown in table 4.

TABLE 4—TOTAL FIRST YEAR ESTIMATED ONE-TIME COST AND HOUR BURDEN TO INCORPORATE THE NEW CONTRACEPTIVE STATEMENT IN THE INTERNET-BASED SELF-SERVICE TOOL, MAKE DESIGN CHANGES, AND DEVELOP OR UPDATE A WEB PAGE TO PROVIDE FURTHER DETAILS REGARDING THE PLAN'S OR POLICY'S CONTRACEPTION COVERAGE FOR ALL HEALTH INSURANCE ISSUERS AND TPAS

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,672	1,672	135	225,720	\$35,089,261

In addition to the one-time cost and hour burden estimated above, issuers and TPAs would incur ongoing annual costs for website maintenance, programming updates, and updates to the list of contraceptive items and

services required to be coded to trigger the statement. The Departments estimate that for each issuer and TPA, it would take a Web Database/ Application Developer IV 5 hours (at \$170.35 per hour) to complete this task.

For all 1,672 issuers and TPAs, the total annual maintenance burden related to the new contraceptive statement would be 8,360 hours with an equivalent total cost of approximately \$1,424,126 as shown in table 5.

TABLE 5—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR MAINTENANCE OF INTERNET-BASED SELF-SERVICE TOOL RELATED TO THE NEW CONTRACEPTIVE STATEMENT FOR ALL ISSUERS AND TPAS

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,672	1,672	5	8,360	\$1,424,126

Issuers and TPAs would also incur an ongoing annual burden and cost associated with customer service representative training related to the new contraceptive statement. The Departments assume that the introduction of the new contraception statement would not necessitate hiring additional full-time customer service representatives. Instead, the

Departments expect issuers and TPAs would utilize their existing customer service representatives for this task. Therefore, the Departments estimate that for each issuer and TPA, one Training Specialist would spend 5 hours at a cost of \$99.95 per hour to train 5 customer service representatives on how to respond to participants, beneficiaries, and enrollees if they call

in because of the new contraception statement, who would also require 5 hours to complete the training at a cost of \$45.83 per hour. For all 1,672 issuers and TPAs, the total annual training hour burden would be 50,160 hours, with an equivalent total annual cost of approximately \$2,751,276 as shown in table 6.

TABLE 6—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS TO TRAIN CUSTOMER SERVICE REPRESENTATIVES TO PROVIDE ASSISTANCE TO CONSUMERS RELATED TO NEW CONTRACEPTIVE STATEMENT IN THE INTERNET-BASED SELF-SERVICE TOOL

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,672	1,672	30	50,160	\$2,751,276

²¹⁹Note that the Departments expect self-insured group health plans would rely on TPAs to

implement the proposed requirements and

compensate them accordingly and thereby bear any implementation costs.

After the training, customer service representatives would be expected to respond to the potential increase in calls resulting from the new contraception statement. The Departments estimate

that for each issuer and TPA, it would take 5 customer service representatives 5 hours (at \$45.83 per hour) to complete this task. For all 1,672 issuers and TPAs, the total annual cost of responding to

these calls would be 41,800 hours, with an equivalent total cost of approximately \$1,915,694 as shown in table 7.

TABLE 7—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAs TO RESPOND TO CALLS REGARDING THE NEW CONTRACEPTIVE STATEMENT ON THE INTERNET-BASED SELF-SERVICE TOOL

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,672	1,672	25	41,800	\$1,915,694

Taking into account their segment of jurisdiction over issuers and TPAs, HHS would assume 50 percent of the total

burden, while the Departments of Labor and the Treasury would each assume 25 percent. Tables 8 to 10 display the share

of each Department's total burden hours to implement the new contraceptive statement.

TABLE 8—ESTIMATED HHS SHARE OF TOTAL BURDEN HOURS FOR IMPLEMENTING THE NEW CONTRACEPTIVE STATEMENT

Year	Number of respondents	Number of responses	Burden hours per respondent	Total burden hours
Year 1	836	836	135	112,860
Year 2	836	836	60	50,160
Year 3	836	836	60	50,160
3-Year Average	836	836	85	71,060

TABLE 9—ESTIMATED DEPARTMENT OF LABOR'S SHARE OF TOTAL BURDEN HOURS FOR IMPLEMENTING THE NEW CONTRACEPTIVE STATEMENT

Year	Number of respondents	Number of responses	Burden hours per respondent	Total burden hours
Year 1	418	418	135	56,430
Year 2	418	418	60	25,080
Year 3	418	418	60	25,080
3-Year Average	418	418	85	35,530

TABLE 10—ESTIMATED DEPARTMENT OF THE TREASURY'S SHARE OF TOTAL BURDEN HOURS FOR IMPLEMENTING THE NEW CONTRACEPTIVE STATEMENT

Year	Number of respondents	Number of responses	Burden hours per respondent	Total burden hours
Year 1	418	418	135	56,430
Year 2	418	418	60	25,080
Year 3	418	418	60	25,080
3-Year Average	418	418	85	35,530

The burden related to the Transparency in Coverage disclosure of certain cost-sharing information for HHS is currently approved under OMB control number 0938–1429 (CMS–10715, Transparency in Coverage).²²⁰ HHS will revise this information collection request to account for the

additional burden associated with the contraceptive disclosure. This information collection request was approved as a host for common forms. The burden related to the Transparency in Coverage disclosure of certain cost-sharing information for DOL and Treasury was submitted to OMB for

each respective Department under 0938–1429 as Request for Common Form (RCF) submissions. Upon OMB approval of the RCF submissions, DOL and Treasury will update and submit their information collection requests.

TABLE 11—SUMMARY OF PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting	Total cost
45 CFR 47.211	0938–1429	836	836	85	71,060	\$119	\$8,721,124
26 CFR 54.9815–2715A2	0938–1429	418	418	85	35,530	119	4,360,562

²²⁰ Available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202410-0938-006.

TABLE 11—SUMMARY OF PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS—Continued

Regulation section	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting	Total cost
29 CFR 2590.715–2715A2	0938–1429	418	418	85	35,530	119	4,360,562
Total	1,672	1,672	142,120	17,442,248

The Departments seek comment on the assumptions made and the burden estimates discussed in this section.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)²²¹ requires agencies to analyze options for regulatory relief of small entities and to prepare an initial regulatory flexibility analysis to describe the impact of a proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” The data and conclusions presented in this section amount to the Departments’ initial regulatory flexibility analysis under the RFA.

1. Need for Regulatory Action, Objectives, and Legal Basis

As discussed in section II of this preamble, ongoing complaints and reports of noncompliance with section 2713 of the PHS Act and its implementing regulations indicate that consumers face barriers when attempting to use their health plan or coverage to access recommended preventive services without cost sharing. As a result of these concerns and other significant activity related to preventive services, the Departments are proposing to amend the regulations governing coverage of recommended preventive services in order to ensure that participants, beneficiaries, and enrollees can access the full range of recommended preventive services to which they are entitled, with particular focus on strengthening coverage requirements with respect to recommended contraceptive items for women, as summarized in section IV.A of this preamble. The Departments consider these provisions to be timely and necessary given the documented

challenges faced by consumers in accessing recommended preventive services, as discussed in section IV.B.2.a of this preamble.

2. Number of Affected Small Entities and Compliance Requirements and Costs

The provisions in these proposed rules would affect small entities including health insurance issuers, ERISA-covered non-grandfathered group health plans, non-grandfathered non-Federal governmental plans, and pharmacies.

The Departments anticipate that health insurance issuers, many of which are part of larger health insurance companies or holding groups, would incur costs associated with the provisions in these proposed rules, as described in section IV.B.2.d of this preamble. Health insurance companies are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards,²²² entities with average annual receipts of \$47 million or less are considered small entities for this NAICS code. The Departments expect that few, if any, insurance companies underwriting health insurance policies fall below these size thresholds. Based on data from medical loss ratio annual report submissions for the 2022 reporting year, approximately 87 out of 487 health insurance companies nationwide had total premium revenue of \$47 million or less.²²³ This estimate may overstate the actual number of small health insurance companies that may be affected, since over 76 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding \$47 million.

Plans and plan sponsors would incur some costs associated with meeting the requirements of these proposed rules, whether directly or indirectly through compensation paid to a TPA. However, the Departments anticipate that most of these costs would ultimately be passed on to plan participants, as discussed in section IV.B.2.e of this preamble. As noted in section IV.B.2.b of this preamble, the Departments estimate that there are 499,299 ERISA-covered self-insured, non-grandfathered group health plans²²⁴ and 1,844,520 ERISA-covered fully-insured, non-grandfathered group health plans.²²⁵ The Departments further estimate that there are 76,345 non-grandfathered non-Federal governmental plans sponsored by State and local governmental entities.²²⁶

²²⁴ The Departments estimate that there are 594,404 ERISA-covered self-insured group health plans based on data from the 2022 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2020 County Business Patterns from the Census Bureau. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan (see KFF, 2020 Kaiser Employer Health Benefits Survey, available at <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>). Thus, the Departments have calculated the number of self-insured, non-grandfathered plans in the following manner: 594,404 ERISA-covered self-insured group health plans × (100 percent minus 16 percent) = 499,299.

²²⁵ The Departments estimate that there are 2,195,857 ERISA-covered fully-insured group health plans based on data from the 2022 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2020 County Business Patterns from the Census Bureau. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan (see KFF, 2020 Kaiser Employer Health Benefits Survey, available at <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>). Thus, the Departments have calculated the number of fully-insured, non-grandfathered plans in the following manner: 2,195,857 ERISA-covered fully-insured group health plans × (100 percent minus 16 percent) = 1,844,520.

²²⁶ According to data from the 2022 Census of Governments, there are 90,887 State and local governmental entities (see U.S. Census Bureau, 2022 Census of Governments, available at <https://www.census.gov/data/tables/2022/econ/gus/2022-governments.html>). The Departments assume that each State and local governmental entity sponsors one health plan on average. Therefore, the Departments estimate that there are 90,887 non-Federal governmental health plans. The 2020 KFF Employer Health Benefits Survey reported that 16 percent of employers offer at least one grandfathered plan (see KFF, 2020 Kaiser Employer

²²² Small Business Administration (2023). “Table of Size Standards (last updated March 2023),” available at <https://www.sba.gov/document/support-table-size-standards>.

²²³ Based on internal calculations. See CMS, Medical Loss Ratio Data and System Resources, available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

²²¹ 5 U.S.C. 601, *et seq.*

Due to limited data, the Departments are unable to quantify the percentages of these plans whose sponsors might be considered small entities under the RFA but anticipate that most could be.²²⁷ The Departments request comment and data on the number of plan sponsors that might be small entities, as well as the potential economic impacts of these proposed rules on plan sponsors.

The Departments anticipate that pharmacies would incur costs to update billing processes and systems for covered OTC contraceptive items, as discussed in section IV.B.2.d of this preamble. Pharmacies are classified under NAICS code 456110 (Pharmacies and Drug Retailers) with a size standard of \$37.5 million or less. According to the Census Bureau's Statistics of U.S. Businesses, there are 19,234 firms in the pharmacies and drug stores sector in the U.S. as of 2017.²²⁸ Based on these firms' receipts in 2017 (adjusted for inflation between 2017 and 2023), 18,879, or 98.2 percent, of these firms, accounting for 22.0 percent of receipts in the sector, operate below the SBA size standard and are therefore considered small entities.²²⁹ The Departments request comment on this analysis.

3. Duplication, Overlap, and Conflict With Other Rules and Regulations

The Departments do not anticipate that these proposed rules would cause any duplication, overlap, or conflict with other rules and regulations.

4. Significant Alternatives

The Departments considered various alternatives to the provisions proposed in these proposed rules in section IV.C. In light of this discussion of regulatory alternatives, the Departments are of the view that there are no significant alternatives that would both achieve the

Health Benefits Survey, available at <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>. The Departments therefore estimate there are approximately 76,345 non-grandfathered non-Federal governmental plans.

²²⁷ Based on data from the 2022 MEPS-IC, the 2020 County Business Patterns from the Census Bureau, and the 2020 Kaiser Employer Health Benefits Survey, the Departments estimate that approximately 2,189,444 ERISA-covered non-grandfathered group health plans have less than 100 participants, or approximately 93 percent of the total number of ERISA-covered non-grandfathered group health plans.

²²⁸ U.S. Census Bureau (2017). 2017 SUSB Annual Data Tables by Establishment Industry (Data by Enterprise Receipts Size), available at <https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html>.

²²⁹ Adjusted for inflation between 2017 and 2023 using the consumer price index for all urban consumers (CPI-U). See U.S. Bureau of Labor Statistics (2024), Consumer Price Index, available at <https://www.bls.gov/cpi/tables/supplemental-files/> (Historical CPI-U, August 2024).

policy objectives and goals of these proposed rules and be less burdensome to small entities.

F. Special Analyses—Department of the Treasury

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

G. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing a proposed rule that includes any Federal mandate that may result in expenditures in any one year by State, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. That threshold is approximately \$183 million in 2024. These proposed rules would not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than \$183 million in any one year. As discussed in section IV.B.2.e of this preamble, the Departments expect that most, if not all, of the transfer effects would be incurred by covered individuals (directly or indirectly) and the Federal government. The Departments also anticipate that the total costs to plans, issuers, and pharmacies identified in section IV.B.2.d of this preamble would be below the threshold. The Departments therefore anticipate that State, local, and Tribal governments, in the aggregate, or the private sector would not experience an increase in expenditure that meets this threshold.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism. It requires adherence to specific criteria by Federal agencies in formulating and implementing policies that have “substantial direct effects” on the States, the relationship between the National Government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have

these federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the proposed rules.

In the Departments' view, these proposed rules have federalism implications because they may have direct effects on the States, the relationship between the Federal government and the States, or on the distribution of power and responsibilities among various levels of government. However, the federalism implications are substantially mitigated because, with respect to health insurance issuers, 45 States are either enforcing the requirements related to coverage of specified preventive services (including contraception) without cost sharing pursuant to State law or otherwise are working collaboratively with HHS to ensure that issuers meet these standards. In five States, HHS ensures that issuers comply with these requirements. In addition, seven States have passed laws requiring State-regulated health plans to cover, without cost sharing, certain OTC contraceptive items without a prescription.²³⁰ Therefore, these proposed rules would not be likely to require substantial additional oversight of States by HHS.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the ACA's preventive service requirements are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with” group or individual health insurance coverage “except to the extent that such standard or requirement prevents the application of” a Federal requirement. The conference report accompanying the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

²³⁰ CA, CO, MD, NJ, NM, NY, WA. KFF, (March 2024). “State Private Insurance Coverage Requirements for OTC Contraception Without a Prescription,” available at <https://www.kff.org/other/state-indicator/state-private-insurance-coverage-requirements-for-otc-contraception-without-a-prescription>.

indicates that this is intended to be the “narrowest” preemption of State laws.²³¹

States may continue to apply State law requirements except to the extent that such requirements prevent the application of the preventive services requirements in section 2713 of the PHS Act.²³² State insurance laws that are more stringent than the Federal requirements are unlikely to prevent the application of the preventive services requirements and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the Federal law.

The Departments request comment on the potential impacts on States (if any) associated with these proposed rules.

Throughout the process of developing these proposed rules, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the preventive services requirements, the Departments have attempted to balance the States’ interests in regulating health insurance issuers, and Congress’ intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments’ view that they have complied with the requirements of Executive Order 13132.

Statutory Authority

The Department of the Treasury regulations are proposed to be adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are proposed to be adopted pursuant to the authority contained in 29 U.S.C. 1002, 1135, 1182, 1185d, 1191a, 1191b, and 1191c; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are proposed to be adopted pursuant to the authority contained in sections 2701 through 2763, 2791, 2792, and 2794 of the PHS Act (42 U.S.C. 300gg–63, 300gg–91, 300gg–92 and 300gg–94), as amended; sections 1311 and 1321 of PPACA (42 U.S.C. 13031 and 18041).

²³¹ See Conf. Rep. No. 104–736, pg. 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018, available at <https://www.congress.gov/congressional-report/104th-congress/house-report/736/1>.

²³² See ERISA section 731 and PHS Act section 2724(a); 29 CFR 2590.731(a) and 45 CFR 146.143(a) and 148.210. See also FAQs Part 54, Q11 and Q12 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Douglas W. O’Donnell,

Deputy Commissioner, Internal Revenue Service.

Lisa M. Gomez,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Xavier Becerra,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and IRS propose to amend 26 CFR part 54 as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *
* * * * *

■ **Par. 2.** Section 54.9815–2713 is amended by revising paragraph (a)(4), adding paragraph (a)(6), and revising paragraph (d) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *
(4) *Reasonable medical management.*

(i) Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline described in paragraph (a)(1) of this section, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management

techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

(ii) For a medical management technique to be considered reasonable under paragraph (a)(4)(i) of this section, a plan or issuer must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on a participant, beneficiary, or attending provider (or other person acting as the individual’s authorized representative) that ensures the individual can receive coverage, without cost-sharing requirements, for the item or service specified in a recommendation or guideline described in paragraph (a)(1) of this section, according to the frequency, method, treatment, or setting, that is medically necessary with respect to the individual, as determined by the individual’s attending provider.

* * * * *

(6) *Contraceptive items—(i) Definitions.* For purposes of this paragraph (a)(6)—

(A) *Drug-led combination product* means a combination product, as defined under 21 CFR 3.2(e), that comprises a drug and a device, and for which the drug component provides the primary mode of action.

(B) *Therapeutic equivalent* has the meaning given the term *therapeutic equivalents* in 21 CFR 314.3(b).

(ii) *Over-the-counter contraception.* Subject to § 54.9815–2713A and 45 CFR 147.132 and 147.133, a plan or issuer is not considered to comply with paragraph (a)(1) of this section with respect to a contraceptive item that can be lawfully obtained by a participant or beneficiary without a prescription and for which the applicable recommendation or guideline does not require a prescription, unless the plan or issuer provides coverage for the contraceptive item without requiring a prescription and without imposing any cost-sharing requirements in accordance with paragraph (a)(1) of this section.

(iii) *Therapeutic equivalents.* For purposes of paragraph (a)(4) of this section, a plan’s or issuer’s medical management techniques are not considered to be reasonable unless the plan or issuer provides coverage, without imposing any cost-sharing requirements, for all contraceptive items recommended under paragraph (a)(1) of this section that are drugs or drug-led combination products, other than those items for which there is at least one therapeutic equivalent drug or drug-led combination product, as applicable, for which the plan or issuer provides

coverage without imposing any cost-sharing requirements.

* * * * *

(d) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. Notwithstanding the previous sentence, the provisions of paragraph (a)(4)(ii) of this section apply beginning on [EFFECTIVE DATE OF FINAL RULE] and the provisions of paragraph (a)(6) of this section apply for plan years beginning on or after January 1, 2026. See § 54.9815–1251 for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

■ **Par. 3.** Section 54.9815–2715A2 is amended by:

■ a. Redesignating paragraphs (b)(1)(vi) and (vii) as paragraphs (b)(1)(vii) and (viii);

■ b. Adding new paragraph (b)(1)(vi); and

■ c. Revising paragraph (c)(1).

The addition and revision read as follows:

§ 54.9815–2715A2 Transparency in coverage—required disclosures to participants and beneficiaries.

* * * * *

(b) * * *

(1) * * *

(vi) If a participant or beneficiary requests cost-sharing information for any covered contraceptive item or service, a statement explaining that over-the-counter contraceptive items are covered without a prescription and without cost sharing in accordance with § 54.9815–2713(a)(6), along with a phone number and internet link to where a participant or beneficiary can learn more information about the plan or policy’s contraception coverage.

* * * * *

(c) * * *

(1) The provisions of this section apply for plan years beginning on or after January 1, 2023, with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years beginning on or after January 1, 2024. Notwithstanding the previous sentence, the provisions of paragraph (b)(1)(vi) of this section apply for plan years beginning on or after January 1, 2026.

* * * * *

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons stated in the preamble, the Department of Labor

proposes to amend 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 1. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a–n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Pub. L. 116–260 134 Stat. 1182; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 2. Section 2590.715–2713 is amended by revising paragraph (a)(4), adding paragraph (a)(6), and revising paragraph (d) to read as follows:

§ 2590.715–2713 Coverage of preventive health services.

(a) * * *

(4) *Reasonable medical management.*

(i) Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline described in paragraph (a)(1) of this section, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

(ii) For a medical management technique to be considered reasonable under paragraph (a)(4)(i) of this section, a plan or issuer must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on a participant, beneficiary, or attending provider (or other person acting as the individual’s authorized representative) that ensures the individual can receive coverage, without cost-sharing requirements, for the item or service specified in a recommendation or guideline described in paragraph (a)(1) of this section, according to the frequency, method, treatment, or setting, that is medically necessary with respect to the individual, as determined by the individual’s attending provider.

* * * * *

(6) *Contraceptive items*—(i) *Definitions.* For purposes of this paragraph (a)(6)—

(A) *Drug-led combination product* means a combination product, as defined under 21 CFR 3.2(e), that comprises a drug and a device, and for which the drug component provides the primary mode of action.

(B) *Therapeutic equivalent* has the meaning given the term *therapeutic equivalents* in 21 CFR 314.3(b).

(ii) *Over-the-counter contraception.* Subject to § 2590.715–2713A and 45 CFR 147.132 and 147.133, a plan or issuer is not considered to comply with paragraph (a)(1) of this section with respect to a contraceptive item that can be lawfully obtained by a participant or beneficiary without a prescription and for which the applicable recommendation or guideline does not require a prescription, unless the plan or issuer provides coverage for the contraceptive item without requiring a prescription and without imposing any cost-sharing requirements in accordance with paragraph (a)(1) of this section.

(iii) *Therapeutic equivalents.* For purposes of paragraph (a)(4) of this section, a plan’s or issuer’s medical management techniques are not considered to be reasonable unless the plan or issuer provides coverage, without imposing any cost-sharing requirements, for all contraceptive items recommended under paragraph (a)(1) of this section that are drugs or drug-led combination products, other than those items for which there is at least one therapeutic equivalent drug or drug-led combination product, as applicable, for which the plan or issuer provides coverage without imposing any cost-sharing requirements.

* * * * *

(d) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. Notwithstanding the previous sentence, the provisions of paragraph (a)(4)(ii) of this section apply beginning on [EFFECTIVE DATE OF FINAL RULE] and the provisions of paragraph (a)(6) of this section apply for plan years beginning on or after January 1, 2026. See § 2590.715–1251 for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

* * * * *

■ 3. Section 2590.715–2715A2 is amended by—

■ a. Redesignating paragraphs (b)(1)(vi) and (vii) as paragraphs (b)(1)(vii) and (viii);

- b. Adding new paragraph (b)(1)(vi); and
- c. Revising paragraph (c)(1).

The addition and revision read as follows:

§ 2590.715–2715A2 Transparency in coverage—required disclosures to participants and beneficiaries.

* * * * *

(b) * * *

(1) * * *

(vi) If a participant or beneficiary requests cost-sharing information for any covered contraceptive item or service, a statement explaining that over-the-counter contraceptive items are covered without a prescription and without cost sharing in accordance with § 2590.715–2713(a)(6), along with a phone number and internet link to where a participant or beneficiary can learn more information about the plan or policy’s contraception coverage.

* * * * *

(c) * * *

(1) The provisions of this section apply for plan years beginning on or after January 1, 2023, with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years beginning on or after January 1, 2024. Notwithstanding the previous sentence, the provisions of paragraph (b)(1)(vi) of this section apply for plan years beginning on or after January 1, 2026.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 147 as set forth below:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

- 1. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

- 2. Section 147.130 is amended by revising paragraph (a)(4), adding paragraph (a)(6), and revising paragraph (d) to read as follows:

§ 147.130 Coverage of preventive health services.

(a) * * *

(4) *Reasonable medical management.*

(i) Nothing prevents a plan or issuer from using reasonable medical

management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline described in paragraph (a)(1) of this section, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

(ii) For a medical management technique to be considered reasonable under paragraph (a)(4)(i) of this section, a plan or issuer must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on a participant, beneficiary, enrollee, or attending provider (or other person acting as the individual’s authorized representative) that ensures the individual can receive coverage, without cost-sharing requirements, for the item or service specified in a recommendation or guideline described in paragraph (a)(1) of this section, according to the frequency, method, treatment, or setting, that is medically necessary with respect to the individual, as determined by the individual’s attending provider.

* * * * *

(6) *Contraceptive items—(i) Definitions.* For purposes of this paragraph (a)(6)—

(A) *Drug-led combination product* means a combination product, as defined under 21 CFR 3.2(e), that comprises a drug and a device, and for which the drug component provides the primary mode of action.

(B) *Therapeutic equivalent* has the meaning given the term *therapeutic equivalents* in 21 CFR 314.3(b).

(ii) *Over-the-counter contraception.* Subject to §§ 147.131, 147.132, and 147.133, a plan or issuer is not considered to comply with paragraph (a)(1) of this section with respect to a contraceptive item that can be lawfully obtained by a participant, beneficiary, or enrollee without a prescription and for which the applicable recommendation or guideline does not require a prescription, unless the plan or issuer provides coverage for the contraceptive item without requiring a prescription and without imposing any cost-sharing requirements in accordance with paragraph (a)(1) of this section.

(iii) *Therapeutic equivalents.* For purposes of paragraph (a)(4) of this section, a plan’s or issuer’s medical

management techniques are not considered to be reasonable unless the plan or issuer provides coverage, without imposing any cost-sharing requirements, for all contraceptive items recommended under paragraph (a)(1) of this section that are drugs or drug-led combination products, other than those items for which there is at least one therapeutic equivalent drug or drug-led combination product, as applicable, for which the plan or issuer provides coverage without imposing any cost-sharing requirements.

* * * * *

(d) *Applicability date.* The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. Notwithstanding the previous sentence, the provisions of paragraph (a)(4)(ii) of this section apply beginning on [EFFECTIVE DATE OF FINAL RULE] and the provisions of paragraph (a)(6) of this section apply for plan years (in the individual market, for policy years), beginning on or after January 1, 2026. See § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

* * * * *

- 3. Section 147.211 is amended by—
- a. Redesignating paragraphs (b)(1)(vi) and (vii) as paragraphs (b)(1)(vii) and (viii);

- b. Adding new paragraph (b)(1)(vi); and

- c. Revising paragraph (c)(1).

The addition and revision read as follows:

§ 147.211 Transparency in coverage—required disclosures to participants, beneficiaries, or enrollees.

* * * * *

(b) * * *

(1) * * *

(vi) If a participant, beneficiary, or enrollee requests cost-sharing information for any covered contraceptive item or service, a statement explaining that over-the-counter contraceptive items are covered without a prescription and without cost sharing in accordance with § 147.130(a)(6), along with a phone number and internet link to where a participant, beneficiary, or enrollee can learn more information about the plan or policy’s contraception coverage.

* * * * *

(c) * * *

(1) The provisions of this section apply for plan years (in the individual

market, for policy years) beginning on or after January 1, 2023, with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years (in the

individual market, for policy years) beginning on or after January 1, 2024. Notwithstanding the previous sentence, the provisions of paragraph (b)(1)(vi) of this section apply for plan years (in the

individual market, for policy years) beginning on or after January 1, 2026.

* * * * *

[FR Doc. 2024-24675 Filed 10-23-24; 4:15 pm]

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Part V

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

Advanced Manufacturing Production Credit; Final Rule

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 1**

[TD 10010]

RIN 1545-BQ85

Advanced Manufacturing Production Credit**AGENCY:** Internal Revenue Service (IRS), Treasury.**ACTION:** Final rule.

SUMMARY: This document sets forth final regulations regarding the advanced manufacturing production credit established by the Inflation Reduction Act of 2022 to incentivize the production of eligible components within the United States. Eligible components include certain solar energy components, wind energy components, inverters, qualifying battery components, and applicable critical minerals. These final regulations also address specific recordkeeping and reporting requirements. These final regulations affect eligible taxpayers who produce and sell eligible components and intend to claim the benefit of an advanced manufacturing production credit, including by making elective payment or credit transfer elections.

DATES:

Effective date: These regulations are effective December 27, 2024.

Applicability date: For date of applicability, see §§ 1.45X-1(j), 1.45X-2(f), 1.45X-3(g), and 1.45X-4(d).

FOR FURTHER INFORMATION CONTACT:

Mindy Chou, John Deininger, Derek Gimbel, or Alexander Scott at (202) 317-6853 (not a toll-free number).

SUPPLEMENTARY INFORMATION:**Authority**

This document contains final regulations (final regulations) that amend the Income Tax Regulations (26 CFR part 1) to implement the statutory provisions of section 45X of the Internal Revenue Code (Code). The final regulations are issued by the Secretary of the Treasury or her delegate (Secretary) under the authority granted under sections 45X(a)(3)(B)(i) and (ii), 1502, 6001, 6417(h), 6418(h), and 7805(a) of the Code.

Section 45X(a)(3)(B)(i) of the Code provides a specific delegation of authority to the Secretary to prescribe the form and manner for a taxpayer to make an election such that “a sale of components by such taxpayer to a related person shall be deemed to have been made to an unrelated person.”

Section 45X(a)(3)(B)(ii) provides a specific delegation of authority to the Secretary, “[a]s a condition of, and prior to, any election described in [section 45X(a)(3)(B)(i)],” to “require such information or registration as the Secretary deems necessary for purposes of preventing duplication, fraud, or any improper or excessive amount determined under [section 45X(a)(1)].”

Section 1502 of the Code requires the Secretary to “prescribe such regulations as he may deem necessary in order that the tax liability of any affiliated group of corporations making a consolidated return and of each corporation in the group, both during and after the period of affiliation, may be returned, determined, computed, assessed, collected, and adjusted, in such manner as clearly to reflect the income-tax liability and the various factors necessary for the determination of such liability, and in order to prevent avoidance of such tax liability.” Section 1502 of the Code also provides that the Secretary “may prescribe rules that are different from the provisions of chapter 1 that would apply if such corporations filed separate returns.”

Section 6001 of the Code provides an express delegation of authority to the Secretary, stating that, “[e]very person liable for any tax imposed by this title, or for the collection thereof, shall keep such records, render such statements, make such returns, and comply with such rules and regulations as the Secretary may from time to time prescribe. Whenever in the judgment of the Secretary it is necessary, [s]he may require any person, by notice served upon such person or by regulations, to make such returns, render such statements, or keep such records, as the Secretary deems sufficient to show whether or not such person is liable for tax under this title.”

Sections 6417(h) and 6418(h) of the Code direct the Secretary to issue such regulations or other guidance as may be necessary to carry out the purposes of each section, respectively.

Finally, section 7805(a) of the Code authorizes the Secretary “to prescribe all needful rules and regulations for the enforcement of [the Code], including all rules and regulations as may be necessary by reason of any alteration of law in relation to internal revenue.”

Background*I. Overview of Section 45X*

Section 45X was added to the Code by section 13502(a) of Public Law 117-169, 136 Stat. 1818 (August 16, 2022), commonly known as the Inflation Reduction Act of 2022 (IRA). In general,

for purposes of the general business credit under section 38 of the Code, section 45X provides for the advanced manufacturing production credit (section 45X credit) with respect to eligible components produced by the taxpayer and sold during the taxable year to an unrelated person. Section 45X applies to eligible components produced and sold after December 31, 2022.

Under section 45X(a)(1), the total section 45X credit amount for the taxable year equals the sum of the credit amounts determined under section 45X(b) with respect to each eligible component (as defined in section 45X(c)(1)). Under section 45X(a)(2), any eligible component produced and sold by the taxpayer is taken into account only if the production and sale is in a trade or business of the taxpayer.

Section 45X(a)(3) generally provides rules regarding the sale of eligible components to an unrelated person. However, section 45X(a)(3)(B) provides a special rule whereby if a taxpayer makes an election in the form and manner prescribed by the Secretary, a sale of eligible components by the taxpayer to a related person will be treated as if made to an unrelated person, referred to in these final regulations as the related person election (Related Person Election). As a condition of, and prior to, a taxpayer making the Related Person Election, the Secretary may require such information or registration as the Secretary deems necessary for purposes of preventing duplication, fraud, or any improper or excessive credit amount.

II. Credit Amounts for Eligible Components

Section 45X(b)(1) generally provides the credit amount determined with respect to any eligible component, including any other eligible component it incorporates, subject to the credit phase out rules provided at section 45X(b)(3). Section 45X(b)(1)(A) through (M) and section 45X(b)(2) set forth the credit amounts for each type of eligible component. The credit amounts are generally subject to phase out rules under section 45X(b)(3), but the phase out rules do not apply to any applicable critical mineral. For any eligible component (except applicable critical minerals) sold after December 31, 2029, the credit amount for such component equals the product of the amount determined under section 45X(b)(1) for such component multiplied by the applicable phase out percentage under section 45X(b)(3)(B)(i) through (iv). In the case of an eligible component sold during calendar year 2030, 2031, and

2032, the phase out percentages are 75 percent, 50 percent, and 25 percent, respectively. For any eligible component sold after December 31, 2032, the phase out percentage is zero percent, and no section 45X credit is allowed other than for applicable critical minerals.

Section 45X(b)(4) provides capacity limitations used to compute the credit amount for battery cells under section 45X(b)(1)(K)(ii) and battery modules under section 45(b)(1)(L)(ii). Section 45X(b)(4)(A) provides that the capacity determined with respect to a battery cell or battery module must not exceed a capacity-to-power-ratio of 100:1. Section 45X(b)(4)(B) defines “capacity-to-power-ratio” as the ratio of the capacity of a battery cell or battery module to the maximum discharge amount of such cell or module.

III. Eligible Components

Section 45X(c)(1)(A) defines an eligible component to mean any solar energy component, any wind energy component, any inverter described in section 45X(c)(2)(B) through (G), any qualifying battery component, and any applicable critical mineral. Section 45X(c)(1)(B) clarifies that eligible components do not include any property that is produced at a facility if the basis of any property that is part of such facility is taken into account for purposes of the qualifying advanced energy project credit allowed under section 48C after August 16, 2022 (the date of enactment of the IRA).

Section 45X(c)(2)(A) generally defines an inverter as an end product that is suitable to convert direct current (DC) electricity from one or more solar modules or certified distributed wind energy systems into alternating current (AC) electricity. Section 45X(c)(2)(B) through (G) defines the following different types of eligible inverters: central inverter, commercial inverter, distributed wind inverter, microinverter, residential inverter, and utility inverter.

Section 45X(c)(3)(A) defines a solar energy component as a solar module, photovoltaic cell, photovoltaic wafer, solar grade polysilicon, torque tube, structural fastener, or polymeric backsheet. Section 45X(c)(3)(B) defines these different types of eligible solar energy components as well as a solar tracker.

Section 45X(c)(4)(A) defines a wind energy component as blades, nacelles, towers, offshore wind foundations, and related offshore wind vessels. Section 45X(c)(4)(B) defines these different types of eligible wind energy components.

Section 45X(c)(5)(A) defines a qualifying battery component as electrode active materials, battery cells, and battery modules. Section 45X(c)(5)(B) defines these different types of qualifying battery components.

Section 45X(c)(6) defines applicable critical minerals. The following minerals are eligible for the section 45X credit if converted or purified to specified purities or forms: aluminum, antimony, arsenic, barite, beryllium, bismuth, cerium, cesium, chromium, cobalt, dysprosium, erbium, europium, fluorspar, gadolinium, gallium, germanium, graphite, hafnium, holmium, indium, iridium, lanthanum, lithium, lutetium, magnesium, manganese, neodymium, nickel, niobium, palladium, platinum, praseodymium, rhodium, rubidium, ruthenium, samarium, scandium, tantalum, tellurium, terbium, thulium, tin, titanium, tungsten, vanadium, ytterbium, yttrium, zinc, and zirconium.

IV. Special Rules

Section 45X(d)(1) provides that persons are related to each other for purposes of the section 45X credit if they would be treated as a single employer under section 52(b) of the Code and § 1.52–1(b). Section 52(b) and § 1.52–1(b) generally provide that trades or businesses that are partnerships, trusts, estates, corporations, or sole proprietorships under common control are members of a controlled group and are treated as a single employer. Section 52(b) requires the regulations under section 52(b) to be based on principles similar to the principles that apply under section 52(a), which generally provide that corporations that are members of a controlled group of corporations are treated as a single employer. Section 52(a) provides that a controlled group of corporations is defined with reference to section 1563(a) of the Code. Section 52(b) and § 1.52–1 provide rules based on principles similar to those under section 52(a), but with certain modifications to account for different types of ownership interests.

Section 45X(d)(2) provides that sales of eligible components are taken into account under section 45X only for eligible components that are produced within the United States (including continental shelf areas described in section 638(1) of the Code), or a U.S. territory (including continental shelf areas described in section 638(2)).¹

¹ The preamble to these section 45X final regulations refers to U.S. territory to mean a possession as defined in section 638(2).

Section 45X(d)(3) directs the Secretary to promulgate regulations adopting rules similar to the rules of section 52(d) to apportion credit amounts between estates or trusts and their beneficiaries on the basis of the income of the estates or trusts allocable to each, and to pass-thru any apportioned credit amounts to the beneficiaries.

Section 45X(d)(4) provides that a person is treated as having sold an eligible component to an unrelated person if such component is integrated, incorporated, or assembled into another eligible component that is sold to an unrelated person.

V. Prior Guidance

On October 24, 2022, the Department of the Treasury (Treasury Department) and the IRS published Notice 2022–47, 2022–43 IRB 312, requesting comments on issues arising under section 45X that may require guidance. On December 15, 2023, after full consideration of all the stakeholder input received in response to Notice 2022–47, the Treasury Department and the IRS published a notice of proposed rulemaking and a notice of public hearing (REG–107423–23) in the **Federal Register** (88 FR 86844) to provide guidance on the advanced manufacturing production credit under section 45X (Proposed Regulations). While the Proposed Regulations are summarized in the Summary of Contents and Explanation of Revisions portion of this preamble, the provisions of the Proposed Regulations are explained in greater detail in the preamble to the Proposed Regulations.

On March 6, 2023, the Treasury Department and the IRS published Notice 2023–18, 2023–10 IRB 508, establishing the qualifying advanced energy project allocation program (section 48C(e) program). On June 20, 2023, the Treasury Department and the IRS published Notice 2023–44, 2023–25 IRB 924, providing additional guidance on the section 48C(e) program, including rules for the interaction between sections 45X and 48C. The rules regarding the interaction between sections 45X and 48C provided in Notices 2023–18 and 2023–44 were addressed in the Proposed Regulations and have been incorporated into these final regulations. Section 5.05(2) of Notice 2023–18 and section 3 of Notice 2023–44 are superseded by these final regulations.

Summary of Comments and Explanation of Revisions

I. Overview

This Summary of Comments and Explanation of Revisions summarizes the Proposed Regulations, all substantive comments submitted in response to the Proposed Regulations, and revisions adopted by these final regulations. The Treasury Department and the IRS received 193 written comments in response to the Proposed Regulations. The comments are available for public inspection at <https://www.regulations.gov> or upon request. A public hearing was held in person and telephonically on February 22, 2024. After full consideration of the comments and testimony, these final regulations adopt the Proposed Regulations with modifications in response to the comments and testimony as described in this Summary of Comments and Explanation of Revisions.

Comments merely summarizing the statute or the Proposed Regulations, recommending statutory revisions to section 45X or other statutes, and addressing issues that are outside the scope of this rulemaking (such as revising other Federal regulations and recommending changes to IRS forms) are generally not addressed in this Summary of Comments and Explanation of Revisions or adopted in these final regulations. Some commenters requested additional time to submit comments. The Proposed Regulations required all comments to be received by February 13, 2024; however, comments received later but before these final regulations were substantially developed were carefully considered in drafting these final regulations. The final regulations retain the same basic structure as the Proposed Regulations with certain revisions.

II. General Rules Applicable to the Advanced Manufacturing Production Credit

A. In general

Proposed § 1.45X-1 would have provided general rules regarding the section 45X credit including generally applicable definitions, rules regarding the computation of the credit amount, the definition of “produced by the taxpayer,” the requirement to produce eligible components in the United States, the production and sale in a trade or business requirement, the sale of integrated components, the interaction between sections 45X and 48C, and an anti-abuse rule. Commenters addressed certain aspects

of these proposed rules, as described in Part II. of this Summary of Comments and Explanation of Revisions. These final regulations generally adopt proposed § 1.45X-1, with the modifications described in this Part II. of the Summary of Comments and Explanations of Revisions.

B. Definition of Produced by the Taxpayer

1. In General

Section 45X(a)(1) allows a section 45X credit with respect to each eligible component which is produced by the taxpayer and sold to an unrelated person during the taxable year. Proposed § 1.45X-1(c)(1) would have defined “produced by the taxpayer” to mean a process conducted by the taxpayer that substantially transforms constituent elements, materials, or subcomponents into a complete and distinct eligible component that is functionally different from that which would result from mere assembly or superficial modification of the elements, materials, or subcomponents. Proposed § 1.45X-1(c)(1)(i) would have provided that “produced by the taxpayer” does not include partial transformation that does not result in substantial transformation of constituent elements, materials, and subcomponents into a complete and distinct eligible component as described in proposed § 1.45X-1(c)(1). Proposed § 1.45X-1(c)(1)(ii) would have provided that “produced by the taxpayer” does not include minor assembly of two or more constituent elements, materials, or subcomponents, or superficial modification of the final eligible component, if the taxpayer does not also engage in the process resulting in a substantial transformation described in proposed § 1.45X-1(c)(1). Proposed § 1.45X-1(c)(1)(iii) would have provided examples illustrating the definition of “produced by the taxpayer.”

Several commenters requested that the final regulations specifically state that taxpayers may produce eligible components using recycled materials. While the preamble to the Proposed Regulations stated that primary and secondary production are included in the definition of “produced by the taxpayer,” that issue was not addressed in the text of the Proposed Regulations. The preamble to the Proposed Regulations further stated that primary production involves producing an eligible component using non-recycled materials while secondary production involves producing an eligible component using recycled materials.

The Treasury Department and the IRS agree with the request to clarify the general rule that production includes primary and secondary production, and these final regulations revise proposed § 1.45X-1(c)(1) and (2) to add secondary production to the definition of produced by the taxpayer.

A few commenters stated the definition of “produced by the taxpayer” should be defined consistently with section 263A of the Code to the extent possible and expressed concern that using different definitions will cause “increased technical uncertainty, additional compliance burden, especially for small business taxpayers, and unnecessary litigation and controversy.” Another commenter stated that the Proposed Regulations introduced new definitions, such as “substantial transformation” as production qualifiers, “raising concerns about its apparent conflict with the enacted statutes.”

The term “produced by the taxpayer” is not defined in section 45X, nor is there any indication in section 45X suggesting that Congress intended the use of any existing statutory definition, such as the standard in section 263A. Section 45X provides a credit based on the production of numerous eligible components and a variety of production processes are utilized by manufacturers in the production of these eligible components.

Given the variety of production processes and the highly technical nature of production, the Treasury Department and the IRS, in close coordination with the Department of Energy, proposed a definition that would apply broadly to eligible components. In addition, the proposed definition of “produced by the taxpayer” focused on requiring production of a complete and distinct eligible component and, accordingly, introduces a substantial transformation requirement to distinguish production from partial transformation, mere assembly, and superficial modification. The proposed definition of “produced by the taxpayer” along with the amendment clarifying that production includes secondary production is the appropriate standard to implement the section 45X credit. The definition provides the necessary flexibility to account for the highly technical nature of the production processes associated with eligible components. This standard also ensures that the section 45X credit is claimed by the taxpayer responsible for the key production activity and that such activity occurs in the United States or a United States territory. In contrast to section 45X, section 263A is designed

to ensure that taxpayers capture the direct and indirect costs associated with producing inventoriable goods for capitalization purposes. Moreover, in section 263A, the definition of production applies to a broad range of produced items, whereas the definition in section 45X applies to a limited number of statutorily enumerated eligible components. For these reasons, the Treasury Department and the IRS have concluded that the definition of “produced by the taxpayer” in the Proposed Regulations with the clarifying amendment addressing secondary production appropriately implements section 45X(a)(1)(A), and thus decline to accept the commenter’s recommendation to define “produced by the taxpayer” for purposes of section 45X consistent with the similar term under section 263A.

Several commenters requested that the final regulations provide more specific guidance for certain eligible components to illustrate whether certain activities or processes result in substantial transformation versus partial transformation, mere assembly, or superficial modification. One commenter, for example, requested that the final rules confirm that the term “produced” in the phrase “produced by the taxpayer” is applied within the context of the standard production process of each eligible component, such that the standard production process for each eligible component is deemed to be “substantial transformation” that meets the requirements of proposed § 1.45X–1(c)(1). The commenter provided an example of the production of a solar module, which “involves the final assembly of the other solar components, many of which separately qualify for their own section 45X credit, into the overall module.” The Treasury Department and the IRS recognize that certain eligible components, such as solar modules and battery modules using battery cells, are produced primarily by assembling other components. In these limited cases, the substantial transformation requirement is met by the taxpayer that assembles the constituent components to produce the solar module or battery module using battery cells. Because assembly is the activity that primarily produces these eligible components, the assembly necessary to achieve production of a solar module or battery module using battery cells should not generally be viewed as disqualifying “minor assembly.” The Treasury Department and the IRS also recognize that certain eligible components, such as nacelles,

that have undergone substantial transformation to be considered “produced by the taxpayer” may be produced and sold to a third party in a manner in which only minor assembly remains left to complete. In these cases, provided all other requirements of section 45X are met, the party that produces and sells the eligible components in such manner is not precluded from claiming the section 45X credit. The third party that completes the eligible component by performing minor assembly is not entitled to the section 45X credit because that third party is not considered to produce the eligible component. For these reasons, and for clarity and consistency, the final regulations replace each instance of “mere assembly” in the Proposed Regulations, with “minor assembly.”

A commenter suggested adding an additional example to proposed § 1.45X–1(c)(1)(iii) to clarify whether the integration of electrical subcomponents and software necessary to enable the functionality of an inverter is disqualifying minor assembly, and another commenter requested clarification on whether the coating of a battery separator is “superficial modification” or “substantial transformation.” A few commenters also requested that the final rules further clarify “substantial transformation” to ensure manufacturers claiming section 45X credits are actually producing an eligible component in the United States and suggested using examples to differentiate between substantial and partial transformation for specific components, such as inverters for solar energy.

As previously discussed, section 45X provides a credit based on the production of numerous eligible components and a variety of production processes are utilized by manufacturers in the production of these eligible components. Thus, listing specific production processes for each eligible component is not practicable and could also imply that other variations of production processes do not qualify as production. The Treasury Department and the IRS have determined that the inquiry into whether production activities or processes result in substantial transformation for a specific eligible component is highly fact dependent and conclude that the examples in proposed § 1.45X–1(c)(1)(iii), which are included in the final regulations, provide sufficient guidance to determine what types of activities or production steps do not qualify as substantial transformation.

2. Special Rule for Production of Certain Eligible Components

Proposed § 1.45X–1(c)(2) would have provided that for solar grade polysilicon, electrode active materials, and applicable critical minerals, produced by the taxpayer means processing, conversion, refinement, or purification of source materials, such as brines, ores, or waste streams, to derive a distinct eligible component. Several commenters requested that in addition to processing, conversion, refinement, and purification, the final regulations clarify that the production process includes extraction, while others requested maintaining the position in the Proposed Regulations to exclude costs of extraction. The Treasury Department and the IRS decline to amend the final regulations to expressly include the term “extraction,” as the action of extraction alone does not produce an eligible component. For the discussion and analysis of whether extraction costs are includible as production costs in the production of electrode active materials or applicable critical minerals, see Part IV.E.1.e. of this Summary of Comments and Explanation of Revisions.

Another commenter asked whether recycling aluminum transformer wire (cleaning, melting, and bailing it) to send to an aluminum smelter constitutes “secondary aluminum production.” The Treasury Department and the IRS note that under both proposed § 1.45X–1(c)(2) and § 1.45X–1(c)(2) of these final regulations, substantial transformation for an applicable critical mineral requires that the applicable critical mineral be “processed, converted, refined, or purified to derive a distinct eligible component.” Because a taxpayer in these circumstances would not derive a distinct eligible component, this would not be an eligible component produced by the taxpayer within the meaning of section 45X(a)(1)(A).

These final regulations make a clarifying revision to the definition of produced by the taxpayer under proposed § 1.45X–1(c)(2) so that it references substantial transformation. While no comments were received on this issue, this revision is needed to appropriately align the definition of “produced by the taxpayer” in § 1.45X–1(c)(2) with the requirements to qualify as an eligible taxpayer in § 1.45X–1(c)(3).

3. Eligible Taxpayer

a. In General

Proposed § 1.45X–1(c)(3)(i) would have provided that the taxpayer

claiming a section 45X credit with respect to an eligible component must be the person that performs the actual production activities that bring about a substantial transformation resulting in the eligible component and that sells such eligible component to an unrelated person.

b. Contract Manufacturing Arrangement

Proposed § 1.45X–1(c)(3)(ii)(A) would have provided that, if the production of an eligible component is performed in whole or in part subject to a contract that is a contract manufacturing arrangement, then the party to such contract that may claim the section 45X credit with respect to such eligible component, provided all other requirements in section 45X are met, is the taxpayer that performs the actual production activities that bring about a substantial transformation resulting in the eligible component. The preamble to the Proposed Regulations stated that this proposed rule was intended to provide an administrable rule that provides clarity and certainty in determining which taxpayer may claim the section 45X credit in a contract manufacturing arrangement.

c. Contract Manufacturing Defined

Proposed § 1.45X–1(c)(3)(ii)(B) would have defined the term “contract manufacturing arrangement” to mean any agreement providing for the production of an eligible component if the agreement is entered into before the production of the eligible component to be delivered under the contract is completed. Proposed § 1.45X–1(c)(3)(ii)(B) would have further provided that a routine purchase order for off-the-shelf property is not treated as a contract manufacturing arrangement. Proposed § 1.45X–1(c)(3)(ii)(B) also would have provided that an agreement will be treated as a routine purchase order for off-the-shelf property if the contractor is required to make no more than *de minimis* modifications to the property to tailor it to the customer’s specific needs, or if at the time the agreement is entered into, the contractor knows or has reason to know that the contractor can satisfy the agreement out of existing stocks or normal production of finished goods. This definition of the term “routine purchase order” is based on the definition found in § 1.263A–2(a)(1)(ii)(B)(2)(ii). The Treasury Department and the IRS requested comments in the preamble to the Proposed Regulations on whether this definition should be further clarified or modified. Comments on the definition of manufacturing arrangements are

discussed in Part II.B.3.d. of this Summary of Comments and Explanation of Revisions.

d. Special Rule for Contract Manufacturing Arrangements

Proposed § 1.45X–1(c)(3)(iii) would have explained the special rule allowing parties to a contract manufacturing arrangement to agree on which party to the contract will claim the section 45X credit for eligible components produced subject to such contract. Proposed § 1.45X–1(c)(3)(iv) would have explained the certification requirements for the special rule. Several commenters expressed support for the contract manufacturing rules, but one commenter expressed concern about the treatment of contract manufacturing arrangements in effect prior to the applicability date of the Proposed Regulations. This commenter recommended that the final regulations adopt a safe harbor rule that would function as an exception to the general rule and provide that when one party is contractually entitled to purchase all or substantially all (for example, at least 90 percent) of the output of the fabricator’s production of a given component for the taxable year, the purchaser would be treated as the producer for purposes of section 45X. The Treasury Department and the IRS decline to adopt the commenter’s request to add a safe harbor for contract manufacturing arrangements in place before the applicability date of the Proposed Regulations, but note that a taxpayer may still have the option of applying the special rule in § 1.45X–1(c)(3)(iii) of these final regulations for contract manufacturing arrangements entered into before the applicability date, provided all requirements of the special rule are met.

The preamble to the Proposed Regulations stated that the Treasury Department and the IRS intend for the production cost incurred rules in proposed § 1.45X–3(e)(2) to apply to a credit claimant in a contract manufacturing arrangement. The Treasury Department and the IRS requested comments on whether the proposed rules need further clarification or modification as applied to contract manufacturing arrangements. One commenter requested allowing taxpayers that extract and recycle raw materials and taxpayers that process such materials and incorporate them into applicable critical minerals to apply the contract manufacturing arrangement provisions, in the event that costs of extraction and direct and indirect material costs are not includible in the eligible production costs of

producing an applicable critical mineral. The Treasury Department and the IRS think that the clarification requested by this commenter is no longer necessary because these final regulations permit the inclusion of extraction and certain material costs in the cost of producing an applicable critical mineral if certain requirements are met. See Parts IV.E.1.e. and V.C. of this Summary of Comments and Explanation of Revisions for further discussion.

Proposed § 1.45X–1(c)(3)(v) would have provided examples illustrating the application of the special rule. One commenter requested that proposed § 1.45X–1(c)(3)(v)(C) (*Example 3*) specifically state that the domestic production requirement requires that each wind tower section must be produced in the United States. Proposed § 1.45X–1(c)(3)(v)(C) (*Example 3*) states that a taxpayer could claim a credit for a tower for which it had three different producers each produce one section, provided that the parties all agree that the taxpayer is the sole party that can claim the credit and “all other requirements of section 45X are met.” The Treasury Department and the IRS have determined that the domestic production requirement is already included by this language and thus, additional clarification is not necessary.

Another commenter questioned whether, in proposed § 1.45X–1(c)(3)(v)(C) (*Example 3*), V must sell the completed wind tower to Z for the special rule in proposed § 1.45X–1(c)(3)(iii) to apply. In the example, V enters into a contract manufacturing arrangement with W, X, and Y to make the wind tower, which V sells to Z. All parties to the contract manufacturing arrangement and Z are unrelated. The commenter stated that if V, W, X, and Y sign a certification statement and Y claims the section 45X credit, Y could claim the section 45X credit in 2025 because that is when it sold the eligible component to V. Contrary to the commenter’s conclusion with respect to Y’s ability to claim a section 45X credit in 2025, Y is not eligible for the section 45X credit until the eligible component, which is the wind tower comprised of all three wind tower sections, is produced and then sold to an unrelated person (in this case Z). Under the contract manufacturing arrangement, W, X, and Y are collectively viewed as producing the entire eligible component (wind tower) because all three sections together result in a single eligible component. Along with the production of the entire wind tower, V has to sell the completed wind tower to an

unrelated person before the designated party is eligible for a section 45X credit.

A commenter suggested revisions to the proposed rules to allow an allocation of any portion of the credit to parties who extract the mineral and perform initial refining processes, rather than allowing a credit to the taxpayer that purifies the critical mineral to the statutory minimum. Section 45X(c)(6) defines a list of applicable critical minerals with specific minimum purity levels which must be met for the taxpayer to have produced an eligible component. The Treasury Department and the IRS do not have the authority to modify these statutory requirements. However, the Treasury Department and the IRS seek to clarify that a taxpayer who performs extracting and refining activities may benefit from the contract manufacturing provisions described in this section. The final regulations accordingly add § 1.45X-1(c)(3)(v)(D) (*Example 4*) to demonstrate how the contract manufacturing provisions may apply in the situation described by the commenter.

4. Timing of Production and Sale

Proposed § 1.45X-1(c)(4)(i) would have provided that production of eligible components for which a taxpayer is claiming a section 45X credit may begin before December 31, 2022, but production of eligible components must be completed, and the eligible components must be sold, after December 31, 2022. Proposed § 1.45X-1(c)(4)(ii) would have provided an example illustrating the timing of the production and sale rule in proposed § 1.45X-1(c)(4)(i).

Some commenters requested further clarity on when production and sale of an eligible component may take place. One commenter requested that the final rules provide that a specific minimum percentage of production of an eligible component must occur after 2022 and that no sale of the eligible component be reported by the taxpayer before 2023. The Treasury Department and the IRS decline to adopt these percentage test suggestions because Congress clearly recognized that some production could occur prior to 2023 but did not specify an exact amount of production that must occur in taxable years either before or after 2023. Moreover, if a sale occurred before 2023, which requires a facts and circumstances analysis based in part on contractual terms, the component sold is not eligible for the section 45X credit. Accordingly, the final regulations adopt proposed § 1.45X-1(c)(4)(i) and the example in proposed § 1.45X-1(c)(4)(ii) without modification.

Another commenter stated that the Proposed Regulations do not specify whether production activities that qualify for the section 45X credit have to occur after the effective date of the rule or whether the activities can be retroactive. The commenter suggests the final rule specify the applicable period for the production activities and provide a reasonable transition rule for taxpayers who produce eligible components before the effective date of the final regulations. The Treasury Department and the IRS have determined that the Proposed Regulations and these final regulations are clear as to the timing of production and sale requirements under section 45X. For clarification, and as described earlier, section 13502(c) of the IRA provides that section 45X applies to components produced and sold after December 31, 2022. The preamble to the Proposed Regulations clarified application of the section 45X effective date, stating that each of proposed §§ 1.45X-1 through 1.45X-4 would have applied to eligible components for which production is “completed” and sales occur after December 31, 2022, and during taxable years ending on or after the date of publication of these final regulations. Proposed § 1.45X-1(c)(4)(i) would have provided that production of eligible components may begin before December 31, 2022, and only required production of eligible components be completed, and sales must occur, after December 31, 2022. Proposed § 1.45X-1(c)(4)(ii) would have provided an example illustrating proposed § 1.45X-1(c)(4)(i). These final regulations adopt these proposed rules. The Treasury Department and the IRS do not have statutory authority to provide for a section 45X credit in a situation in which production was completed on or before December 31, 2022.

C. Produced in the United States

Consistent with section 45X(d)(2), proposed § 1.45X-1(d)(1) would have provided that sales are taken into account for purposes of the section 45X credit only for eligible components that are produced within the United States, as defined in section 638(1) of the Code, or a United States territory. Proposed § 1.45X-1(d)(2) would have clarified that constituent elements, materials, and subcomponents used in the production of eligible components are not subject to the domestic production requirement provided in proposed § 1.45X-1(d)(1). Thus, while the eligible component must be produced domestically, its

constituent elements, materials, and subcomponents need not be.²

Some commenters agreed with this approach in the Proposed Regulations. According to these commenters, the Proposed Regulations appropriately allowed the credit for eligible components produced in the United States provided that the activities necessary to transform them into eligible components are conducted in the United States. Furthermore, these commenters expressed concern that a contrary rule ignores the reality that some constituent elements, materials, and subcomponents cannot be sourced in the United States and would discourage investment in production activities that rely on foreign-sourced constituent elements, materials, and subcomponents. However, other commenters disagreed with the proposed approach, suggesting that allowing eligible components to be produced using foreign subcomponents is inconsistent with the section 45X credit’s objective of incentivizing domestic production of eligible components.

The Treasury Department and the IRS note that, while section 45X specifically requires domestic production of an eligible component for credit eligibility, it is silent regarding the location of production or sourcing of constituent elements, materials, and subcomponents. Accordingly, imposing a domestic production requirement for constituent elements, materials, and subcomponents is not supported by the statutory language of section 45X. For these reasons, the Treasury Department and the IRS decline to adopt these suggestions and adopt the proposed rule without change.

Beyond agreement or disagreement with this proposed rule, some commenters inquired about its scope. One commenter asked whether the domestic production rule applicable to eligible components also applies to eligible components that are both an eligible component and a “constituent element, material or subcomponent” of another eligible component. Another commenter asked whether raw materials and intermediate products used to produce eligible components are included in the definition of “constituent elements, materials or subcomponents.”

² See Joint Committee on Taxation, *General Explanation of Tax Legislation Enacted in the 117th Congress*, JCS-1-23 (December 21, 2023) at 267 (“The credit only applies to sales where the eligible components are produced within the United States or U.S. territories. This requirement is not intended to apply to subcomponents or materials used to produce eligible components.”).

The Treasury Department and the IRS confirm that all three of these categories of items are included in the definition of “constituent elements, materials, and subcomponents.” An eligible component that is a “constituent element, material or subcomponent” of another eligible component is not subject to the domestic production rule, and thus, an eligible component may incorporate another eligible component that is also a foreign-sourced “constituent element, material or subcomponent” and still be eligible for a section 45X credit. In addition, raw materials and intermediate products generally qualify as constituent elements, materials, or subcomponents.

A commenter also requested confirmation in the final regulations that there is no requirement that eligible components be *used* in the United States for section 45X credit eligibility. Consistent with section 45X(d)(2), proposed § 1.45X–1(d)(1) would have provided that sales are taken into account for purposes of the section 45X credit only for eligible components that are produced within the United States (or a United States territory). Thus, the Proposed Regulations specify only the location of production of the eligible component, and not the location of the sale or the use of such eligible component. Accordingly, the Treasury Department and the IRS conclude that the additional confirmation requested by the commenter is unnecessary, as there would be no statutory basis for requiring domestic sale or use.

D. Production and Sale in a Trade or Business

Proposed § 1.45X–1(e) would have stated that an eligible component must be produced and sold in a trade or business of the taxpayer, with the term “trade or business” defined as a trade or business within the meaning of section 162 of the Code.

A commenter requested that proposed § 1.45X–1(e) expressly include eligible components that are produced and then used to replace defective units pursuant to a contractual obligation entered into at the time of the original sale. The commenter stated that these warranty transactions do not appear to violate any of the anti-abuse provisions at proposed § 1.45X–1(i). If an eligible component is produced and sold to an unrelated person in the normal course of a trade or business, and the eligible component is then replaced with a new eligible component produced by the same taxpayer, there is no new sale to an unrelated person for the replacement eligible component, but the replacement eligible component relates back to the

original sales transaction. The precise issue is whether section 45X should be read to effectively incentivize the production of two eligible components where each is related to a single sales transaction. The Treasury Department and the IRS decline to adopt this suggestion because only one credit may be claimed with respect to the sale of an eligible component.

E. Sale of Integrated Components

1. In General

Section 45X(d)(4) provides that, for purposes of section 45X, a person is treated as having sold an eligible component to an unrelated person if such component is integrated, incorporated, or assembled into another eligible component which is sold to an unrelated person. Proposed § 1.45X–1(f)(1) was intended to be consistent with section 45X(d)(4), and thus would have provided that a taxpayer is treated as having produced and sold an eligible component to an unrelated person if such component is integrated, incorporated, or assembled into another eligible component that is then sold to an unrelated person.

Although no comments were received regarding this general rule in the Proposed Regulations, the Treasury Department and the IRS want to clarify that section 45X(d)(4) provides only for deemed sale treatment and not deemed production. A taxpayer must produce (rather than merely purchase or acquire) an eligible component that is integrated, incorporated, or assembled into another eligible component that is then sold to an unrelated person in order for the deemed sale rule to apply. Thus, these final regulations clarify that a taxpayer is “treated as having sold” an eligible component to an unrelated person if the taxpayer produced such component and the component is integrated, incorporated, or assembled into another eligible component that is then sold to an unrelated person, rather than “treated as having produced and sold” an eligible component that the taxpayer did not itself produce that is then integrated, incorporated, or assembled into another eligible component and then sold to an unrelated person. Proposed § 1.45X–1(f)(1) is clarified accordingly in these final regulations.

2. Application of Section 45X(d)(4) to Produced Products

Proposed § 1.45X–1(f)(2)(i) would have clarified that a taxpayer may claim a section 45X credit for each eligible component that the taxpayer produces and sells to an unrelated person, including any eligible component the

taxpayer produces that was used as an element, material, or subcomponent and integrated, incorporated, or assembled into another complete and distinct eligible component or another complete and distinct product (that is not itself an eligible component) that the taxpayer also produces and sells to an unrelated person. Proposed § 1.45X–1(f)(2)(ii) would have provided an example of the credit eligibility of a sale of a product with incorporated eligible components to a related person.

Commenters expressed agreement with proposed § 1.45X–1(f)(2)(i). One commenter stated that the clarification in § 1.45X–1(f)(2)(i) avoids the need for some vertically integrated producers of eligible components that incorporate the eligible components into another product that is not an eligible component to artificially restructure in order to create an intercompany sale. Another commenter requested a flexible interpretation of section 45X(d)(4) that would apply the section 45X credit as an additive credit across the supply chain to the final assembler. The commenter stated such an interpretation is consistent with the language in section 45X(b)(1), which provides that the section 45X credit amount is determined with respect to any eligible component, including any eligible component it incorporates. For example, in the commenter’s view, a taxpayer that produces a structural fastener would be eligible to receive a credit for its production of an eligible component as would the integrator, incorporator, assembler of the structural fastener into another eligible component. Although the Treasury Department and the IRS agree that section 45X(b)(1) provides that the credit amount is determined with respect to any eligible component produced by the taxpayer, including any eligible component the taxpayer incorporates that was also produced by the taxpayer, the Treasury Department and the IRS disagree with the implication that the calculation of the section 45X credit should be additive based on the number of eligible components used to produce an item in a case in which each eligible component is not produced by the taxpayer. Only the producer of an eligible component would be eligible for a section 45X credit. Proposed § 1.45X–1(f)(1) and (2) are finalized with no modifications because the Treasury Department and the IRS conclude the rules provide clarity as currently written.

F. Interaction Between Sections 45X and 48C

1. In General

Consistent with section 45X(c)(1)(B), proposed § 1.45X–1(g)(1) would have provided that, for purposes of section 45X, an eligible component must be produced at a section 45X facility and does not include any property (produced property) that is produced at a facility if the basis of any property that produces the produced property is eligible property that is included in a section 48C facility and is taken into account for purposes of a credit allowed under section 48C (section 48C credit) after August 16, 2022.

Proposed § 1.45X–1(g)(2)(i) would have provided that a section 45X facility includes all tangible property that comprises an independently functioning production unit that produces one or more eligible components. Proposed § 1.45X–1(g)(2)(ii) would have provided that a production unit is comprised of the tangible property that substantially transforms material inputs to complete the production process of an eligible component.

Proposed § 1.45X–1(g)(3)(i) would have provided that a section 48C facility includes all eligible property included in a qualifying advanced energy project for which a taxpayer receives an allocation of section 48C credits and claims such credits after August 16, 2022. Proposed § 1.45X–1(g)(3)(ii) would have defined eligible property that is included in a section 48C facility.

With respect to the proposed rules on the interaction between sections 45X and 48C various comments were received. A commenter requested that the final rules not apply section 45X(c)(1)(B) to disallow the section 45X credit in the event that the taxpayer claiming the section 45X credit incorporates into its eligible component a subcomponent that was produced by a section 48C facility, as long as that same taxpayer was not eligible for the section 48C credit with respect to the section 48C facility that produced the subcomponent. Revisions were made to these final regulations to clarify that the only equipment, or other tangible property, that must be included in the section 45X facility is the equipment used by the taxpayer that is necessary to be considered the producer of the potential eligible component. As further explained later, if production of a subcomponent (or like property) is not a requirement to be considered the producer under section 45X, then the equipment that is part of that section 48C facility used to produce the

subcomponent is not part of the section 45X facility. As a result, it is possible that the same taxpayer could receive a section 48C credit on equipment used to produce a subcomponent (or like property), and a section 45X credit on the production of an eligible component.

One commenter requested an example to help determine whether an eligible component produced at a facility located “adjacent” to a section 48C facility that received a section 48C credit impacts eligibility for the section 45X credit. The physical proximity of a section 45X facility to a section 48C facility does not determine whether a product may be an eligible component and revisions to these final regulations were made to clarify that point.

Another commenter requested more clarity to determine whether a facility that shares upstream raw materials and processes as a section 48C facility is still eligible for a section 45X credit and requested examples of upstream supply chains and processes that are eligible and ineligible for both sections 48C and 45X. Several commenters requested additional clarity regarding the meaning and extent of the term “production unit.”

Based on the comments and further consideration of the Proposed Regulations, revisions were made in these final regulations to simplify the rules and examples in proposed § 1.45X–1(g)(1) through (4). Specifically, these final regulations make clear that the general rule is that property that would otherwise qualify as an eligible component (otherwise qualified property) is only an eligible component if the property is produced at a section 45X facility and no part of that section 45X facility is also a section 48C facility. These final regulations also revise the definition of section 45X facility, clarifying that a section 45X facility is the independently functioning tangible property used by the taxpayer that is necessary to be considered the producer of the otherwise qualified property within the meaning of § 1.45X–1(c)(1) or (2), as applicable. The Proposed Regulations would have relied on the concept of a “production unit” to define the scope of a section 45X facility, but there was overlap between the term production unit as proposed and the definition of a section 45X facility. After careful consideration, the Treasury Department and the IRS determined that the proposed term “production unit” introduced unnecessary complexity, particularly in light of the revisions to the definition of section 45X facility in these final regulations. Accordingly,

these final regulations do not use the term production unit.

The definition of section 45X facility in these final regulations includes independently functioning tangible property that is used and that is necessary for the otherwise qualified property to be considered produced by the taxpayer within the meaning of § 1.45X–1(c)(1) or (2), as applicable. Accordingly, tangible property used to produce a subcomponent or other property which is later integrated, incorporated, or assembled into a distinct and final eligible component is not part of the section 45X facility. This rule, however, does not apply if the other property is of a type that the taxpayer must produce for the resulting eligible component to be considered produced by the taxpayer. This analysis can depend on the definition of the eligible component being ultimately produced. For example, section 45X(c)(3)(B)(ii)(I)(bb) requires a single manufacturer to produce a photovoltaic wafer through formation of an ingot from polysilicon and subsequent slicing. Thus, the section 45X facility with respect to the photovoltaic wafers would include any equipment that is tangible property that is used to produce the ingot and any equipment that is tangible property that is used to perform the subsequent slicing. In contrast, equipment used to produce front glass of a solar module under section 45X(c)(3)(B)(v) could be excluded from a section 45X facility because it is not necessary to use the front glass equipment to be considered the producer of the solar module for section 45X. This rule may benefit a taxpayer that produces a subcomponent or other property of an eligible component using equipment that is also eligible property for purposes of the section 48C credit, but uses other equipment not related to the section 48C credit to produce the eligible component.

Lastly, these final regulations add a specific rule for contract manufacturing arrangements in § 1.45X–1(g)(2)(ii) to address any uncertainty with respect to how to determine a section 45X facility in that situation. This rule clarifies that the tangible property used to produce the otherwise qualified property (regardless of who claims the credit) must be considered.

4. Examples of Sections 45X and 48C Interaction

Proposed § 1.45X–1(g)(4)(i) through (v) would have provided examples to illustrate the application of these rules. A few commenters requested that, contrary to proposed § 1.45X–1(g)(4)(ii) (*Example 2*), ingot and wafer production

should be treated as two separate manufacturing activities so that an ingot facility is eligible for the section 48C credit while a wafer facility is eligible for the section 45X credit. As required by section 45X(c)(3)(B)(ii)(I)(bb), however, a photovoltaic wafer must be produced by a single manufacturer either by forming an ingot from molten polysilicon (for example, Czochralski method) and then subsequently slicing it into wafers, or by forming molten or evaporated solar grade polysilicon or deposition into a sheet or layer (that is, thin-film deposition). As the statute requires production of a photovoltaic wafer by a single manufacturer that both forms an ingot and slices it into wafers, it is not appropriate to treat ingot and wafer production as two separate manufacturing activities. Rather, as both activities are necessary, it follows that the tangible property used to complete each activity must be within a single section 45X facility with respect to the eligible component produced. No comments were received on the other examples in proposed § 1.45X-1(g)(4)(i) through (v). However, all of the examples in proposed § 1.45X-1(g)(4)(i) through (v) were modified consistent with the revisions in § 1.45X-1(g)(1) through (3).

A few commenters suggested that parties in a contract manufacturing arrangement under proposed § 1.45X-1(c)(3)(iii) could circumvent the prohibition under section 45X(c)(1)(B) that disallows a section 45X credit for items produced at a section 48C facility. More specifically, commenters suggested that a taxpayer could enter into a contract manufacturing arrangement under proposed § 1.45X-1(c)(3)(iii) to produce photovoltaic wafers that are then used to manufacture photovoltaic cells. If the taxpayer itself integrated, incorporated, or assembled the photovoltaic cells into solar modules, the taxpayer might claim a section 45X credit for all three products upon their sale, even though the photovoltaic wafers were manufactured by the contract manufacturer at a section 48C facility while the photovoltaic cells were manufactured at a section 45X facility, if the taxpayer was unaware that the contract manufacturer manufactured the photovoltaic wafers at a section 48C facility. The Proposed Regulations did not allow this, and the final regulations would continue to disallow a section 45X credit for the photovoltaic wafers in this scenario. To the extent that the photovoltaic wafers were produced at a section 48C facility, the photovoltaic wafers would not qualify as an eligible

component to any party to the contract manufacturing arrangement. As described earlier, these final regulations add a rule in § 1.45X-1(g)(2)(ii) to clarify the rules in a contract manufacturing arrangement situation, and the examples in § 1.45X-1(g)(4) have also been modified.

G. Anti-Abuse Rule

As explained in the preamble to the Proposed Regulations, proposed § 1.45X-1(i)(1) would have provided a general anti-abuse rule that would make the section 45X credit unavailable in extraordinary circumstances in which, based on a consideration of all the facts and circumstances, the primary purpose of the production and sale of an eligible component is to obtain the benefit of the section 45X credit in a manner that is wasteful, such as discarding, disposing of, or destroying the eligible component without putting it to a productive use. Proposed § 1.45X-1(i)(1) would have provided that the rules of section 45X and the section 45X regulations must be applied in a manner consistent with the purposes of section 45X and the section 45X regulations (and the regulations in this chapter under sections 6417 and 6418 related to the section 45X credit). A purpose of section 45X and the section 45X regulations (and the regulations in this chapter under sections 6417 and 6418 related to the section 45X credit) is to provide taxpayers an incentive to produce eligible components in a manner that contributes to the development of secure and resilient supply chains. Accordingly, the section 45X credit is not allowable if the primary purpose of the production and sale of an eligible component is to obtain the benefit of the section 45X credit in a manner that is wasteful, such as discarding, disposing of, or destroying the eligible component without putting it to a productive use. A determination of whether the production and sale of an eligible component is inconsistent with the purposes of section 45X and the section 45X regulations (and the regulations in this chapter under sections 6417 and 6418 related to the section 45X credit) is based on all facts and circumstances. Proposed § 1.45X-1(i)(2) would have provided an example illustrating this anti-abuse rule.

One commenter suggested that, in applying the anti-abuse rule, the taxpayer claiming a section 45X credit should not be held responsible for the activities of the customer after a sale has occurred (unless the customer is a related entity); the determination of whether a component is defective should be made at the factory gate; and

“productive use” should include the sale of an eligible component to an entity engaged in the business of directly (such as a utility) or indirectly (such as a project developer) deploying the batteries. Proposed § 1.45X-1(i)(1) provides that a determination of whether the production and sale of an eligible component is inconsistent with the purposes of section 45X and the section 45X regulations (and the regulations under sections 6417 and 6418 related to the section 45X credit) is based on all the facts and circumstances. Under a facts and circumstances analysis, no single factor is determinative, and the considerations listed by the commenter would have to be evaluated in the context of all other facts and circumstances. The Treasury Department and the IRS thus decline to list specific parameters that automatically result in a finding of a favorable or unfavorable primary purpose.

Another commenter suggested adding additional examples to proposed § 1.45X-1(i) to make clear that the section 45X credit is never allowable with respect to any cost the primary purpose of which is to increase the amount of the section 45X credit. While both examples offered by the commenter involve possible abuses, the anti-abuse rule is intended to cover a broad range of abuses. Proposed § 1.45X-1(i) would have provided that a determination of whether the production and sale of an eligible component is inconsistent with the purposes of section 45X and the section 45X regulations is based on all facts and circumstances, and no single factor is determinative. Accordingly, the Treasury Department and the IRS decline to adopt the commenter's suggestion.

III. Sale to Unrelated Person

A. In General

Proposed § 1.45X-2(a) would have stated that the amount of the section 45X credit for any taxable year is equal to the sum of the credit amounts determined under section 45X(b) (and described in proposed §§ 1.45X-3 and 1.45X-4) with respect to each eligible component that is produced by the taxpayer and, during the taxable year, sold by the taxpayer to an unrelated person. Applicable Federal income tax principles apply to determine whether a transaction is in substance a sale (or the provision of a service, or some other disposition). Proposed § 1.45X-2(a) also would have cross-referenced proposed § 1.45X-1(d) and (e) for additional requirements relating to sales. Section

45X(d)(1) provides that persons are treated as related to each other if such persons would be treated as a single employer under the regulations prescribed under section 52(b). Proposed § 1.45X–2(b) would have provided definitions of the terms “person,” “related person,” and “unrelated person” for purposes of the section 45X credit.

A few commenters requested additional clarity in the final rules on how a sale is defined and when a sale is determined for the purpose of section 45X. One commenter recommended that a sale be defined for 45X as the point when a taxpayer signs a binding contractual agreement with a buyer in the taxpayer’s trade or business for the purchase of an eligible component. Section 45X provides special rules addressing sales of eligible components to related persons that may be treated as sales to unrelated persons, and a general rule that an eligible component produced and sold by the taxpayer is only taken into account if such production and sale is in a trade or business of the taxpayer, but otherwise does not provide any specific rules regarding whether and when a sale has occurred. Proposed § 1.45X–2(a) would have provided that applicable Federal income tax principles apply to determine whether a transaction is in substance a sale (or the provision of a service, or some other disposition), and those same principles apply in determining when a transaction is a sale. More specific rules on the determination of whether and when a sale occurs is beyond the scope of these final regulations. Accordingly, the Treasury Department and the IRS maintain the standard in proposed § 1.45X–2(a) and finalize the proposed rule without modification.

Another commenter requested further clarification on the sale of eligible components in two scenarios. In the first scenario, Company A is a U.S. based company producing eligible components that it sells to Company B, which is not directly using the eligible components but resells to Company C to use in a manufacturing process or otherwise in its trade or business. For this first scenario, the commenter requested clarification on whether Company A is eligible to claim the section 45X credit for the domestic production and sale of the eligible components. In the second scenario, the commenter assumed the same facts as in the first scenario, but Company B or Company C is using Company A’s eligible component outside the United States. In this second scenario, the commenter requested clarification on

whether Company A remains eligible to claim the section 45X credit for the domestic production and sale of the eligible components.

In both scenarios under the Proposed Regulations, Company A is eligible to claim the section 45X credit for the domestic production and sale of the eligible components if the production and sale is in a trade or business of Company A, regardless of whether the first purchaser is using the eligible component in its trade or business or sells to a subsequent purchaser for use in the subsequent purchaser’s trade or business, and regardless of whether the purchaser or subsequent purchaser uses the eligible component in the United States. Because the Proposed Regulations clearly provide this result, no further revision is necessary in these final regulations.

B. Special Rules for Sales to a Related Person

Consistent with section 45X(a)(3)(A), proposed § 1.45X–2(c)(1) would have provided a special rule that, for purposes of section 45X(a), a taxpayer is treated as selling an eligible component to an unrelated person if such component is sold to such person by a person who is related to the taxpayer. Proposed § 1.45X–2(c)(2) would have provided an example to illustrate this special rule.

Given the importance of whether parties are related persons or unrelated persons, a commenter proposed a particular fact pattern and requested clarification on who the purchaser is and whether they were related or unrelated to the producer and seller. In general, section 45X(d)(1) and proposed § 1.45X–2(b)(2) provides that persons are treated as related to each other if such persons would be treated as a single employer under the regulations prescribed under section 52(b). A request for application of the section 52(b) regulations by the Treasury Department and the IRS to a particular fact pattern requiring a facts and circumstances analysis is outside the scope of these final regulations.

Another commenter requested that the final rules clarify whether a Related Person Election is necessary when eligible components are sold by the producer to an unrelated person, who subsequently sells them to a person related to the producer of such eligible components. The commenter proposes amending proposed § 1.45X–2(c) to clarify that direct or indirect sales to a related person qualify if the producer knows or has reason to know the unrelated person is intending to sell the same eligible components to a person

related to the producer. To provide assurance to commenter, a Related Person Election is not necessary in this situation because the first sale was to an unrelated party, but the Treasury Department and the IRS have determined that the rules as set out by proposed § 1.45X–2(c) do not require further clarification on this point. In addition, if there are circumstances in which purported sales are made to unrelated persons to circumvent the requirements of section 45X, proposed § 1.45X–2(a) provides that applicable Federal income tax principles apply to determine whether a transaction will be respected as a sale.

C. Related Person Election

1. Availability of Election—In General

Proposed § 1.45X–2(d)(1)(i) would have provided that a taxpayer may make a Related Person Election under section 45X(a)(3)(B) to treat a sale of eligible components by such taxpayer to a related person as if made to an unrelated person. As a condition of, and prior to, a taxpayer making a Related Person Election, the Secretary may require such information or registration as the Secretary deems necessary for purposes of preventing duplication, fraud, or any improper or excessive credit amount determined under section 45X(a)(1). Proposed § 1.45X–2(d)(1)(ii) would have provided the rules regarding the Related Person Election for members of a consolidated group (as defined in § 1.1502–1(h)).

One commenter requested that taxpayers be allowed to exercise the Related Person Election in situations where it is difficult for the taxpayer to determine whether two entities are related under the section 52(b) regulations. Allowing the exercise of the Related Person Election as commenter requested would conflict with the language in section 45X(d)(1), which requires the parties be treated as a single employer under the section 52(b) regulations, not just that it be difficult to determine the status. Therefore, these final regulations do not adopt the commenter’s request.

2. Anti-Abuse Rule

Proposed § 1.45X–2(d)(4) would have provided an anti-abuse rule for the Related Person Election consistent with section 45X(a)(3)(B)(ii) for preventing duplication, fraud, or any improper or excessive amount of the section 45X credit. Proposed § 1.45X–2(d)(4)(i) would have provided that a Related Person Election may not be made if the taxpayer fails to provide the information required by proposed § 1.45X–2(d)(2)

with respect to the relevant eligible components, the taxpayer provides information that shows such components were put to an improper use as defined in proposed § 1.45X-2(d)(4)(ii) or were defective as defined in proposed § 1.45X-2(d)(4)(iii), or such components were actually put to an improper use or were defective.

Proposed § 1.45X-2(d)(4)(ii) would have provided that an eligible component is put to an improper use if it is so used by the related person to which the eligible component is sold. The term improper use would mean a use that is wasteful, such as discarding, disposing of, or destroying the eligible component without putting it to a productive use. The Treasury Department and the IRS requested comments in the preamble to the Proposed Regulations on the definition of the term improper use and whether any clarifications to its scope are necessary.

Proposed § 1.45X-2(d)(4)(iii) would have provided that a defective component means a component that does not meet the requirements of section 45X and the section 45X regulations. The Treasury Department and the IRS requested comments in the preamble to the Proposed Regulations on the definition of defective components and whether clarifications to its scope are necessary.

In response to the Treasury Department and the IRS's request for comments, one commenter requested additional guidance regarding when an eligible component can be deemed defective under section 45X. The commenter recommended clarification that an eligible component can be deemed defective and therefore ineligible for a tax credit under section 45X "up until the point of sale of the eligible component to an unrelated party." However, in circumstances where a taxpayer has made a valid Related Person Election, a sale of eligible components to a related person is treated as if made to an unrelated person, thus making a sale to an unrelated person not relevant for section 45X credit determination purposes. The preamble to the Proposed Regulations stated that the Treasury Department and the IRS are concerned that the Related Person Election may be used by taxpayers to claim a credit for eligible components that are defective, not capable of being used for its intended purpose, do not meet the requirements for the section 45X credit, and therefore are not eligible for the section 45X credit. The Treasury Department and the IRS agree that if an eligible component is not defective at the time

of sale, defects arising after the point of sale may occur in the ordinary course of a business and do not generally raise the improper claim concerns regarding defective components described in the Preamble to the Proposed Regulations. Accordingly, the final rules modify proposed § 1.45X-2(d)(4)(iii) to clarify that components with respect to which defects arise after the deemed sale are not considered defective components for purposes of the anti-abuse rule.

Another commenter suggested that the definitions of improper use and defective components should provide an exception for a defective component that can be sold or given to a related or unrelated person conducting legitimate recycling operations and allowing defective components to earn a section 45X credit provided they are properly recycled in the United States. The Treasury Department and the IRS decline to adopt this request because section 45X does not authorize allowing a section 45X credit for a defective component that does not meet the definition of an eligible component and is not capable of being used for its intended purpose without further substantial modification.

D. Sales of Integrated Components to a Related Person

1. In General

Section 45X(d)(4) provides that for purposes of section 45X, a person is treated as having sold an eligible component to an unrelated person if such component is integrated, incorporated, or assembled into another eligible component that is sold to an unrelated person. See Part II.E. of this Summary of Comments and Explanation of Revisions for rules applicable to eligible components that are integrated, incorporated, or assembled into other eligible components and sold to an unrelated person.

Proposed § 1.45X-2(e)(1) would have provided that, for purposes of section 45X and the section 45X regulations (and the regulations in this chapter under sections 6417 and 6418 related to the section 45X credit), a taxpayer that produces and sells an eligible component to a related person who then integrates, incorporates, or assembles the taxpayer's eligible component into another complete and distinct eligible component that is subsequently sold to an unrelated person may claim a section 45X credit in the taxable year of the sale to the unrelated person.

Proposed § 1.45X-2(e)(2) would have provided examples to illustrate the treatment of sales of multiple incorporated eligible components to

related and unrelated persons. One commenter questioned the practical application of the requirements in proposed § 1.45X-2(e)(2)(i) (*Example 1*) and expressed concern that although Company X and Y are related, the proposed rule would require a significant amount of coordination of information. This coordination would be necessary for the credit to be claimed in the proper tax year in which the ultimate product (photovoltaic cells produced by Y using photovoltaic wafers produced by X and purchased by Y) was sold to Company Z. Proposed § 1.45X-2(e)(2)(i) (*Example 1*) illustrates the rule in section 45X(d)(4) requiring an ultimate actual sale to an unrelated person of an eligible component. Because section 45X(d)(4) expressly conditions the deemed sale on an actual subsequent sale to an unrelated person by the related person, the Treasury Department and the IRS do not have the authority to change this statutorily imposed conditional timing requirement despite any practical difficulties taxpayers may experience in obtaining such information. Taxpayers may, however, make a Related Person Election as illustrated in the example in § 1.45X-2(e)(3)(ii) and claim the section 45X credit upon the sale to the related person. This would obviate the need for such taxpayer to know when the related person actually makes the subsequent sale to an unrelated person. For these reasons, the final regulations adopt proposed § 1.45X-2(e)(2)(i) (*Example 1*) without modification.

2. Special Rules Applicable to Related Person Election

Proposed § 1.45X-2(e)(3) would have provided that if a taxpayer makes a valid Related Person Election under section 45X(a)(3)(B)(i) and proposed § 1.45X-2(d)(1), and the taxpayer produces and then sells an eligible component to a related person, who then integrates, incorporates, or assembles the taxpayer's eligible component into another complete and distinct eligible component that is subsequently sold to an unrelated person, the taxpayer's sale of the eligible component to the related person is treated (solely for purposes of the section 45X credit and the section 45X regulations, and the regulations in this chapter under sections 6417 and 6418 related to the section 45X credit) as if made to an unrelated person in the taxable year in which the sale to the related person occurs. One commenter expressed support for this proposed rule, as it applies thoughtfully to vertically integrated electric vehicle manufacturers engaging in sales of

multiple integrated eligible components to related and unrelated persons (with a Related Person Election). No other comments were received on this special rule, so it is adopted in these final regulations without revision.

IV. Eligible Components

A. In General

Proposed § 1.45X-3(a) would have defined the term “eligible component” as any solar energy component, any wind energy component, any inverter, any qualifying battery component, and any applicable critical mineral, as each is respectively defined in the Proposed Regulations. For solar energy components, wind energy components, inverters, and qualifying battery components, proposed § 1.45X-3(b) through (e) would have provided definitions, rules for determining the credit amount, and documentation requirements. Proposed § 1.45X-3(f) would also have provided rules for applying the phase out of the section 45X credit. Proposed § 1.45X-4 would have provided such information for applicable critical minerals (other than rules for applying the phase out, which does not apply to applicable critical minerals).

Commenters addressed certain aspects of these proposed rules, as described in this Part IV. of the Summary of Comments and Explanation of Revisions. These final regulations generally adopt the rules as proposed in § 1.45X-3, with the modifications described in this Part IV. of the Summary of Comments and Explanation of Revisions.

B. Solar Energy Components—in General

Consistent with section 45X(c)(3), proposed § 1.45X-3(b) would have provided that solar energy component means a solar module, photovoltaic cell, photovoltaic wafer, solar grade polysilicon, torque tube, structural fastener, or polymeric backsheet. Several commenters requested that the final regulations add other non-listed solar energy components (or alternatively, to provide a safe harbor) to allow for section 45X credit eligibility. Examples of other non-listed solar energy components commenters raised include the encapsulant used to protect the photovoltaic cells and hold the entire system together; charge transport materials used in photovoltaic cells; photovoltaic wire; solar mirror facets; and solar thermal receivers. A commenter also suggested adopting a functionally interdependent and integral part test analogous to section 48

of the Code to include additional solar energy components.

Section 45X(c)(3) expressly identifies the qualifying solar energy components that are eligible for the section 45X credit. The Treasury Department and the IRS do not have the authority to add to the set of solar energy components that are identified by statute, for example, by applying a functional interdependence or integral part test. For this reason, the Treasury Department and the IRS decline to adopt the commenters' requests in these final regulations.

1. Photovoltaic Cell

Proposed § 1.45X-3(b)(1)(ii) would have provided that the credit amount for a photovoltaic cell is equal to the product of 4 cents multiplied by the capacity of such photovoltaic cell. The proposed rule provided that the capacity of each photovoltaic cell is expressed on a direct current watt basis and capacity is the nameplate capacity in direct current watts using Standard Test Conditions (STC), as defined by the International Electrotechnical Commission (IEC). The proposed rule further provided that in the case of a tandem technology produced in serial fashion, such as a monolithic multijunction cell composed of two or more sub-cells, capacity must be measured at the point of sale at the end of the single cell production unit; and, in the case of a four-terminal tandem technology produced by mechanically stacking two distinct cells or interconnected layers, capacity must be measured for each cell at each point of sale.

A few commenters expressed concern that the proposed rule treats two-terminal and four-terminal tandem technologies differently, and that by labeling a monolithic two-terminal configuration as composed of sub-cells, the proposed rule would require this technology to be measured as a single cell rather than two distinct tandem cells. In contrast, proposed § 1.45X-3(b)(1)(ii) provides that mechanically stacked four-terminal tandem technology consists of “two distinct cells.” In the commenters' view, the proposed rule would allow four-terminal cells to be measured before they are combined, while two-terminal cells would be measured after they are combined, resulting in higher capacity for four-terminal cells and increased credit amounts for four-terminal cells. A commenter also suggested that proposed § 1.45X-3(b)(1)(ii) is currently problematic for future tandem technology cell production and, perhaps unintentionally, directs the

development of certain tandem technologies.

The Treasury Department and the IRS agree with the commenters' concerns regarding disparate treatment between four-terminal and two-terminal cells and capacity and credit amounts. Accordingly, these final regulations revise proposed § 1.45X-3(b)(1)(ii) to add additional text at the end as follows: “Where that cell is sold to a customer who will use it as the bottom cell in a tandem module, its capacity should be measured with the customer's intended top cell placed between the bottom cell and the one-sun light source.”

2. Photovoltaic Wafer

Consistent with section 45X(c)(3)(B)(ii), proposed § 1.45X-3(b)(2)(i) would have defined a photovoltaic wafer to mean a thin slice, sheet, or layer of semiconductor material of at least 240 square centimeters that comprises the substrate or absorber layer of one or more photovoltaic cells. A photovoltaic wafer must be produced by a single manufacturer by forming an ingot from molten polysilicon (for example, Czochralski method) and then subsequently slicing it into wafers, forming molten or evaporated polysilicon into a sheet or layer, or depositing a thin-film semiconductor photon absorber into a sheet or layer (that is, thin-film deposition).

Some commenters suggested revisions to the definition of a photovoltaic wafer to include non-traditional methods of producing wafers. For example, a commenter requested expanding the definition to include wafers produced by any of the emerging ‘kerfless’ or ‘direct’ wafer technologies, as well as the polysilicon used by these technologies. The Treasury Department and the IRS have determined that direct wafer technologies fall within the statutory definition of photovoltaic wafers, if they are produced directly from evaporated solar grade polysilicon but disagree that any further clarification is needed in these final regulations.

A commenter requested that the final regulations clarify that ingots must be produced within the United States for solar wafers to be eligible for the section 45X credit. As required by section 45X(c)(3)(B)(ii)(I)(bb), to qualify for a section 45X credit, a photovoltaic wafer must be produced by a single manufacturer either by forming an ingot and then subsequently slicing it into wafers, or by forming molten or evaporated solar grade polysilicon or deposition into a sheet or layer. Thus,

to qualify for a section 45X credit, both the ingot and the wafer must be produced domestically in accordance with section 45X(d)(2). Proposed § 1.45X-1(d)(2) would have clarified that constituent elements, materials, and subcomponents used in the production of eligible components are not subject to the domestic production requirement provided in proposed § 1.45X-1(d)(1). Because the ingot production is part of the wafer production, ingots are not constituent elements, materials, or subcomponents. The Treasury Department and the IRS have determined it is unnecessary to specify that the ingot must be domestically produced as section 45X and proposed § 1.45X-3(b)(2)(i) require the wafer to be domestically produced, which includes production of the ingot. See also Part II.F.2. of this Summary of Comments and Explanation of Revisions for a discussion of proposed § 1.45X-1(g)(4)(ii) (*Example 2*) concerning the production of ingots and wafers.

3. Polymeric Backsheet

Consistent with section 45X(c)(3)(B)(iii), proposed § 1.45X-3(b)(3) would have defined polymeric backsheet to mean a sheet on the back of a solar module that acts as an electric insulator and protects the inner components of such module from the surrounding environment.

Certain commenters recommended that the term be considered to include a product that qualifies solely based on the property's functionality and not the property's composition, in order for backsheets made of glass to be eligible components. One commenter stated that its product is used in solar panels and therefore its request is consistent with Congressional intent of expediting the transition to clean energy, the underlying intent of section 45X to create parity among technologies, and incentivizing the creation of a U.S.-based supply chain for current and future solar technologies. The commenter thought that other energy components were defined based on their function, not their "composition" (for example, inverter, photovoltaic cell, and solar module) and believes that glass performs the same function as a backsheet made of plastic. The commenter suggested that clarity on whether a backsheet made of glass is part of the definition of "polymeric backsheet" is important because it will help with decisions on pursuing a section 48C credit and for avoiding penalties under section 6694 of the Code (preparer penalty) or section 6662 of the Code (substantial understatement). Another commenter

recommended adding back glass as a solar energy component because it is better for the environment in that a domestic facility that uses recycled glass from retired solar modules is "cleaner" than an overseas facility.

In considering these comments, the Treasury Department and the IRS determined that the best reading of the statute is that the term "polymeric backsheet" is limited to backsheets made of polymeric materials that also meet the functional definition provided in section 45X(c)(3)(B)(iii). This excludes most glass backsheets because they are typically not composed of a polymer, but of soda-lime glass. The final regulations add the word "polymeric" into the definition as a clarification. In reaching this determination, the Treasury Department and the IRS considered that when drafting the statute, Congress affirmatively included "polymeric" in the term and this inclusion should be given effect. Thus, the final regulations clarify that the definition is limited to a sheet on the back of solar modules composed, at least in part, of a polymer, that acts as an electric insulator and protects the inner components of such module from the surrounding environment.

4. Solar Grade Polysilicon

Consistent with section 45X(c)(3)(B)(iv), proposed § 1.45X-3(b)(4) would have defined solar grade polysilicon to mean silicon that is suitable for use in photovoltaic manufacturing and purified to a minimum purity of 99.999999 percent silicon by mass. A commenter requested that the final rules state that the production of the silicon gas that is used for direct wafer production may receive the section 45X credit for polysilicon for the mass of silicon in the gas. The Treasury Department and the IRS have determined, in close consultation with the Department of Energy, that gas used for direct wafer production includes molecules of silicon contained within another substance. Accordingly, such gas is not a complete and distinct eligible component within the meaning of proposed § 1.45X-1(c)(1)(i). For this reason, the Treasury Department and the IRS decline to adopt this request in these final regulations.

A few commenters requested guidance on how the purity level for solar grade polysilicon should be determined. One commenter requested that the final rules clarify that only impurities that are "material to the industry" should be counted in determining whether the minimum purity level is met. Because these final

regulations add the purity standard in SEMI Specification PV17-1012 Category 1 to proposed § 1.45X-3(b)(4), which distinguishes between material and immaterial impurities, the Treasury Department and the IRS decline to adopt the commenter's suggestion of clarifying that the statutory purity level refers only to impurity levels that are "material to the industry."

A commenter recommended adopting the standards for polysilicon feedstock in SEMI Specification PV17-1012. The Treasury Department and the IRS, in close consultation with the Department of Energy, have determined that SEMI Specification PV17-1012 Category 1 meets the purity standard of 99.999999 percent, while Categories 2 through 5 do not. The Treasury Department and the IRS thus agree with this request but only for Category 1, and these final regulations accordingly revise proposed § 1.45X-3(b)(4) to add the purity standard in SEMI Specification PV17-1012 Category 1.

5. Solar Module

Proposed § 1.45X-3(b)(5)(ii) would have stated that the credit amount for a solar module is equal to the product of 7 cents multiplied by the capacity of such module. The proposed rule also provided that the capacity of each solar module is expressed on a direct current watt basis, and that capacity is the nameplate capacity in direct current watts using STC, as defined by the IEC. A commenter requested producers be required to use "flash" values to determine the value of the tax credit for modules. The preamble to the Proposed Regulations explained that nameplate capacity is an appropriate, accurate, and consistent standard for the measurement of solar module capacity that can be used to measure the capacity of other eligible components. Using an industry standard such as nameplate capacity that is widely applicable to various eligible components provides greater taxpayer certainty, reduces taxpayer compliance burdens, and aids IRS administration. For these reasons, the Treasury Department and the IRS have determined that the best application of the statute is to require the use of nameplate capacity to measure the capacity of a solar module. The Treasury Department and the IRS therefore decline to adopt this suggestion to permit the use of "flash" value capacity measurements in these final regulations.

6. Solar Tracker

Consistent with section 45X(c)(3)(B)(vi), proposed § 1.45X-3(b)(6) would have provided that a solar

tracker means a mechanical system that moves solar modules according to the position of the sun and to increase energy output. Section 45X(c)(3)(B)(vii) provides that torque tubes (as defined in proposed § 1.45X-3(b)(7)) or structural fasteners (as defined in proposed § 1.45X-3(b)(8)) are solar tracker components that are eligible components for purposes of the section 45X credit.

Commenters requested that the definition of a solar tracker (not an eligible component) in section 45X(c)(3)(B)(vi) be modified to allow solar thermal collectors, heliostats, and fixed tilt systems (additional items) to be solar tracker components as defined in section 45X(c)(3)(B)(vii). A solar tracker is defined in 45X(c)(3)(B)(vi) as a “mechanical system that moves solar modules according to the position of the sun to increase energy output.” To be a solar tracker, a device must be a mechanical system that *moves* a solar module. The Treasury Department and the IRS do not have authority to expand the definition of solar tracker to include additional items such as the ones suggested that increase energy output without moving solar modules. Moreover, modification of the definition of a solar tracker in the manner the commenter requested would not result in such additional items qualifying as eligible components because a solar tracker is not a solar energy component that is an eligible component under section 45X(c)(1)(A)(i). Section 45X(c)(3)(B)(vii) provides that torque tubes and structural fasteners are the only two solar tracker components that may qualify as eligible components. The Treasury Department and the IRS do not have authority to expand the categories of eligible solar tracker components. For these reasons, the Treasury Department and the IRS decline to adopt this request in the final regulations.

7. Torque Tube

Consistent with section 45X(c)(3)(B)(vii)(I), proposed § 1.45X-3(b)(7)(i) would have provided that torque tube means a structural steel support element (including longitudinal purlins) that: (i) is part of a solar tracker; (ii) is of any cross-sectional shape; (iii) may be assembled from individually manufactured segments; (iv) spans longitudinally between foundation posts; (v) supports solar panels and is connected to a mounting attachment for solar panels (with or without separate module interface rails); and (vi) is rotated by means of a drive system.

Commenters suggested various statutory revisions to the definition of torque tube in section

45X(c)(3)(B)(vii)(I). A commenter recommended replacing the definition with a more generalized term such as “Tracker Structural Frame” to allow for other common solar collector morphologies. Another commenter requested removing or revising section 45X(c)(3)(B)(vii)(I)(dd) to include single foundation mounted structures or ground-mounted carousel structures. One commenter proposed clarifying that aluminum bearings, steel damper arms, steel saddle brackets, and steel bottom brackets are included in the definition of torque tubes or structural fasteners. Alternatively, the commenter suggested providing either: (i) a non-exclusive list of items that are included in the definition of torque tube or structural fasteners, or (ii) a test similar to the functionally interdependent or integral part tests under proposed § 1.48-9(f)(2)(ii) and (f)(3) to determine when a component is included in the definition of a torque tube or structural fastener.

Because section 45X(c)(3)(B)(vii)(I) specifically defines torque tube for purposes of section 45X, the Treasury Department and the IRS do not have the authority to expand the definition of torque tubes and solar tracker components in the final regulations to include additional solar energy components. As previously discussed, the Treasury Department and the IRS also lack authority to incorporate a functional interdependence or integral part tests that would allow other components not specified in the statute to qualify for the section 45X credit. For these reasons, the Treasury Department and the IRS decline to adopt these comments in the final regulations.

8. Structural Fastener

Consistent with section 45X(c)(3)(B)(vii)(II), proposed § 1.45X-3(b)(8)(i) would have defined a structural fastener to mean a component that is used: (i) to connect the mechanical and drive system components of a solar tracker to the foundation of such solar tracker; (ii) to connect torque tubes to drive assemblies; or (iii) to connect segments of torque tubes to one another.

Several commenters requested revisions to the definition of structural fastener in proposed § 1.45X-3(b)(8)(i). For example, commenters requested that the definition of structural fastener be extended “beyond steel and iron torque tubes to specifically allow for innovations made from other materials,” such as durable plastic; that solar frames made from greenhouse gas reducing steel and roll-form fabricated frames (as opposed to the current industry standard, imported extruded aluminum

frames) qualify as structural fasteners, solar modules, or torque tubes; and that the definition of structural fasteners be expanded to include those that secure the photovoltaic module to the torque tube or module interface rails. The Treasury Department and the IRS do not have the authority to expand the definition of structural fasteners and solar tracker components in the final regulations to include additional solar energy components. However, the Treasury Department and the IRS note that a component that is used for any of the functions described in section 45X(c)(3)(B)(vii)(II) would be considered a structural fastener for purposes of section 45X. The Treasury Department and the IRS think that proposed § 1.45X-3(b)(8)(i) and the statutory definition of a structural fastener is sufficiently clear to address the requested clarifications. Proposed § 1.45X-3(b)(8)(i) is therefore adopted in these final regulations without revision.

Proposed § 1.45X-3(b)(8)(iii) would have required that, for substantiation purposes, a taxpayer must document that a structural fastener is used in a manner described in proposed § 1.45X-3(b)(8)(i)(A), (B), or (C), with a bill of sale or other similar documentation that explicitly describes such use. One commenter specifically supported the substantiation requirement for structural fasteners in proposed § 1.45X-3(b)(8)(iii). Another commenter requested the final rules require taxpayers to substantiate that the structural fasteners for which they are claiming the section 45X credit include only the manufactured component (bolt or rivet) itself. The Treasury Department and the IRS have determined there is no need for further clarification of the substantiation requirement for structural fasteners in addition to the specific requirements relating to use in proposed § 1.45X-3(b)(8)(iii) and the general substantiation requirements in section 6001 of the Code. For this reason, the Treasury Department and the IRS decline to adopt this comment in the final regulations.

C. Wind Energy Components

1. In General

Consistent with section 45X(c)(4), proposed § 1.45X-3(c) would have provided that a wind energy component means a blade, nacelle, tower, offshore wind foundation, or related offshore wind vessel. Commenters generally requested expanding proposed § 1.45X-3(c) to include other non-listed wind energy components such as structural fasteners. Section 45X(c)(4) specifically provides a list of qualifying wind energy

eligible components. The Treasury Department and the IRS do not have the authority to expand the statutorily enumerated list of wind energy components eligible for a section 45X credit. For this reason, the Treasury Department and the IRS decline to adopt the commenters request in these final regulations.

2. Nacelle

Consistent with section 45X(c)(4)(B)(iii), proposed § 1.45-3(c)(3)(i) would have defined a nacelle to mean the assembly of the drivetrain and other tower-top components of a wind turbine (with the exception of the blades and the hub) within their cover housing.

A commenter stated that guidance should distinguish between manufacturing of eligible wind energy components (for example, in a manufacturing facility) from the installation of wind energy components at the relevant project site, as the latter does not constitute manufacturing or production of eligible components. The Treasury Department and the IRS have determined that the definition of “produced by the taxpayer” provided in proposed § 1.45X-1(c)(1) is sufficient to clarify that production of an eligible component requires substantially transforming constituent elements, materials, or subcomponents into a complete and distinct eligible component that is functionally different from that which would result from disqualifying minor assembly or superficial modification of the elements, materials or subcomponents.

Another commenter requested that the final regulations recognize that, where a new drivetrain and associated equipment (the pitch bearing, pitch system, main shaft, main bearing, gearbox, flex coupling, and slip ring) are produced for use in repowering of existing wind turbines and installed into an existing nacelle cover housing with certain other used equipment (including yaw bearing and baseplate), the nacelle is eligible for the section 45X credit. Under this commenter’s approach, the drivetrain of the nacelle must be new to be eligible for the section 45X credit. Another commenter also suggests inclusion of a “reasonable computation” of the section 45X credit for repowered eligible components.

The Treasury Department and the IRS note that repowering is a form of onsite re-manufacturing that is typically accomplished through a hybrid of primary and secondary production that utilizes a mix of existing and new components. To produce a nacelle within the definition of proposed

§ 1.45X-3(c)(3)(i), the taxpayer would need to meet the requirements of the definition of “produced by the taxpayer” provided in proposed § 1.45X-1(c)(1), including by substantially transforming the combination of existing and new subcomponents into a new nacelle that is distinct from the original nacelle. In some circumstances, nacelle repowering may constitute production of an eligible component. For example, a taxpayer that manufactures and installs a new drivetrain and associated subcomponents within housing atop a wind tower will be considered to have substantially transformed the combination of new and existing subcomponents, so that taxpayer will have produced an eligible nacelle. In contrast, a taxpayer that merely replaces the controller in a nacelle with a new one will not have substantially transformed the combination of new and existing subcomponents, so that taxpayer will not have produced an eligible nacelle. Routine maintenance or part replacement would fall under the definition of disqualifying minor assembly or “superficial modification.”

3. Related Offshore Wind Vessel

Consistent with section 45X(c)(4)(B)(iv), proposed § 1.45X-3(c)(4)(i) would have defined related offshore wind vessel to mean any vessel that is purpose-built or retrofitted for purposes of the development, transport, installation, operation, or maintenance of offshore wind energy components. Proposed § 1.45X-3(c)(4)(i) would have clarified that a vessel is purpose-built for development, transport, installation, operation, or maintenance of offshore wind energy components if it is built to be capable of performing such functions and it is of a type that is commonly used in the offshore wind industry. Proposed § 1.45X-3(c)(4)(i) would have further clarified that a vessel is retrofitted for development, transport, installation, operation, or maintenance of offshore wind energy components if such vessel was incapable of performing such functions prior to being retrofitted, the retrofit causes the vessel to be capable of performing such functions, and the retrofitted vessel is of a type that is commonly used in the offshore wind industry.

Under proposed § 1.45X-3(c)(4)(ii), consistent with section 45X(b)(1)(F)(i), the credit amount for a related offshore wind vessel would have been equal to 10 percent of the sales price of the vessel. Under the Proposed Regulations the sales price of the vessel does not include the price of maintenance,

services, or other similar items that may be sold with the vessel. For a related offshore wind vessel with respect to which a Related Person Election under section 45X(a)(3)(B)(i) has been made, the election would not cause the sale price of such vessel to be treated as having been determined with respect to a transaction between uncontrolled taxpayers for purposes of section 482 of the Code and the regulations thereunder.

One commenter requested clarification on the valuation of retrofitted offshore wind vessels and requested guidance on whether the section 45X credit applies to the cost of the retrofit itself, the value-add of the retrofit, the cost of the final sale of a retrofitted vessel, or some other amount. The Treasury Department and the IRS confirm that the credit amount specified in section 45X(b)(1)(F)(i)—ten percent of the sales price of such vessel—specifically applies to any related offshore wind vessel which is purpose-built or retrofitted as provided in section 45X(c)(4)(B)(iv).

A commenter stated that the definition of an offshore wind vessel is too narrow and that more standard vessel types (for example, tugboats and barges) that are capable of doing offshore wind work should also be eligible for the section 45X credit if they are being constructed or retrofitted for the purpose of offshore wind work. The Treasury Department and the IRS note that section 45X(c)(4)(B)(iv) and proposed § 1.45X-3(c)(4)(i) would have defined a related offshore wind vessel to mean “any vessel” that is purpose-built or retrofitted for purposes of the development, transport, installation, operation, or maintenance of offshore wind energy components. Proposed § 1.45X-3(c)(4)(i) would have clarified that a vessel is purpose-built for development, transport, installation, operation, or maintenance of offshore wind energy components if it is built to be capable of performing such functions and it is of a type that is commonly used in the offshore wind industry. Proposed § 1.45X-3(c)(4)(i) would have further clarified that a vessel is retrofitted for development, transport, installation, operation, or maintenance of offshore wind energy components if such vessel was incapable of performing such functions prior to being retrofitted, the retrofit causes the vessel to be capable of performing such functions, and the retrofitted vessel is of a type that is commonly used in the offshore wind industry. Thus, if a vessel meets the definition of a related offshore wind vessel in proposed § 1.45X-3(c)(4)(i), there are no limitations as to the type of

vessel that may be an eligible component.

The commenter's requested clarification would require an application of the standard in proposed § 1.45X-3(c)(4)(i) to specific cases for which a categorical determination of eligibility for additional vessel types would not be appropriate in these final regulations because such a determination would depend on the specific facts of each case.

Although no comments were received on proposed § 1.45X-3(c)(4)(i), the Treasury Department and the IRS revise proposed § 1.45X-3(c)(4)(i) in these final regulations to clarify that Federal income tax principles apply in determining the accuracy of the sales price used to calculate the section 45X credit. This revision provides greater certainty as to what principles apply for purposes of the section 45X credit and is in addition to the specific exclusions from a vessel's sales price in proposed § 1.45X-3(c)(4)(i), which included maintenance, services, or other similar items that may be sold with the vessel.

4. Total Rated Capacity of the Completed Wind Turbine

Proposed § 1.45X-3(c)(6) would have provided that, for purposes of proposed § 1.45X-3(c), the total rated capacity of the completed wind turbine means, for the completed wind turbine for which a blade, nacelle, offshore wind foundation, or tower was manufactured and sold, the nameplate capacity at the time of sale as certified to the relevant national or international standards, such as IEC 61400, or American National Standards Institute (ANSI)/American Clean Power Association (ACP) 101-1-2021, the Small Wind Turbine Standard (Standard). Under proposed § 1.45X-3(c)(6), certification of the turbine to such Standards must be documented by a certificate issued by an accredited certification body and the total rated capacity of a wind turbine must be expressed in watts.

One commenter expressed support for the proposal requiring that qualifying wind turbine components must be made and sold for use on certified wind turbines. Another commenter recommended including both American Wind Energy Association (AWEA) 9.1-2009 and ANSI/ACP 101-1-2021 as acceptable wind turbine certification standards. The commenter explained that ANSI/ACP 101-1-2021 is a revision of the AWEA standard (the original small wind certification standard, and all currently certified small wind systems are certified to this standard) that streamlines the certification process, but there is no requirement that

turbines with the original certification must recertify to the new ANSI/ACP standard. Thus, the commenter states that including both standards in the final rules will allow currently certified turbines made in the United States to earn section 45X credits as well as new turbines currently in the certification process following the newer standard. The Treasury Department and the IRS agree with this request and these final regulations revise proposed § 1.45X-3(c)(6) to add both AWEA 9.1-2009 and ANSI/ACP 101-1-2021 as acceptable wind turbine certification standards.

A commenter sought clarification as to whether a wind tower producer may rely on a certification of the total rated capacity of the turbine obtained from the original equipment manufacturer (OEM) that produces the completed wind turbine in which the wind tower is incorporated, provided the certificate was issued by an accredited certification body. The commenter noted that requiring wind tower producers to independently verify the capacity of the completed turbine would cause "undue expense and delay." To provide assurance to the commenter, a wind tower producer may rely on an OEM's certification of the total rated capacity of the completed wind turbine in which the tower was incorporated, but the Treasury Department and the IRS have determined that the rules as set out by proposed § 1.45X-3(c)(6) and (7) do not require further clarification on this point.

D. Inverters

1. In General

Consistent with section 45X(c)(2), proposed § 1.45X-3(d) would define an inverter as an end product that is suitable to convert direct current (DC) electricity from one or more solar modules or certified distributed wind energy systems into alternating current (AC) electricity. Proposed § 1.45X-3(d) would have further provided that an end product is suitable to convert DC electricity from one or more solar modules or certified distributed wind energy systems into AC electricity if, in the form sold by the manufacturer, it is able to connect with such modules or systems and convert DC electricity to AC electricity from such connected source. For purposes of section 45X, the term inverter includes a central inverter, commercial inverter, distributed wind inverter, microinverter, or residential inverter. Proposed § 1.45X-3(d) would have clarified the definition of each of these types of inverters, including the required rated outputs.

The preamble to the Proposed Regulations stated that section 45X(c)(2) requires certain types of inverters be "suitable to" or "suitable for" a statutorily required use or application to be considered an eligible component. Proposed § 1.45X-3(d) would also have provided the calculation of the credit amount for each type of inverter. In general, the credit amount for each type of inverter would be equal to the product of the inverter's total rated capacity and the amount prescribed in section 45X(b)(2)(B) for such inverter.

One commenter requested the final rules provide a credit for utility-scale power converters and that a "utility-scale power converter" be defined in a manner consistent with section 2.1.9 of Underwriters Laboratories Standard 1741 (2002). Specifically, the commenter requested modifying the final rules to provide a credit for products that only convert direct current to direct current or alternating current to direct current. Because section 45X(c)(2)(A) specifically defines the term inverter to mean "an end product which is suitable to convert direct current electricity . . . into alternating current electricity," the Treasury Department and the IRS do not have the authority to expand the definition of inverter in the final regulations to include these additional products. For this reason, the Treasury Department and the IRS decline to adopt this comment in the final regulations.

Another commenter requested that, for each type of inverter provided for under section 45X(c)(2), the rated output of alternating current power be defined as "the maximum continuous grid-tied power rating the inverter is capable of handling." The commenter asserts that the suggested change will "ensure consistent interpretation across technologies despite consumer-driven decisions impacting output." Section 45X(c)(2) uses the term "rated output" to define, in part, a commercial inverter, distributed wind inverter, microinverter, residential inverter, or utility inverter. The Treasury Department and the IRS decline to adopt this comment in the final regulations because the term rated output is in the statutory definition for these inverters.

Several commenters requested that the final rules provide a section 45X credit for inverters that convert direct current from sources other than solar modules or certified distributed wind energy systems as long as these inverters meet the technical requirements of an inverter defined under section 45X(c)(2). Section 45X(c)(2)(A)

specifically defines the term inverter to mean “an end product which is suitable to convert direct current electricity from one or more solar modules or certified distributed wind energy systems into alternating current electricity.” Other types of inverters such as bidirectional electric vehicle inverters or utility and commercial inverters that are in practice used with battery modules can meet the existing suitability standard within the definition without additional clarification required. For this reason, the Treasury Department and the IRS decline to adopt this comment in the final regulations.

2. Central Inverter

Consistent with section 45X(c)(2)(B), proposed § 1.45X–3(d)(2)(i) would have defined a central inverter as an inverter that is suitable for large utility-scale systems and has a capacity that is greater than 1,000 kilowatts, expressed on an alternating current watt basis. Proposed § 1.45X–3(d)(2)(i) would have further clarified that an inverter is suitable for large utility-scale systems if, in the form sold by the manufacturer, it is capable of serving as a component in a large utility-scale system and meets the core engineering specifications for such application. Proposed § 1.45X–3(d)(2)(ii) would have provided a credit equal to the product of 0.25 cents multiplied by the total rated capacity of the central inverter where the total rated capacity is expressed on an alternating current watt basis.

One commenter requested the credit amount available for a central inverter be changed to match the credit available for utility inverters because utility inverters are eligible for a credit that is six times higher than central inverters. Because section 45X(b)(2)(B) provides the credit amounts available for central inverters and utility inverters, the Treasury Department and the IRS do not have the authority to make the requested change. For this reason, the Treasury Department and the IRS decline to adopt this comment in the final regulations.

3. Commercial Inverter

a. Definition

Consistent with section 45X(c)(2)(C), proposed § 1.45X–3(d)(3)(i) would have provided that a commercial inverter means an inverter that is suitable for commercial or utility-scale applications, has a rated output of 208, 480, 600 or 800 volt three-phase power, and has a capacity expressed on an alternating current watt basis that is not less than 20 kilowatts and not greater than 125 kilowatts.

One commenter requested the definition of a commercial inverter be changed to provide a credit for inverters with a rated output greater than 800 volt three-phase power. Section 45X(c)(2)(C)(ii) defines a commercial inverter, in part, as having “a rated output of 208, 480, 600, or 800 volt three-phase power.” The Treasury Department and the IRS do not have the authority to expand the definition of a commercial inverter in the final regulations to those with a rated output greater than 800 volt three-phase power. For this reason, the Treasury Department and the IRS decline to adopt this comment in the final regulations.

A few commenters requested that the final rules modify the definition of a commercial inverter to include a DC optimized commercial inverter system, and that, when DC optimizers are paired with a commercial inverter, the credit amount available for commercial inverters should be determined in a manner similar to the credit computation for direct current optimized inverter systems (DC optimized inverter systems, as the term would have been defined in Proposed § 1.45X–3(d)(5)(iii)(B) and discussed in Part IV.D.3.a. of this Summary of Comments and Explanation of Revisions). Generally, these commenters requested that, with the modified definition of commercial inverter, the available credit be computed as a product of \$0.02 multiplied by the lesser of the sum of the alternating current capacity of each DC optimizer when paired with the inverter in the DC optimized inverter system or the alternating current capacity of the inverter in the DC optimized inverter system. No language in the statutory text or proposed rules prohibits the use of direct current optimizers with commercial inverters. Thus, it is unnecessary to modify the final rules to state that DC optimizers may be used with a commercial inverter.

Section 45X(b)(1)(I) provides that the amount of the section 45X credit for an inverter is equal to the applicable amount with respect to each type of inverter multiplied by the capacity of such inverter (expressed on a per alternating current watt basis). The Treasury Department and the IRS do not have the authority to change the method for computing the credit for commercial inverters. In contrast, language that appears only in the definition of “microinverter” in section 45X(c)(2)(E) (‘suitable to connect to one solar module’) does require clarification about how to apply the definition to DC optimized systems and multi-module

microinverters. Because this language does not appear in the definition of “commercial inverter” in section 45X(c)(2)(C), there is no analogous need to clarify the application of the definition or credit calculation. For this reason, the Treasury Department and the IRS decline to adopt these requests pertaining to commercial inverters in the final regulations.

b. Credit Amount

Proposed § 1.45X–3(d)(3)(iii) would have provided a credit equal to the product of 2 cents multiplied by the total rated capacity of the commercial inverter where the total rated capacity is expressed on an alternating current watt basis.

Commenters requested that DC optimizers be allowed to be paired with commercial or utility scale system configurations, like microinverters. This comment is not adopted for the reasons provided in Part IV.D.3.a. of this Summary of Comments and Explanation of Revisions.

4. Microinverters

a. Definition

Consistent with section 45X(c)(2)(E), proposed § 1.45X–3(d)(5)(i) would have defined a microinverter as an inverter that is suitable to connect with one solar module; has a rated output of 120 or 240 volt single-phase power, or 208 or 480 volt three-phase power; and has a capacity, expressed on an AC watt basis, that is not greater than 650 watts. One commenter requested the final rules change the maximum capacity limit for the microinverter from 650 watts to 700 watts to accommodate future technological advancements. Because section 45X(c)(2)(E)(iii) provides the maximum capacity of a microinverter, the Treasury Department and the IRS do not have the authority to make the requested change. For this reason, the Treasury Department and the IRS decline to adopt this comment in the final regulations.

b. Suitable To Connect to One Solar Module—in General

Proposed § 1.45X–3(d)(5)(iii)(A) would have clarified that an inverter is suitable to connect to one solar module if, in the form sold by the manufacturer, it is capable of connecting to one or more solar modules and regulating the DC electricity from each module independently before that electricity is converted into alternating current electricity.

Proposed § 1.45X–3(d)(5)(iii)(B) would have clarified that a DC optimized inverter system may qualify as a microinverter. Proposed § 1.45X–

3(d)(5)(iii)(B) would have defined a DC optimized inverter system to mean an inverter that is comprised of an inverter connected to multiple DC optimizers that are each designed to connect to one solar module. Proposed § 1.45X–3(d)(5)(iii)(B) would have provided that a DC optimized inverter system is suitable to connect with one solar module if, in the form sold by the manufacturer, it is capable of connecting to one or more solar modules and regulating the DC electricity from each module independently before that electricity is converted into alternating current electricity. Proposed § 1.45X–3(d)(5)(iv)(B) would have provided that a DC optimized inverter system qualifies as a microinverter if each DC optimizer paired with the inverter in a DC optimized inverter system meets the requirements of section 45X(c)(2)(E) and a taxpayer must produce and sell the inverter and the DC optimizers in the DC optimized inverter system together as a combined end product.

Several commenters agreed with the proposed rule permitting DC optimizers paired with an inverter to qualify as microinverters and receive the corresponding credit amount. One commenter suggested revising the definition of a DC optimized inverter systems to more clearly define the qualifying system components of a DC optimized inverter system. This commenter proposed that qualifying system components include items that control the DC output of one or more solar modules and are integral to the function of the inverter and modules. The Treasury Department and the IRS, in consultation with the Department of Energy, conclude that the additional confirmation the commenter is requesting is not necessary as it would not provide additional clarity. For this reason, the Treasury Department and the IRS decline to adopt this suggestion in the final regulations.

Several commenters requested that the final rules remove the requirement that a taxpayer produce and sell both the inverter and the DC optimizers in the DC optimized inverter system as a combined end product. One commenter expressed the view that the requirement distorts the market, provides an unfair advantage to companies that already manufacture both items, and requires companies to seek out partnerships solely for the purpose of obtaining the section 45X credit. Other commenters that manufacture both products state that the proposed requirement is inconsistent with standard industry practices where a manufacturer sells the items separately. In contrast, one

commenter supported the “combined end product” requirement and suggested it also be applied to multi-module inverters to prevent multiple entities from claiming section 45X credits for the same system. Section 45X(c)(2)(A) defines an inverter as an end product that is suitable to convert DC electricity from one or more solar modules or certified distributed wind energy systems into AC electricity. For each type of inverter listed under section 45X(c)(2), section 45X(b)(1)(I) provides the applicable credit is determined as an amount equal to the product of each inverter’s applicable amount multiplied by the capacity of such inverter. The section 45X credit is separately computed for each inverter. The Treasury Department and the IRS do not have the authority to allow a credit solely for a DC optimizer, because it does not convert DC electricity into AC electricity as the definition of inverter in section 45X(c)(2) requires. The Treasury Department and the IRS also do not have the authority to change the number of inverter units used to compute the available credit amount. For these reasons, the Treasury Department and the IRS decline to adopt these comments in these final regulations. However, while proposed § 1.45X–3(d)(5)(iv)(B) requires that the inverter and DC optimizer in the DC optimized inverter system must be produced and sold as a combined end product, the Treasury Department and the IRS clarify that the inverter and the DC optimizer do not need to be physically packaged together at sale, and the inverter and DC optimizer do not need to be fully interconnected and assembled at the time of sale.

Proposed § 1.45X–3(d)(5) would have clarified that a multi-module inverter may also qualify as a microinverter. Proposed § 1.45X–3(d)(5)(iii)(C) would have defined a multi-module inverter to mean an inverter that is comprised of an inverter with independent connections and DC optimizing components for two or more modules. Proposed § 1.45X–3(d)(5)(iii)(C) would have further provided that a multi-module microinverter is suitable to connect with one solar module if it is capable of connecting to one or more solar modules and regulating the DC electricity from each module independently before that electricity is converted into alternating current electricity. Proposed § 1.45X–3(d)(5)(iv)(C) would have provided that multimodule inverter qualifies as a microinverter if it meets the requirements of section 45X(c)(2)(E).

One commenter suggested revising the definition of a multi-module

inverter to more clearly define the qualifying system components of a multi-module inverter. The commenter suggested that qualifying system components should be those items that control the DC output of one or more solar modules and are integral to the function of the inverter and modules. The same commenter also suggested revising the definition of a multi-module inverter to clarify that for a multi-module inverter to qualify as a microinverter, a taxpayer must produce and sell the inverter and the DC optimizers together as a combined end product. A different commenter agreed with this suggestion.

A few commenters suggested revising the definition of a multi-module inverter to provide that a multi-module inverter includes a DC optimized inverter system such that each DC optimizer may connect with more than one solar module and the credit amount in such a system is computed similarly to a DC optimized inverter system, except that the DC optimizers are not required to be sold with the inverter as a “combined end product.” Other commenters disagreed with this suggestion and support the proposed rule that would not have allowed solar modules to share a connection to a multi-module inverter.

The reasons provided for retaining the rule for DC optimized inverter systems also apply to adopting the requirement for multi-module inverters. The Treasury Department and the IRS think that requiring taxpayers to produce and sell the inverter and the DC optimizers together as a combined end product will create parity with DC optimized inverter systems and avoid potential abuse. For these reasons, the Treasury Department and the IRS adopt these comments in the final regulations.

c. Credit Amount

Proposed § 1.45X–3(d)(5)(iv)(A) would have provided that generally, the credit amount for a microinverter is equal to the product of 11 cents multiplied by the total rated capacity of the microinverter where the total rated capacity is expressed on an alternating current watt basis.

Proposed § 1.45X–3(d)(5)(iv)(B) would have clarified how to determine the credit amount for a DC optimized inverter system that qualifies as a microinverter. Proposed § 1.45X–3(d)(5)(iv)(B) would have provided that the credit amount for a DC optimized inverter system that qualifies as a microinverter is equal to the product of 11 cents multiplied by the lesser of the sum of the alternating current capacity of each DC optimizer when paired with

the inverter in the DC optimized inverter system or the alternating current capacity of the inverter in the DC optimized inverter system where capacity is measured in watts of alternating current converted from DC electricity by the inverter in a DC optimized inverter system.

One commenter requested that the alternating current capacity of each DC optimizer when paired with the inverter in the DC optimized inverter system be calculated as the product of the optimizer's rated input power capacity, the optimizer's DC-to-DC conversion efficiency percentage, and the inverter's DC-to-AC conversion efficiency percentage. Section 45X(b)(1)(I) provides the applicable credit is determined as an amount equal to the product of each inverter's applicable amount multiplied by the capacity of such inverter (expressed on a per alternating current watt basis). The requirement that capacity is "expressed on an alternating current watt basis" already factors in any DC-to-DC conversion efficiency upstream of the DC-to-AC conversion, and the inverter's DC-to-AC conversion efficiency percentage is accounted for by the use of "capacity of such inverter" (expressed on a per alternating current watt basis). Therefore, these requirements are duplicative of rules contained in the statutory text. For this reason, the Treasury Department and the IRS decline to adopt this suggestion in the final regulations.

5. Utility Inverter

Consistent with section 45X(c)(2)(G), proposed § 1.45X-3(d)(7)(i) would have defined a utility inverter as an inverter that is suitable for commercial or utility-scale systems, has a rated output of not less than 600 volt three-phase power, and has a capacity expressed on an alternating current watt basis that is greater than 125 kilowatts and not greater than 1000 kilowatts.

One commenter requested reducing the required rated output from "not less than 600 volt three-phase power" to "not less than 480 volt three-phase power." Section 45X(c)(2)(G)(ii) defines a utility inverter, in part, as having "a rated output of not less than 600 volt three-phase power." The Treasury Department and the IRS decline to adopt the commenter's request because defining a utility inverter to include those with a rated output of not less than 480 volt three-phase power would be inconsistent with the statute.

E. Qualifying Battery Components

Proposed § 1.45X-3(e)(1) would define a qualifying battery component

as electrode active materials, battery cells, or battery modules.

1. Electrode Active Materials

a. In General

Proposed § 1.45X-3(e)(2)(i)(A) would have defined electrode active materials to include cathode electrode materials, anode electrode materials, and electrochemically active materials that contribute to the electrochemical processes necessary for energy storage. In general, electrode active materials are materials that are capable of being used within a battery for energy storage. Proposed § 1.45X-3(e)(2)(i)(A) would also have provided that the following materials in a battery or vehicle would not qualify for the section 45X credit as an electrode active material: battery management systems, terminal assemblies, cell containments, gas release valves, module containments, module connectors, compression plates, straps, pack terminals, bus bars, thermal management systems, and pack jackets. Proposed § 1.45X-3(e)(2)(v) would have clarified that a taxpayer may claim only one section 45X credit with respect to a material that qualifies as both an electrode active material and an applicable critical mineral.

Some commenters recommended altering the definition of electrode active materials as defined in section 45X(c)(5)(B)(i) and in proposed § 1.45X-3(e)(2)(i)(A). The Treasury Department and the IRS do not have the authority to alter the definition of electrode active materials as provided by the statute. For this reason, the Treasury Department and the IRS decline to adopt these recommendations in the final regulations.

One commenter raised a concern that certain definitions in the Proposed Regulations applicable to electrode active materials would inadvertently exclude separators from being treated as an eligible component because those definitions do not include language specific to the separator production process. As proposed § 1.45X-3(e)(2)(i)(D) specifically included separators in the definition of electrochemically active materials, such changes to definitions are unnecessary, and the Treasury Department and the IRS decline to adopt the commenter's recommendation.

b. Cathode Electrode Materials and Anode Electrode Materials

Proposed § 1.45X-3(e)(2)(i)(B) would have defined "cathode electrode materials" to mean the materials that comprise the cathode of a commercial battery technology, such as binders, and

current collectors (that is, cathode foils). Proposed § 1.45X-3(e)(2)(i)(C) would have defined "anode electrode materials" to mean the materials that comprise the anode of a commercial battery technology, including anode foils.

A commenter recommended that the definition of cathode electrode materials in proposed § 1.45-3(e)(2)(i)(B) and of anode electrode materials in proposed § 1.45-3(e)(2)(i)(C) be clarified to specify that the materials be "battery-grade" so the precursor materials are eligible for the section 45X credit. Because these proposed definitions would require that the materials comprise the cathode or anode of a commercial battery technology, the Treasury Department and the IRS conclude that specifying that such materials be "battery-grade" would be redundant. For this reason, the Treasury Department and the IRS decline to adopt these recommendations in the final regulations.

Another commenter recommended that the definition of cathode electrode materials be clarified to address its concern that the qualifier "commercial battery technology" excludes hydrogen fuel cells contrary to the definition of the term in the statute, which contains no such qualifier. The Treasury Department and the IRS do not have the authority to alter the definition of electrode active materials as battery components as provided by the statute. For this reason, the Treasury Department and the IRS decline to adopt this recommendation in the final regulations. The Treasury Department and the IRS note, however, that although electrode active materials in general must be capable of being used within a battery for energy storage, such materials would still be eligible for the section 45X credit if they are also capable of being used in other applications, such as hydrogen fuel cells.

c. Electrochemically Active Materials

Proposed § 1.45X-3(e)(2)(i)(D) would define "electrochemically active materials that contribute to the electrochemical processes necessary for energy storage" to mean the battery-grade materials that enable the electrochemical storage within a commercial battery technology. In addition to the list of electrochemically active materials provided in section 45X(c)(5)(B)(i) (that is, solvents, additives, and electrolytic salts), these may include electrolytes, catholytes, anolytes, separators, and metal salts and oxides.

One commenter requested the definition of electrochemically active

materials explicitly include solid-state electrolytes. Solid-state electrolytes are included in the definition of electrochemically active materials because Proposed § 1.45X-3(e)(2)(i)(D) includes “electrolytes,” with no particular form required. The Treasury Department and the IRS conclude that specifying that such materials are included in this definition would be redundant. For this reason, the Treasury Department and the IRS decline to adopt these recommendations in the final regulations.

d. Battery Grade Materials

Proposed § 1.45X-3(e)(2)(i)(F) would have defined “battery-grade materials” to mean the processed materials found in a final battery cell or an analogous unit, or the direct battery-grade precursors to those processed materials. A few commenters requested the final rules clarify the meaning of direct battery-grade precursors. Commenters also requested the final rules provide that silane gas, ultra-high molecular weight polyethylene, and needle coke meet the definition of electrochemically active materials as direct battery-grade precursors. While the Treasury Department and the IRS understand the desire for assurance, listing specific precursors that qualify as electrochemically active materials would not be possible or advisable because it could imply that unlisted materials do not qualify as electrochemically active materials, particularly as battery technologies may evolve over time. For this reason, the Treasury Department and the IRS decline to adopt these recommendations in these final regulations.

e. Production Costs Incurred

Proposed § 1.45X-3(e)(2)(iv) would have provided that costs incurred for purposes of determining the credit amount includes costs as defined in § 1.263A-1(e) that are paid or incurred within the meaning of section 461 of the Code by the taxpayer for the production of an electrode active material only. Thus, under the Proposed Regulations, production costs with respect to an electrode active material would not include any costs incurred after the production of the electrode active material.

The Proposed Regulations would not have allowed direct material costs as defined in § 1.263A-1(e)(2)(i)(A), indirect material costs as defined in § 1.263A-1(e)(3)(ii)(E), or any costs related to the extraction or acquisition of raw materials to be taken into account as production costs. This limitation disallowed, for purposes of calculating

the credit: the inclusion of the cost of acquiring the raw material used to produce the electrode active materials; the cost of materials used for conversion, purification, or recycling of the raw material; and other material costs related to the production of electrode active materials. The Proposed Regulations applied section 263A and the regulations under section 263A (section 263A regulations) solely to identify the types of costs that are includible in production costs incurred for the purpose of computing the amount of the section 45X credit. The Proposed Regulations did not apply section 263A or the section 263A regulations for any other purposes, such as to determine whether a taxpayer is engaged in production activities.

The preamble to the Proposed Regulations explained that the rationale for the proposed rule was that the credit for the production of electrode active materials provides incentives for taxpayers to conduct activities that add value to the production of electrode active materials. Merely purchasing raw materials may enable a taxpayer to produce an electrode active material but it is not by itself an activity that adds value. In addition, excluding the costs of acquiring electrode active materials mitigates the risk of crediting the production costs for the same underlying material more than once as that material is used in various stages of the production process. For these reasons, material costs were not creditable costs under the Proposed Regulations.

The Treasury Department and the IRS requested comments on the proposed rule for determining the costs incurred with respect to the production of electrode active materials. Specifically, comments were sought as to whether and how extraction and other similar value-added activities in the production of raw materials used in electrode active materials should be taken into account and how extraction should be defined, including whether the term should be defined consistent with proposed § 1.30D-3(c)(8). Comments were also requested with respect to applicable critical minerals, which are summarized in Part V.C. of this Summary of Comments and Explanation of Revisions. Many of these comments had similarities, and the reasoning and revisions in these final regulations are described in this Part IV.E.1.e. of this Summary of Comments and Explanation of Revisions and are adopted for both electrode active materials and applicable critical minerals.

Approximately 72 of the comments received addressed the definition and

scope of production costs generally. Many commenters recommended that, contrary to the Proposed Regulations, all costs with respect to the production of electrode active materials be included in production costs for purpose of determining the credit, including direct material costs as defined in § 1.263A-1(e)(2)(i)(A), indirect material costs as defined in § 1.263A-1(e)(3)(ii)(E), and costs related to the extraction of raw materials.

A significant number of commenters focused their recommendations on material costs or the costs of extraction, but there was agreement among many of them that “costs of production” should be interpreted broadly to include all costs. In support of this position, commenters asserted that section 45X(b)(1)(J) and (M) do not place limits or otherwise qualify production costs eligible for the credit and that the regulations should not impose limitations not explicitly present in the Code itself. Some of these commenters also argued that, because the costs excluded from production costs in the Proposed Regulations are often a substantial or predominant portion of the total costs of producing some electrode active materials, substantial limitations on the inclusion of these costs would contradict Congress’s goal of incentivizing the production of electrode active materials. Commenters also disputed that direct and indirect costs are not incurred in value-adding activities.

Some commenters also disagreed that the potential for over crediting (that is, crediting the same production costs multiple times) justifies denying a credit for these costs. A subset of these commenters disagreed that over crediting was a legitimate concern, arguing instead that section 45X provides a credit for costs incurred at different stages of production attributable to the same underlying material. Others agreed that over crediting might not be permissible but that the concern was insufficient to deny entirely credits for all costs that might be impermissibly claimed more than once for the same underlying material. In the view of these commenters, prohibiting crediting these same production costs multiple times would be the proper approach rather than entirely denying all credits for these costs. Some commenters noted that, in the case of certain specifically identified electrode active materials, there was no risk of crediting the same production costs multiple times and thus direct and indirect costs should be included in the costs of production for these electrode active materials. A third

set of commenters argued that credits should be permissible once under section 45X(b)(1)(M) for applicable critical minerals and again under section 45X(b)(1)(J) for electrode active materials.

In the case of electrode active materials that are precursors for the production of other electrode active materials, one commenter recommended that the cost of the precursor electrode active materials only be included in the cost of production for which a credit may be claimed if the precursor electrode active materials are completely consumed in the production process and are not used for any other commercial purpose.

A number of commenters proposed solutions to the problem of potentially crediting the same production costs multiple times. One solution commenters proposed was to reduce the basis of property for which a credit has been claimed by an upstream producer. Commenters also proposed a system under which a taxpayer would only be eligible for a credit on costs of material for which no other taxpayer had previously claimed a credit. This arrangement could be administered through a system of certifications in which taxpayers would be required to verify that its suppliers had not previously claimed credits for costs associated with the same materials for which the taxpayer is claiming credits. A commenter also urged that producers of electrode active materials be able to claim a credit if they can establish that the acquired electrode active materials and applicable critical minerals used in the production of electrode active materials were acquired from extraction or production outside the United States and thus were previously ineligible for a section 45X credit.

In addition to general comments regarding the inclusion of direct, indirect, and extraction costs, commenters recommended clarification about more specific costs, including costs associated with transportation. Another commenter requested the final rules be modified to include costs of the production of anodes used in the aluminum production to convert alumina into aluminum. Other commenters asserted that the costs of processing and purification of materials in the production of electrode active materials add value and should, on that basis, be included in the scope of the credit.

Several commenters recommended that the direct and indirect costs of the production of electrode active materials from recycled feedstock should be classified as production costs for

purposes of the credit. According to one commenter, recycling processes begin with waste products at what is essentially a new supply chain.

A commenter supported the Proposed Regulations' exclusion of direct material, indirect material, and extraction costs from production costs eligible for the credit. This commenter was concerned that a contrary rule would invite fraud, waste, and abuse and that, in the case of extraction costs, would be difficult to administer without the creation of a tracing system.

With respect to costs related to extraction, the Proposed Regulations would have excluded extraction costs because extraction could be far removed, particularly in the case of electrode active materials, in the supply chain from the ultimate production of the eligible component. However, commenters highlighted the critical importance of extraction to the production of both applicable critical minerals and electrode active materials as well as the close connection these costs often have to the final production of these materials.

The Treasury Department and the IRS have reconsidered the treatment of extraction costs in these final regulations for taxpayers that extract raw materials domestically and for taxpayers that acquire either domestically or foreign-sourced extracted raw materials. For both electrode active materials and applicable critical minerals, the final regulations in §§ 1.45X-3(e)(2)(iv) and 1.45X-4(c)(3), respectively, allow taxpayers to include extraction costs related to the extraction of raw materials in the United States or a United States territory, but only if those costs are paid or incurred by the taxpayer that claims the section 45X credit with respect to the relevant electrode active material or applicable critical mineral. The Treasury Department and the IRS note that the section 45X credit is available only to taxpayers that produce and sell an eligible component. Thus, the final regulations provide that extraction costs may be included in production costs consistent with the rules provided under section 263A only if such costs are incurred by the taxpayer that claims the section 45X credit with respect to the relevant applicable critical mineral or electrode active material. The Treasury Department and the IRS have determined that this inclusion of extraction costs incurred by the taxpayer most accurately captures the meaning "the costs incurred by the taxpayer with respect to the production of" applicable critical minerals and electrode active materials under section

45X(b)(1)(J) and (M). If, however, a taxpayer acquires extracted raw material as a direct (or indirect) material cost, the material costs may be included as production costs consistent with the rules provided under section 263A regardless of whether the extracted material is domestically- or foreign-sourced.

With respect to direct and indirect material costs, the Proposed Regulations would have excluded direct and indirect material costs from production costs for both applicable critical minerals and electrode active materials. The Proposed Regulations excluded material costs from production costs based on an interpretation of the term "costs incurred by the taxpayer with respect to production" in section 45X(b)(1)(J) and (M) as being limited to value-added activities in the production process. Electrode active materials and applicable critical minerals differ from all other eligible components described in section 45X because their credit amounts are calculated as a percentage of production costs rather than specifying a fixed dollar amount or rate. The preamble to the Proposed Regulations stated that the mere purchase of materials does not itself add value in a production process despite being a necessary part of such process. Furthermore, it is unlikely that Congress intended to allow production costs associated with applicable critical minerals or electrode active materials to be credited multiple times, due to the high risk of fraud, waste, and abuse; the administrative burden of preventing these outcomes; and the limited effectiveness in supporting domestic production of new eligible components. The exclusion of direct and indirect material costs addressed these concerns.

Numerous commenters highlighted the importance and appropriateness of including material costs in production costs. There was, however, disagreement as to whether and to what extent the costs of non-U.S. produced constituent elements, materials, and subcomponents used in the production of electrode active materials should be included in production costs. Some commenters recommended that the costs of all materials be included while others urged limitations to only credit materials produced domestically. One commenter proposed that the final regulations modify the proposed rule regarding constituent elements, materials, and subcomponents used in the production of applicable critical minerals to distinguish between imports of materials otherwise available from domestic sources and imported

materials that are not available from domestic sources.

The Treasury Department and the IRS, after consultation with the Department of Energy, have reconsidered the proposed exclusion of all material costs based on these comments. The final regulations adopt a rule allowing taxpayers that produce applicable critical minerals and electrode active materials as specified in the statute to include direct and indirect materials costs (as described in the referenced section 263A regulations) in production costs if certain conditions are met, but only if those direct or indirect material costs do not relate to the purchase of materials that are an eligible component at the time of acquisition (such as an electrode active material or applicable critical mineral). In addition, two examples illustrating the revised production costs rule are included in § 1.45X-3(e)(2)(iv)(A)(2).

In finalizing this rule, the Treasury Department and the IRS considered the provisions of section 45X and determined this final rule appropriately implements the statute as a whole. Section 45X(a)(1) and (2) limit the section 45X credit to the sum of the credit amounts determined under section 45X(b) with respect to each eligible component that is produced by the taxpayer and, during such taxable year, sold to an unrelated person in the taxpayer's trade or business. The statute allows a section 45X credit for the sale of an applicable critical mineral or electrode active material produced and sold by the taxpayer in its business. The section 45X credit for an applicable critical mineral or electrode active material is equal to 10 percent of the costs incurred by the taxpayer with respect to production, under section 45X(b)(1)(M) and (J), respectively.

In calculating a taxpayer's costs incurred in the production of applicable critical minerals and electrode active materials, it is necessary to consider situations involving the integration of eligible components (whether directly made by the taxpayer or purchased from another taxpayer) in the course of producing an applicable critical mineral or electrode active material. Generally, integrating one eligible component into another produced eligible component results in two credits pursuant to section 45X(d)(4) if the taxpayer produced both, while integrating a purchased eligible component into another produced eligible component will only result in a credit for the eligible component produced by the taxpayer. In the case of an applicable critical mineral or electrode active material, however, the section 45X

credit calculation differs from the other eligible components. Thus, further examination was needed to determine how a credit should be calculated in such a case.

The Treasury Department and the IRS considered the treatment of a vertically integrated taxpayer. For example, assume a taxpayer produced an applicable critical mineral or electrode active material and incurred \$50X of costs with respect thereto (EC 1) and integrated EC 1 into a separate applicable critical mineral or electrode active material (EC 2), incurring an additional \$100X of costs with respect to the production of EC 2 (total production costs of \$150X), with EC 2 ultimately being sold by the taxpayer to an unrelated person. In calculating the section 45X credit, pursuant to section 45X(d)(4), taxpayer is treated as having sold an eligible component to an unrelated person if such component is integrated, incorporated, or assembled into another eligible component which is sold to an unrelated person. It is important to note that section 45X makes no distinction between integrated eligible components that were purchased or produced by the taxpayer. As section 45X(d)(4) directs the taxpayer to treat itself as selling both EC 1 and EC 2 to the unrelated person, it is necessary to determine a credit for each EC 1 and EC 2 when both were produced by the taxpayer.

In this example, the \$50X of production costs attributable to EC 1 were not incurred with respect to the production of EC 2, since the production of EC 2—in other words, the substantial transformation of EC 1 into EC 2—does not include the production of EC 1. Thus, the taxpayer would be eligible for a total section 45X credit of \$15X: \$5X (10% of \$50X) for EC 1 and \$10X (10% of \$100X) for EC 2. If the \$50X of production costs attributable to EC 1 were included for both EC 1 and EC 2, then the same costs would be double credited. Double crediting would result in the taxpayer generating a \$20X credit from the sale of EC 1 and EC2, which would provide an increased credit amount as compared to the credit amount that should result from the \$150X of actual production costs incurred (or, stated differently, a section 45X credit that was 13.33 percent of the taxpayer's actual \$150X of production costs in the example). The correct result is taxpayer should be viewed as having incurred \$50X of production costs for EC 1 and \$100X of production costs for EC 2, resulting in a \$15X credit, which also matches 10 percent of the taxpayer's actual production costs

(\$150X) and does not create a double crediting of costs.

Alternatively, consider a taxpayer that, instead of producing EC 1, purchases EC 1 for \$60X. The taxpayer then spends another \$100X producing EC 2, using EC 1. Similar to the vertically integrated taxpayer, when the taxpayer sells EC 2, pursuant to section 45X(d)(4), the taxpayer is treated as having sold EC 1 and EC 2 to an unrelated person. The difference is that in this case the taxpayer did not produce EC 1, and therefore the taxpayer does not satisfy section 45X(a)(1)(A) for a section 45X credit for the sale of EC 1. If the taxpayer were permitted to include the costs for EC 1 (\$60X) in calculating the credit for EC 2, then the taxpayer would receive a larger credit for producing EC 2 than if the taxpayer had produced both EC 1 and EC 2. Without a clearer indication in the statute that Congress intended to treat these two fact patterns differently, in a way that disadvantages vertically integrated production, the statute as a whole is appropriately implemented when the result is the same credit amount for EC 2 (\$10X in these examples) whether the taxpayer purchases or produces EC 1.

In comparing the two results of these examples under the final rule, the vertically integrated taxpayer gets a larger total section 45X credit by directly engaging in more credit generating activities, while the non-vertically integrated taxpayer receives a section 45X credit commensurate with its activities of producing EC 2, but no credit for integrated eligible components that it did not produce. These results are consistent with the general rule of section 45X(a)(1) and (2) and avoid allowing taxpayers to use the same cost in multiple credit calculations.

Section 45X(d)(2) provides that only sales of eligible components produced within the United States, or a United States territory, are taken into account for purposes of section 45X and is additional support for the rule that does not include foreign applicable critical minerals or electrode active materials in production costs, regardless of whether purchased or produced by the taxpayer. Allowing a foreign produced applicable critical mineral or electrode active material to increase the section 45X credit conflicts with section 45X(d)(2), particularly when considered with the rule under section 45X(d)(4). The Treasury Department and the IRS also note that section 45X(d)(2) confirms that treatment as an "eligible component" is not dependent on where production occurred, and so a foreign applicable critical mineral or electrode active

material is an eligible component subject to the rule in section 45X(d)(4).

The final rule is also consistent with the overall purpose of section 45X and addresses the concerns described in the preamble of the Proposed Regulations. While the final rule adopts certain commenters' position that incurring material costs is necessary and may add value to a production process, the Treasury Department and IRS maintain that the inclusion of material costs must be balanced against the risk of multiple crediting of the same costs and the creation of incentives that are contrary to the purpose of section 45X. The final rule accomplishes this balance. Further, although applicable critical minerals and electrode active materials, or any other eligible component, produced outside the United States do not pose a risk of multiple crediting, permitting the production costs of a non-U.S. produced applicable critical mineral or electrode active material to be included in production costs would provide an incentive for the purchase of electrode active materials or applicable critical minerals produced abroad, which is inconsistent with the overall statutory scheme and purpose of section 45X (that is, to encourage domestic production of eligible components). Thus, excluding all costs of acquiring materials that are eligible components (for example, an applicable critical mineral or electrode active material at the time of acquisition) as a direct or indirect material cost with respect to the production of another applicable critical mineral or electrode active material appropriately implements the statute. It is also appropriate to have the same rules for applicable critical minerals and electrode active materials with respect to production costs, as the statutory language regarding calculation of the credit for applicable critical minerals and electrode active materials is the same.

These final regulations also include certain substantiation requirements for a taxpayer that is claiming a section 45X credit with respect to an applicable critical mineral or electrode active material. The preamble to the Proposed Regulations supported not including all direct and indirect material costs by referencing the possibility that the same production costs may be credited multiple times and the potential for increased fraud and abuse related to claiming the section 45X credit. Proposed § 1.45X-4(c)(4) would have required the taxpayer to document that their product meets the criteria for an applicable critical mineral as described in section 45X(c)(6) with a certificate of analysis (COA) provided by the taxpayer

to the person to which the taxpayer sold the applicable critical mineral. The Treasury Department and the IRS requested comments on this substantiation requirement, including whether a similar requirement should be applied to electrode active materials.

Based on a review of the comments, including comments specifically suggesting certification statements, and the need to balance the expansion of costs included as production costs with respect to the Proposed Regulations while mitigating the risk of fraud, waste and abuse, these final regulations revise the substantiation rules in proposed § 1.45X-4(c)(4) for applicable critical minerals and added substantiation rules for electrode active materials in § 1.45X-3(e)(2)(iv)(C). In order to include direct or indirect materials costs as defined in § 1.263A-1(e)(2)(i)(A) and (e)(3)(ii)(E) as production costs when calculating a section 45X credit for the production and sale of an applicable critical mineral or electrode active material, a taxpayer must include, as at attachment to the return on which the section 45X credit is claimed, certifications from any supplier, including the supplier's employer identification number and that is signed under penalties of perjury, from which the taxpayer purchased any constituent elements, materials, or subcomponents of the taxpayer's eligible component, stating that the supplier is not claiming the section 45X credit with respect to any of the material acquired by the taxpayer, nor is the supplier aware that any prior supplier in the chain of production of that material claimed a section 45X credit for the material. A taxpayer must also prepare the following information, and maintain that information in the taxpayer's books and records: (1) a document that provides an analysis of any constituent elements, materials, or subcomponents that concludes the material did not meet the definition of an eligible component (for example, did not meet the definition of applicable critical mineral or electrode active material) at the time of acquisition by the taxpayer (the document may be prepared by the taxpayer or ideally by an independent third-party); (2) a list of all direct and indirect material costs and the amount of such costs that were included within the taxpayer's total production cost for each electrode active material or applicable critical mineral, as applicable; and (3) a document related to the taxpayer's production activities with respect to the direct and indirect material costs that establishes the materials were used in the production of

the electrode active material or applicable critical mineral, as applicable (the document may be prepared by the taxpayer or ideally by an independent third-party). Finally, the taxpayer must provide any other information related to the direct or indirect materials specified in guidance and comply with the directions for providing such information as specified in guidance. Failure to provide this documentation with the return filing, or providing a "available upon request" statement, will constitute a failure to substantiate the claim. The Treasury Department and the IRS have determined, in consultation with the Department of Energy, that these revisions to the Proposed Regulations are necessary in order to properly substantiate credit amounts claimed under section 45X for applicable critical minerals and electrode active materials.

2. Battery Cells—Definition

a. In General

Consistent with section 45X(c)(5)(B)(ii), proposed § 1.45X-3(e)(3)(i) would have defined the term battery cell as an electrochemical cell comprised of one or more positive electrodes and one or more negative electrodes, with an energy density of not less than 100 watt-hours per liter, and capable of storing at least 12 watt-hours of energy.

Commenters asked for additional guidance clarifying the volumetric energy density calculation methodology given the variety of battery shapes, sizes, and construction methodologies that exist in the market. The Treasury Department and the IRS understand these comments to be made with respect to calculating energy density under proposed § 1.45X-3(e)(3)(i)(B) and agree that clarification would be helpful. Energy density can refer to volumetric energy density but is commonly used to refer to gravimetric (mass-based) energy density. These final regulations clarify that energy density is referring to volumetric energy density in § 1.45X-3(e)(3)(i)(B).

One commenter asked that the final rules provide that hydrogen fuel cells be included under the definition of battery cells by amending the definition of a battery cell to waive the requirement that a battery cell be capable of storing at least 12 watt-hours of energy and permitting this requirement to be met by "a large hydrogen storage tank." The Treasury Department and the IRS do not have the authority to amend the definition of a battery cell in the final regulations or to waive the requirement that it be capable of storing at least 12

watt-hours of energy. For this reason, the Treasury Department and the IRS decline to adopt this comment in the final regulations.

At least one commenter raised a matter involving a vertically integrated manufacturer of electric vehicles that, together with a related person, operates a battery cell production facility. According to the commenter, the commenter purchases battery cells from this production facility and assembles, integrates, and incorporates them into battery modules at battery assembly facilities located in other States. Modules produced at these assembly facilities are then shipped to various electric vehicle production facilities. As described by the commenter, the process of taking completed battery cells and integrating, incorporating, and assembling them into completed battery packs happens across several different facilities, all of which are operated by the commenter and its affiliates that are separate legal entities. Each facility is neither solely a battery module facility nor solely a battery pack facility. The commenter requested that the final regulations allow a vertically integrated manufacturer and related parties to elect which facility will receive the credit in situations where the manufacturer and related parties complete all stages of the production process and can substantiate that the corresponding credit will not be duplicated. The Treasury Department and the IRS appreciate the complex operations that may be inherent in battery production. However, the statute requires a determination of the taxpayer that produces an eligible component and does not authorize the relief requested by the commenter.

b. Capacity Measurement

Proposed § 1.45X–3(e)(3)(ii) would have provided that taxpayers must measure the capacity of a battery cell in accordance with a national or international standard, such as IEC 60086–1 (Primary Batteries), or an equivalent standard. Taxpayers can reference the United States Advanced Battery Consortium (USABC) Battery Test Manual for additional guidance.

Several commenters agreed with the proposed definition because it provided taxpayers the ability and needed flexibility to determine the appropriate standard, but others recommended additional guidance or information be included in these final regulations. A commenter requested that the final regulations “retain the criteria that the standard used by the taxpayer must be one issued by a recognized standards setting body.” While not specifically using that language, these final

regulations do maintain that concept by continuing to require measurement in accordance with a national or international standard.

Another commenter requested that the final regulations eliminate the reference to “an equivalent standard” to IEC 60068–1 because “IEC 60086–1 is not applicable to rechargeable battery chemistries, and it is unknown therefore what an equivalent standard would be.” The Treasury Department and the IRS have determined that this clarification is unnecessary because the reference to IEC 60068–1 or “an equivalent standard” merely provides a non-exclusive example of an acceptable national or international standard for capacity measurement. These final regulations therefore do not adopt the commenter’s suggestion.

Other commenters suggested the addition of various specific national or international standards to the language provided in proposed § 1.45X–3(e)(3)(ii) regarding the standards to be used for battery cell capacity measurement. The Treasury Department and the IRS understand the desire for assurance but have determined that these proposed additions, if included as examples, will not add further clarity to the final regulations. The Treasury Department and the IRS further do not think that there is a basis to include any of these proposed additions as the exclusive standard or standards for capacity measurement. The final regulations therefore do not adopt these commenters’ suggestions regarding particular national or international standards to be used for capacity measurement in § 1.45X–3(e)(3)(ii).

Another commenter recommended that the final regulations require that battery cell “capacity” must be mathematically normalized to a 100-hour discharge time, regardless of the time otherwise dictated by the appropriate national or international standard. The Treasury Department and the IRS do not think there is a basis to adopt this requirement, as this would displace other national or international standards with a new requirement that is not in the statute. Therefore, the Treasury Department and the IRS decline to adopt additional specific standards in these final regulations beyond those provided in the Proposed Regulations.

Some commenters noted that the USABC Battery Test Manual, which proposed § 1.45X–3(e)(3)(ii) states may be used for additional guidance regarding measurement of the capacity of a battery cell, is not applicable to all battery cell applications and technologies that may be eligible for the

section 45X credit. One commenter suggested removing the reference to the USABC Battery Test Manual for this reason. Because the inclusion of this reference is intended to inform taxpayers of a resource that may be helpful in some cases, even if it may not be applicable in all cases, the Treasury Department and the IRS decline to adopt this suggestion.

Another commenter suggested an additional requirement to conduct a performance test in a certified laboratory once every three years to verify the capacity of the battery cell. It was unclear from the comment when this performance testing would be required. Section 45X requires the production and sale of eligible components. Because an eligible component must meet the requirements under section 45X at the time of sale, it would be inappropriate to verify capacity once every three years. Thus, the Treasury Department and the IRS decline to adopt this additional capacity measurement requirement in the final regulations.

3. Battery Modules—Definition

Under section 45X(c)(5)(B)(iii), the term battery module, in the case of a module using battery cells, is a module with two or more battery cells which are configured electrically, in series or parallel, to create voltage or current, as appropriate, to a specified end use, with an aggregate capacity of not less than 7 kilowatt-hours (or, in the case of a module for a hydrogen fuel cell vehicle, not less than 1 kilowatt-hour). Similarly, under section 45X(c)(5)(B)(iii), a battery module with no cells means a module with an aggregate capacity of not less than 7 kilowatt-hours (or, in the case of a module for a hydrogen fuel cell vehicle, not less than 1 kilowatt-hour). Consistent with section 45X(c)(5)(B)(iii), proposed § 1.45X–3(e)(4)(i) would have defined battery module to mean a module described in proposed § 1.45X–3(e)(4)(i)(A) (with cells) or (B) (without cells) with an aggregate capacity of not less than 7 kilowatt-hours (or, in the case of a module for a hydrogen fuel cell vehicle, not less than 1 kilowatt-hour).

Some commenters suggested lowering the aggregate capacity limitation to incentivize domestic production of all battery types used in various industrial applications. One commenter recommended eliminating the capacity thresholds entirely for battery modules when used in medical or military applications. While the Treasury Department and the IRS appreciate commenters’ desire to incentivize domestic battery manufacturing, section 45X(c)(5)(B)(iii)(II) provides the

aggregate capacity thresholds that battery modules must meet in order to be eligible components. The Treasury Department and the IRS decline to adopt the commenters' request to alter or eliminate the aggregate capacity requirements for battery modules as such revisions would be inconsistent with the statute. Thus, these final regulations adopt proposed § 1.45X-3(e)(4)(i) without change.

a. Modules Using Battery Cells

Proposed § 1.45X-3(e)(4)(i)(A) would have defined a module using battery cells as a module with two or more battery cells that are configured electrically, in series or parallel, to create voltage or current (as appropriate), to a specified end use, meaning an end-use configuration of battery technologies. Under the proposed rule, an end-use configuration is the product that ultimately serves a specified end use. It is the collection of interconnected cells, configured to that specific end-use and interconnected with the necessary hardware and software required to deliver the required energy and power (voltage and current) for that use. The preamble to the Proposed Regulations explained that, as applied to batteries commonly used in electric vehicles, proposed § 1.45X-3(e)(4)(i)(A) would have permitted a credit for the production and sale of the battery pack in an electric vehicle, but it would not have permitted a credit for the production of a module that is not the end-use configuration. The Treasury Department and the IRS requested comments on this proposed interpretation of the phrase "to a specified end use" in section 45X(c)(5)(B)(iii)(I)(aa).

Many commenters raised concerns with the interpretation of the phrase "to a specified end use" in proposed § 1.45X-3(e)(4)(i)(A). Some commenters asserted that requiring that modules be in an end-use configuration would be overly restrictive for certain product categories. For example, certain types of modules may be transported to the end-use site only partially assembled due to safety considerations, with final assembly performed by the battery manufacturer, the customer, or a third-party contractor.

Similarly, a few commenters expressed concern that no taxpayer may be eligible for the battery module credit in certain cases. One commenter suggested that this result might occur if module manufacturers do not manufacture a pack in its end-use configuration. Further, those who purchase such items and convert them to their end-use configuration may

struggle to demonstrate their activities amount to substantial transformation. One commenter suggested changing proposed § 1.45X-3(e)(4)(i)(A) to provide that "an end-use configuration is the product that ultimately serves a specified end use—whether delivered pre-assembled or assembled on-site." Further, the commenter recommended an additional sentence at the end of proposed § 1.45X-3(e)(4)(i)(A) to identify the section 45X claimant in cases where assembly occurs by someone other than the taxpayer.

Several commenters stated that proposed § 1.45X-3(e)(4)(i)(A) created confusion because the definition of battery module could, in some circumstances, include the items that are referred to in industry as "battery packs." One commenter noted that while battery cells and modules predominantly originate from battery manufacturers, battery packs are assembled by electric vehicle manufacturers before being installed in electric vehicles.

Some commenters requested that, if the definition of battery modules includes battery packs in the case of electric vehicle battery modules, the process to transform what is colloquially referred to in industry as a battery module into what is known as a "battery pack" be clarified in the final regulations to constitute disqualifying minor assembly or "partial transformation." Another commenter requested that the final regulations state that the rules are agnostic as to the form or manner in which a battery module with cells is incorporated into the electric vehicle.

Other commenters supported the proposed definition of battery module with cells, stating that this definition appropriately captures the intention of the section 45X credit. One commenter asserted that the battery pack production covered by the proposed definition is a more valuable activity than the production of a single battery module and is the activity closer to the downstream consumer.

The Treasury Department and the IRS appreciate the comments received regarding battery modules and have determined, in close consultation with the Department of Energy, that additional clarification is needed. Section 45X(c)(5)(B)(iii)(I)(aa) defines battery module using battery cells as "a module using battery cells, with two or more battery cells which are configured electrically, in series or parallel, to create voltage or current, as appropriate, to a specified end use[. . .]." Section 45X(c)(5)(B)(iii)(II) provides a capacity threshold limitation of "[an] aggregate

capacity of not less than 7 kilowatt-hours (or, in the case of a module for a hydrogen fuel cell vehicle, not less than 1 kilowatt-hour)" that such battery module using battery cells (as defined in section 45X(c)(5)(B)(iii)(I)(aa)) must meet.

In reviewing comments, the Treasury Department and the IRS understand that the explanation in the preamble of the Proposed Regulations regarding application to electric vehicles may not have aligned with industry understanding and the statutory text. Upon review of the comments received, the Treasury Department and the IRS wish to restate that the requirement found in section 45X(c)(5)(B)(iii)(I)(aa), that battery modules using battery cells that contain battery cells configured to a specified end use, applies regardless whether the items are typically called "battery modules" or "battery packs" in industry practice. These final regulations are therefore clarified to provide that a battery module using battery cells becomes an eligible component upon first meeting the requirements of section 45X(c)(5)(B)(iii)(I)(aa) and (c)(5)(B)(iii)(II), notwithstanding when this transformation may occur in a manufacturing production chain.

At least one commenter requested a rule allowing the entity that assembles the pack to assign tax credits to the joint venture that manufactured the module. Alternatively, if the definition of specified end use is not adopted with respect to joint ventures, the regulations should instead allow for joint venture partners to assign battery-related section 45X credits to the joint venture as the parties see fit, or in cases where the parties do not choose to assign the credits to one of the parents, the joint venture itself. This comment is not adopted as issues specific to joint ventures are outside the scope of these final regulations. For discussion of "produced by the taxpayer" and the associated rules for who may claim the section 45X credit, see Part II.B. of this Summary of Comments and Explanation of Revisions.

b. Modules With No Battery Cells

Proposed § 1.45X-3(e)(4)(i)(B) would have defined the term "module with no battery cells" as a product with a standardized manufacturing process and form that is capable of storing and dispatching useful energy; that contains an energy storage medium that remains in the module (for example, it is not consumed through combustion); and that is not a custom-built electricity generation or storage facility. This proposed definition would allow battery

technologies, such as flow batteries and thermal batteries, to be eligible for the section 45X credit, but would not permit technologies that do not meet this definition, such as standalone fuel storage tanks or fuel tanks connected to engines or generation systems, to qualify as a module with no battery cells.

Several commenters supported the proposed definition of a battery module, and specifically the inclusion of thermal batteries. Commenters also asked for clarification regarding a technology-neutral application of the proposed definition of a battery module. Other commenters suggested specific clarifications to the final regulations regarding certain types of thermal battery systems, such as thermal ice storage or thermal bricks. Some commenters requested that the final regulations incorporate similar language used in the section 48 proposed regulations to facilitate this technology-neutral treatment. For example, these commenters suggested that the final regulations should adopt the language in proposed § 1.48–9(e)(10)(ii) by specifically stating that “batteries of all types (such as lithium ion, vanadium flow, sodium sulfur, and lead-acid)” are eligible components. Commenters asserted that there is symmetry between the investment tax credits for energy storage property and advanced manufacturing credits for energy storage products. Additionally, commenters raised that technology-neutral treatment aligns with Congressional intent to establish eligibility criteria based on performance thresholds, not technology.

The Treasury Department and the IRS, in close consultation with the Department of Energy, agree with commenters that a battery module with no battery cells does not require a specific storage medium nor are there chemistry-based requirements for qualifying battery modules. However, the Treasury Department and the IRS decline to include specific language as a non-exhaustive list of possible storage mediums. Including a non-exhaustive list of current storage mediums on an industry-by-industry basis is not practical and may inadvertently create confusion for other emerging technologies on whether those mediums would qualify for the section 45X credit.

Some commenters disagreed with the requirement in proposed § 1.45X–3(e)(4)(i)(B) that the storage medium remain in the module, asserting that the requirement “may inadvertently exclude technologies” such as compressed air “that can deliver on the intent of the regulations.” The Treasury Department and the IRS decline to amend proposed § 1.45X–3(e)(4)(i)(B) in

response to this comment. The Treasury Department and the IRS, in consultation with the Department of Energy, have determined that the proposed rule appropriately implements the statute. The requirement that the storage medium remain in the module gives meaning to both “battery” and to “module.” For batteries, this requirement describes a feature common to electrochemical and more nascent types of batteries and distinguishes batteries from technologies that rely on fuel. For modules, this requirement helps segregate qualifying technologies from those that are self-contained and not merely one component of a larger system.

Manufacturing the constituent components of battery modules without manufacturing the entire energy storage system does not result in the production of a module with no battery cells under the final regulations. For example, in thermal energy storage applications, the taxpayer must produce and sell the entire system and not just the storage medium. A manufacturer that only produces a thermal storage medium (for example, molten salt) in a thermal energy storage system would not be eligible for the credit. Requiring the production of the entire energy storage system from “energy in” through “energy out” provides similar treatment for purposes of the section 45X credit to the production of a battery module using battery cells.

Numerous comments requested additional clarification of “custom-built electricity . . . storage facility.” Commenters noted that the definition in proposed § 1.45X–3(e)(4)(i)(B) creates ambiguity as to which modifications made in order to meet site or use specifications would trigger the “custom-built” disqualifier. Several commenters asserted that the Proposed Regulations create additional limitations on battery modules without cells that do not apply to the other eligible components. Commenters contended that the terms in the Proposed Regulations, such as “manufacturing,” “standardized,” and “not custom-built,” do not appear in the statutory text and diverge from the general approach taken by the Proposed Regulations with respect to other eligible components. Some commenters asserted that nearly all thermal battery implementations are associated with custom-built generation and storage facilities.

These commenters requested that the final regulations clarify that the eligible components may be assembled with other property to comprise a functioning energy generation or storage facility. Commenters also suggested additional

clarity regarding the physical boundaries of a battery module and thought that using the proposed definition of “produced by the taxpayer” would allow for an eligible component to be assembled on-site, such as battery modules with no battery cells that are too heavy and large to transport fully assembled. Commenters asserted that most or all batteries will require some amount of on-site installation. Commenters generally requested that the final regulations provide a clear and principled definition of “custom-built” that continues to support a technology-neutral and inclusive implementation of section 45X.

Commenters provided various alternatives to further clarify the definition of “custom-built” in the Proposed Regulations. One commenter recommended clarifying the definition of “a custom-built electricity storage facility” as “a facility (1) that contains an energy storage medium and (2) of which all, or substantially all, of the integral components are designed specifically for the facility and are not interchangeable with components of other facilities that utilize the same or similar electricity storage technology.” Another commenter asked that the final regulations clarify that a module with no battery cells is not treated as custom-built if modules are produced by the taxpayer using the same or similar components or property generally used by the taxpayer to produce such modules but in different configurations or amounts to accommodate the storage needs or the site layout applicable to the storage asset. A commenter recommended clarifying the definition that a module with modular components manufactured offsite may undergo final assembly at its installation site without being considered a custom-built facility and include an example regarding final assembly on site. Another suggestion included clarifying that modules with no cells are items of property that must be combined with other tangible personal property to store energy.

Separately, a commenter noted that for contract manufacturing arrangements, “a routine order for off-the-shelf-property” is not eligible for the section 45X credit. The commenter suggested the final regulations provide that an agreement will be treated as a routine purchase order for off-the-shelf property if the contractor is required to make no more than *de minimis* modifications to the property to tailor it to the customer’s specific needs. However, if the manufacturer does make more than *de minimis* modifications,

the module may be custom-built. The commenter asserted that the proposed rule sets up a complicated dichotomy under which manufacturers of modules with no battery cells who enter into contract manufacturing arrangements will have to establish an undefined standard that are neither off the shelf nor custom-built.

Commenters also provided specific examples regarding whether certain technologies or configurations would be considered custom-built. For example, physical site conditions at a customer's site may require that the same components used for one pumped heat energy storage (PHES) are differently arranged for another PHES. The use of the PHES by a customer may require modified storage durations (for example, 20 hours versus 10 hours), which would require additional storage media and vessels. The commenter asserted that this should not be considered custom-built. Commenters also noted that, for closed-loop pumped storage hydropower systems, pipes and other related components are otherwise produced in a standardized process, and neither resemble nor are functionally equivalent to standalone fuel storage tanks or fuel tanks connected to engines or generation systems custom-built electricity generation or storage facility. Commenters also raised that these differences are based on the topography of the site where the system is located and not on the intended function of these components or the system as a whole.

One commenter requested that the Treasury Department and the IRS include hydrogen fuel cell systems under the definition of a battery module using battery cells. Proposed § 1.45X-3(e)(4)(i)(B) would define the term "module with no battery cells" as a product with a standardized manufacturing process and form that is capable of storing and dispatching useful energy, that contains an energy storage medium that remains in the module (for example, it is not consumed through combustion), and that is not a custom-built electricity generation or storage facility.

In general, the Treasury Department and the IRS appreciate the complexity of the issues raised by commenters. Given the myriad of technologies, industry-specific applications, and customary business practices, the final regulations provide additional clarifications. The Treasury Department and the IRS understand the need for clear, administrable rules for both taxpayers and the IRS. The comments also illustrate the impracticality of providing rules to specifically address

all situations. The Treasury Department and the IRS, in close consultation with the Department of Energy, have determined that the definition provided in proposed § 1.45X-3(e)(4)(i)(B) strikes the appropriate balance between bright-line rules and the necessary flexibility for evolving industries. The Treasury Department and the IRS therefore decline to adopt suggested revisions to the definition of "module with no battery cells" in the final regulations.

The Treasury Department and the IRS, in close consultation with the Department of Energy, also have determined that requiring battery modules be modular in the sense that they are both self-contained and not highly customized appropriately implements the statutory definition provided in section 45X(c)(5)(B)(iii). Because of this, the preamble to the Proposed Regulations further clarified that this proposed definition would allow battery technologies such as flow batteries and thermal batteries to be eligible for the section 45X credit, but it would not permit technologies that do not meet this definition such as standalone fuel storage tanks or fuel tanks connected to engines or generation systems to qualify as a module with no battery cells. For these reasons, the Treasury Department and the IRS decline to adopt this comment in the final regulations.

One commenter recommended adopting the definition of modules using battery cells for the definition of modules with no battery cells, with the addition that the module should receive, store, and deliver energy for conversion to electricity. However, adopting the commenter's recommended definition would not be appropriate for modules with no battery cells because the definition of modules using battery cells requires the inclusion of battery cells in the module. Accordingly, The Treasury Department and the IRS decline to adopt the commenter's recommendation.

The Treasury Department and the IRS agree with commenters who suggest that the examples illustrating the contrast between "substantial transformation" and disqualifying minor assembly, explained in Part II.B. of this Summary of Comments and Explanation of Revisions provide useful guidelines for taxpayers and the IRS in determining what is a standardized manufacturing process and not a custom-built electricity generation or storage facility. Thus, incidental onsite assembly of prefabricated modular components for final assembly that are generally produced in the ordinary course of a taxpayer's trade or business would

constitute a standardized manufacturing process for purposes of § 1.45X-3(e)(4)(i)(B). Battery modules with no battery cells that undergo a substantial transformation onsite or are specially manufactured for a single customer would constitute a custom-built electricity generation or storage facility. The Treasury Department and the IRS decline to provide a *de minimis* threshold which would exclude certain manufacturing or configurations that would otherwise qualify for the section 45X credit using the principles described in Part II.B. of this Summary of Comments and Explanation of Revisions.

c. Capacity Measurement

Proposed § 1.45X-3(e)(4)(ii)(A) would have provided that, for modules using battery cells, taxpayers must measure the capacity of a module with a testing procedure that complies with a national or international standard published by a recognized standard setting organization. The capacity of a battery module using battery cells may not exceed the total capacity of the battery cells in the module. Proposed § 1.45X-3(e)(4)(ii)(B) would have provided that, for modules with no battery cells, taxpayers must measure the capacity using a testing procedure that complies with a national or international standard published by a recognized standard setting organization. If no such standard applies to a type of module with no battery cells, taxpayers must measure the capacity of such module as the Secretary may prescribe in regulations or other guidance. The Treasury Department and the IRS requested comments on what recognized national or international standards are currently available for measuring capacity of modules with no battery cells and whether further guidance may be required.

One commenter suggested that the aggregate capacity measurement outlined in section 45X and the Proposed Regulations for battery modules is challenging to apply in the context of thermal battery modules with no cells. Another commenter explained that battery capacity measurements are subject to variations contingent upon environmental conditions during measurement and that capacity assessment for both battery cells and battery modules must occur within a standard testing environment. Some commenters agreed with the approach in the Proposed Regulations of allowing taxpayers to determine the appropriate national or international standards because taxpayers are in a better position to determine the appropriate

standard. Moreover, this approach provides the flexibility necessary for emerging technologies to qualify for the credit. Such commenters requested that the final regulations retain the criteria that the taxpayer must use a testing procedure issued by a recognized standards setting body.

Other commenters explained that the Treasury Department and the IRS should prescribe a flexible approach to capacity measurement for battery modules with no battery cells such that different technologies are appropriately measured and provide alternative testing procedures that complies with a national or international standard published by a recognized standard setting organization that is relevant and applicable for the varying technologies. One commenter asserted that, in their view, such standards may include American Society of Mechanical Engineers (ASME) or International Standards Organization (ISO), but specifically recommended that capacity should be measured based on nameplate capacity as provided in 40 CFR 96.202 in the absence of a bright-line standard. Another commenter supported this approach because of alleged difficulties in determining the minimum capacity of battery modules with no cells before they are placed in service. Other commenters suggested various standards, including ASME PTC 53; ANSI/American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Standard 94.2–2010; and ASHRAE 94 testing methods (specifically, 94.1, 94.2, and 94.3). Another commenter recommended that the final regulations require use of a conversion factor of $1.16RT/kW = 14/12$ and recommended that the regulations provide a capacity measure if there is no national or international standard for a given technology.

A different commenter raised concerns regarding capacity measurement for battery modules with no battery cells and suggested adding to proposed § 1.45X–3(e)(4)(iii)(B), “. . . The capacity of each battery module is expressed on a kilowatt-hour basis in the actual useful energy unit that is specific to the battery module without cells. For example, both thermal and thermochemical battery modules have their capacity expressed on a kilowatt-hour-thermal basis.”

The Treasury Department and the IRS, after consultation with the Department of Energy, have determined that taxpayers producing thermal and thermochemical battery modules with no battery cells must convert the energy storage to a kilowatt-hour basis and provide both methodology and testing

regarding this conversion. Taxpayers must maintain this testing and methodology as part of books and records under section 6001. However, the kilowatt-hour conversion cannot exceed the direct conversion of the total nameplate capacity of the thermal battery module to kilowatt-hours (the capacity that is sold to the consumer). The taxpayer claiming the section 45X credit must use the same methodology consistently, subject to any updated standard of the same methodology and testing, for battery modules (with or without cells) sold in the taxpayer's trade or business. The final regulations incorporate these clarifications in § 1.45X–3(e)(4)(ii) regarding testing and methodology with respect to battery modules.

One commenter requested the final rules remove the requirement that the capacity of a battery module not exceed the total capacity of the battery cells in the module because the different structures of each eligible component may affect the capacity measurement of the module. The Treasury Department and the IRS, in consultation with the Department of Energy, have determined that this rule serves an important function in reducing the potential to manipulate testing conditions in the measurement of capacity and in encouraging the application of reliable measurement standards for battery cells. The Treasury Department and the IRS therefore decline to remove the requirement that the capacity of a battery module not exceed the total capacity of the battery cells in the module.

Another commenter requested that the final regulations provide that the entity that manufactures a battery module that exceeds the statutory 7 kilowatt-hours threshold limitation in section 45X(c)(5)(B)(iii)(II) receives the \$10/kWh module credit. As discussed in Part IV.E.3.a. of this Summary of Comments and Explanation of Revisions, the taxpayer that produces and sells the eligible component (when a battery module first becomes the eligible component) may claim the section 45X credit. Whether an eligible component is produced by the taxpayer is generally discussed in Part II.B. of this Summary of Comments and Explanation of Revisions.

A commenter noted that proposed § 1.45X–3(e)(4)(i), which provides the definition for battery modules “with an aggregate capacity of not less than 7 kilowatt-hours,” aligns with section 30D. The language in section 30D is based on the capacity of the complete battery installed on the vehicle. The commenter asserted that the parallel

language describing the capacity threshold in section 45X and in section 30D indicates that the eligible component for the section 45X credit for battery modules are the items commonly referred to in industry as “battery packs.” This comment is not adopted. As explained in Part IV.E.3.a. of this Summary of Comments and Explanation of Revisions, a battery module (within the meaning of section 45X) is an eligible component, regardless of whether industry nomenclature would describe that module as a “battery pack.”

Proposed § 1.45X–3(e)(5)(i) would have provided a special rule where the capacity determined with respect to a battery cell or battery module must not exceed a capacity-to-power ratio of 100:1. At least one commenter requested clarification on the definition of “capacity to power ratio.” The commenter noted that term could mean either the maximum energy that the battery cell and module can hold or the maximum output that the battery cell and module can release instantaneously. The final regulations retain the proposed rule defining “capacity to power ratio” in § 1.45X–3(e)(5). The Treasury Department and the IRS confirm that the rule, with respect to a battery cell or battery module, the capacity-to-power ratio refers to both the power and the capacity as a cap on the section 45X credit amount, rather than an eligibility criterion. Power is the battery cell's maximum rate of discharge; capacity is the maximum amount of energy the component can store.

F. Phase-Out Rule

Consistent with section 45X(b)(3), proposed § 1.45X–3(f)(1) would have provided that, in the case of any eligible component sold after December 31, 2029, the amount of the section 45X credit determined with respect to such eligible component is equal to the product of the amount determined under proposed § 1.45X–3(b) through (e) with respect to such eligible component, multiplied by the phase out percentage under proposed § 1.45X–3(f)(2). Consistent with section 45X(b)(3)(C), proposed § 1.45X–3(f)(3) would have provided that the phase out rules described in proposed § 1.45X–3(f)(1) and (2) apply to all eligible components except applicable critical minerals. Proposed § 1.45X–3(f)(2) would have provided the phase out percentage is equal to 75 percent for eligible components sold during calendar year 2030; 50 percent for eligible components sold during calendar year 2031; 25 percent for eligible

components sold during calendar year 2032, and zero percent for eligible components sold after calendar year 2032.

A commenter expressed concern that the phase out rules create disparate treatment of an applicable critical mineral produced by a taxpayer that with further value-added processing would result in the production of an electrode active material and provided the example of the production of natural graphite active anode materials. The commenter stated that if the production of the applicable critical mineral and production of the electrode active material occurs in a vertically integrated company, the taxpayer may only claim a section 45X credit for one component. Thus, the commenter requests the phase out rule be modified to not apply to electrode active materials.

The Treasury Department and the IRS decline to adopt the commenter's request. The Treasury Department and the IRS do not have the authority to allow a section 45X credit for the production of an electrode active material in amounts in excess of what is permitted under section 45X(b)(3).

For these reasons, these final regulations adopt proposed § 1.45X-3(f) without modification.

V. Applicable Critical Minerals

Proposed § 1.45X-4 would have provided definitions for the listed applicable critical minerals (generally in accordance with section 45X(c)(6)), the credit amounts, and rules regarding production costs for purposes of determining credit amounts. Commenters addressed certain aspects of these proposed rules, as described in this Part V. of the Summary of Comments and Explanation of Revisions. These final regulations generally adopt the rules as proposed in § 1.45X-4, with the modifications described in this Part V. of the Summary of Comments and Explanation of Revisions.

A. In General

Section 45X(c)(6) defines applicable critical minerals that are eligible components for purposes of the section 45X credit. Consistent with section 45X(c)(6), proposed § 1.45X-4 provides that an applicable critical mineral means any of the minerals that are listed in section 45X(c)(6) and defined in proposed § 1.45X-4(b).

Several commenters requested that the final rules generally clarify and expand the eligibility of metals and metal alloys (including alloys made from primary and secondary metal production) under the purity

requirements. Section 45X generally provides specific minimum purity requirements or forms for applicable critical minerals. Metals or metal alloys under the specified purity requirements that do not meet specified forms do not qualify for the section 45X credit. Thus, the Treasury Department and the IRS do not have the statutory authority to add additional metals and alloys to the list of applicable critical minerals in these final regulations.

B. Definitions

1. Aluminum

Section 45X(c)(6)(A) provides that aluminum that is converted from bauxite to a minimum purity of 99 percent alumina by mass or purified to a minimum purity of 99.9 percent aluminum by mass qualifies as an applicable critical mineral. Proposed § 1.45X-4(b)(1) would have defined aluminum to mean aluminum that is converted from bauxite to a minimum purity of 99 percent alumina by mass or purified to a minimum purity of 99.9 percent aluminum by mass. The preamble to the Proposed Regulations stated that section 45X(c)(6)(A) should be interpreted in light of the dynamics of the aluminum industry and the role that critical materials like aluminum play in the renewable energy and energy storage industry. Proposed § 1.45X-4(b)(1) would have interpreted section 45X(c)(6)(A) to mean aluminum, including commodity-grade aluminum, described in section 45X(c)(6)(A)(i) and (ii). Proposed § 1.45X-4(b)(1) would have defined "commodity-grade aluminum" as aluminum that has been produced directly from aluminum that is described in proposed § 1.45X-4(b)(1)(i) or (ii), is limited to primary production of unwrought forms, and is in a form that is sold on international commodity exchanges, which would include commercial grade aluminum that is 99.7 percent aluminum by mass.

A commenter expressed support for the definition of aluminum in the proposed rule, and stated that the statutory definition could be read to apply only to the refining of alumina and, as a result, not benefit domestic primary aluminum producers, nor achieve the spirit of the legislation to increase domestic manufacturing. The commenter noted confusion with the statutory definition, which stated in part, that aluminum "which is converted from bauxite to a minimum purity of 99 percent alumina by mass" meets the definition of aluminum—however, alumina is converted from bauxite, not aluminum. Thus, the commenter noted that the proposed rule

correctly states the primary aluminum production process and will help United States primary aluminum producers bolster domestic operations and strengthen global competitiveness.

A commenter requested that the final regulations provide that aluminum oxide (alumina) is a form of aluminum for the purposes of section 45X(c)(6)(A)(i). The Treasury Department and the IRS note that section 45X(c)(6)(A)(i) provides eligibility for the credit for aluminum that is converted from bauxite to a minimum purity of 99 percent alumina by mass. One commenter requested that the definition of primary aluminum include molten metal. The Treasury Department and the IRS note that section 45X(c)(6)(A)(ii) does not restrict the form of aluminum purified to a minimum purity of 99.9 percent aluminum by mass. One commenter proposed lowering the eligible purity for aluminum to 96 percent. The Treasury Department and the IRS view this request as inconsistent with the statute.

A few commenters requested the definition of primary aluminum include all unwrought primary aluminum smelted from aluminum oxide (that is, alumina). One commenter requested that the final rules clarify that aluminum produced through secondary production is eligible for the section 45X credit. The preamble to the Proposed Regulations stated that proposed § 1.45X-4(b)(1) clarifies that the term "commodity-grade aluminum" is limited to primary production of unwrought forms by specifying that commodity-grade aluminum must be "produced directly" from certain forms of aluminum. The Treasury Department and the IRS understand that the ability to ascertain and substantiate the process or processes used at an earlier point in the lifecycle of feedstock aluminum for secondary production is limited. The Treasury Department and the IRS are concerned that such limitations would pose significant substantiation and administrability issues if secondary production were permitted for commodity-grade aluminum under proposed § 1.45X-4(b)(1).

A few commenters requested that the final rules replace the requirement that commodity-grade aluminum be "in a form sold on international commodity exchanges" with the requirement that such aluminum "has the ability to meet the chemical specifications of aluminum sold on international commodity exchanges," because not all aluminum sold to third-party customers is traded through the London Metal Exchange, which imposes the shape requirements. The commenters state

that commercial grade aluminum is made into products that are alloyed to different specifications and shapes that are not traded through commodity markets, and the final rules should not distinguish among the end markets. Although the Treasury Department and the IRS view the requirement that commodity-grade aluminum be “in a form sold on international commodity exchanges” as providing important clarity and certainty for taxpayers and the IRS, as well as an objective and observable standard to determine eligibility, the Treasury Department and the IRS will continue to consider these comments as they work to finalize proposed § 1.45X–4(b)(1).

One commenter requested the final regulations clarify “aluminum that is converted from alumina with a minimum purity of 99 percent on a fired basis should qualify as an applicable critical mineral.” The Treasury Department and the IRS think that the additional language specifying whether the purity is measured on a fired basis or dried basis is not necessary due to the specific purity standards already listed in section 45X and the proposed rules. In addition, although these terms are often included on a Certificate of Analysis (COA), the Treasury Department and IRS anticipate that using these terms may cause confusion in circumstances in which these terms are not included on a COA.

With respect to all of the comments related to the definition of aluminum, the Treasury Department and the IRS have determined that additional consideration is necessary prior to finalizing proposed § 1.45X–4(b)(1), which the Treasury Department and the IRS intend to do at a later date. For that reason, § 1.45X–4(b)(1) is reserved in these final regulations.

2. Neodymium

Consistent with section 45X(c)(6)(R), proposed § 1.45X–4(b)(18) would have provided that the term neodymium means neodymium that is converted to neodymium-praseodymium oxide that is purified to a minimum purity of 99.5 percent neodymium oxide by mass; or purified to a minimum purity of 99.9 percent neodymium by mass.

One commenter requested that the final rules provide that the following are eligible for the section 45X credit: (1) neodymium if purified to the industry standard minimum purity of 99.0 percent neodymium by mass; (2) neodymium converted to neodymium-

praseodymium and purified to a minimum purity of 99.0 percent neodymium-praseodymium by mass; (3) neodymium-praseodymium that is purified to a minimum purity of 99.0 percent neodymium-praseodymium by mass; and (4) neodymium-iron-boron alloy or neodymium-praseodymium-iron-boron alloy purified to 99.0 percent by mass. The Treasury Department and the IRS do not have the statutory authority to modify the definition of neodymium or to modify purity percentages in proposed § 1.45X–4(b)(18) and these final regulations adopt this proposed rule without change.

3. Vanadium

Consistent with section 45X(c)(6)(X), proposed § 1.45X–4(b)(24) would have provided that the term vanadium means vanadium that is converted to ferrovandium or vanadium pentoxide. One commenter requested that the definition of vanadium includes vanadium when it is purified to a minimum purity of 99 percent vanadium by mass. The Treasury Department and the IRS do not have the statutory authority to modify the definition of vanadium to include purity percentages, and these final regulations adopt this proposed rule without change.

4. Magnesium

Consistent with section 45X(c)(6)(Z)(x), proposed § 1.45X–4(b)(26)(x) would have provided that the term magnesium means magnesium purified to a minimum purity of 99 percent by mass. One commenter requested that the definition of magnesium be expanded to include magnesium oxide and magnesium hydroxide at purity levels that range from 90–98 percent. The Treasury Department and the IRS do not have the statutory authority to modify the definition of magnesium or to modify purity percentages in proposed § 1.45X–4(b)(26)(x), and these final regulations adopt this proposed rule without change.

C. Credit Amount—in General

Section 45X(b)(1) generally provides the credit amount determined with respect to any eligible component, including any eligible component it incorporates, subject to the credit phase out provided at section 45X(b)(3). Section 45X(b)(3)(C) provides that the credit phase out does not apply with respect to any applicable critical mineral.

Section 45X(b)(1)(M) provides that, in the case of any applicable critical

mineral, the credit amount is an amount equal to 10 percent of the costs incurred by the taxpayer with respect to production of such mineral. Proposed § 1.45X–4(c)(3) would have provided that the costs incurred for purposes of determining the credit amount includes costs as defined in § 1.263A–1(e) that are paid or incurred within the meaning of section 461 of the Code by the taxpayer for the production of an applicable critical mineral only. As explained in the preamble to the Proposed Regulations, this rule has the effect of excluding any costs incurred after the production of the applicable critical mineral. The Proposed Regulations applied section 263A and the section 263A regulations solely to identify the types of costs that are includible in production costs incurred for purposes of computing the credit amount. The Proposed Regulations did not apply section 263A or the section 263A regulations for any other purposes, such as to determine whether a taxpayer is engaged in production activities.

Under the Proposed Regulations, direct or indirect materials costs, as defined in § 1.263A–1(e)(2)(i)(A) and (e)(3)(ii)(E), respectively, and any costs related to the extraction or acquisition of raw materials would not be taken into account as production costs. The Proposed Regulations would have attributed a wide range of costs to the production of an applicable critical mineral as costs incurred in producing the applicable critical mineral, including, but not limited to, labor, electricity used in the production of the applicable critical mineral, storage costs, depreciation or amortization, recycling, and overhead. However, the cost of acquiring the raw material used to produce the applicable critical mineral; the cost of materials used for conversion, purification, or recycling of the raw material; and other material costs related to the production of the applicable critical mineral were not taken into account.

The Proposed Regulations provided a credit for the costs associated with production activities that add value to the applicable critical mineral and are conducted by the taxpayer that produces the applicable critical mineral. Because purchasing raw materials may enable a taxpayer to produce an applicable critical mineral but it is not by itself an activity that adds value, the Proposed Regulations excluded material costs from creditable costs. This exclusion of material costs mitigates the risk of crediting the same costs multiple times.

Many commenters made similar arguments with respect applicable critical minerals and the inclusion of direct material costs as defined in § 1.263A–1(e)(2)(i)(A), indirect material costs as defined in § 1.263A–1(e)(3)(ii)(E), and costs related to the extraction of raw materials in their production costs for purposes of determining the credit. Commenters argued that there was insufficient textual support for a limitation, and any such limitation would work against the purposes of the credit. As with electrode active materials, commenters asserted that direct costs were often a substantial or predominant cost of producing applicable critical minerals. Denying credits for these costs would, in the opinion of commenters, be contrary to the goal of incentivizing extraction and production of applicable critical minerals. Commenters also disputed that direct and indirect costs are not incurred in value-adding activities.

A number of commenters also disputed that a credit should only be available once for the same material. Several commenters argued that the statutory language and structure did, at a minimum, give taxpayers credits for production of applicable critical minerals and, when those applicable critical minerals were used to produce electrode active materials, additional credits for the production of the electrode active materials. According to these commenters, the dual credits reflect the fact that these are separate productive activities for which section 45X provides separate credits. A commenter also urged that producers of applicable critical minerals be able to claim a credit if they can establish that the applicable critical minerals used in the production were acquired from production or extraction outside the United States and thus were previously ineligible for a section 45X credit. For applicable critical minerals that are produced using other precursor applicable critical minerals, a commenter recommended that the cost of the precursor applicable critical minerals be excluded from the cost of producing the applicable critical minerals.

A number of commenters proposed solutions to the problem of crediting the same production costs multiple times. One solution commenters proposed was to reduce the basis of property for which a credit has been claimed by an upstream producer. Commenters also proposed a system under which a taxpayer would only be eligible for a credit on costs of material for which no other taxpayer had previously claimed a credit. This arrangement could be

administered through a system of certification or tracing in which taxpayers would be required to verify that its suppliers had not claimed previously claimed credits for costs associated with the same materials for which the taxpayer is claiming credits. Commenters generally agreed that producers should not need to be vertically integrated to claim credits. Instead, these commenters argued that each producer in the supply chain should be eligible to claim credits for, at a minimum, their addition to the value of the applicable critical minerals produced.

Some commenters addressed the requirement in section 45X(d)(2) that extraction or production of applicable critical minerals occur within the United States or a possession of the United States. A commenter urged that only the cost of extraction of applicable critical minerals occurring in the geology of the United States or its possessions should qualify for the section 45X credit in calculating the cost of production of such mineral. Other commenters urged that credits be permitted to taxpayers that process applicable critical minerals extracted outside the United States provided that the processing occurs within the United States or its possessions. One commenter proposed that the final regulations modify the proposed rule regarding constituent elements, materials, and subcomponents used in the production of applicable critical minerals to distinguish between imports of materials otherwise available from domestic sources and imported materials that are not available from domestic sources. Although this suggested proposal deviates from the Proposed Regulations, it would still allow for credits associated with costs of foreign-sourced constituent elements, materials, and subcomponents but only where domestic alternatives are not available.

Three commenters supported the Proposed Regulations' exclusion of direct, indirect, and extraction costs from production costs eligible for the credit. One commenter was concerned that a contrary rule would invite fraud, waste, and abuse and that, in the case of extraction costs, would be difficult to administer without the creation of a tracing system. Two commenters specifically identified extraction costs as something that should be excluded from the costs of production for the credit. One recommended more explicit clarification that the cost of the extraction of raw materials is excluded from creditable production costs.

With respect to these comments, refer to Part IV.E.1.e. of this Summary of Comments and Explanation of Revisions, which describes the revisions to the proposed rules for production costs of both electrode active materials and applicable critical minerals that are in these final regulations.

Proposed § 1.45X–4(c)(4) would have required the taxpayer to document that their product meets the criteria for an applicable critical mineral as described in section 45X(c)(6) with a certificate of analysis provided by the taxpayer to the person to which the taxpayer sold the applicable critical mineral. The Treasury Department and the IRS requested comments on this substantiation requirement, including whether a similar requirement should be applied to electrode active materials. With respect to this proposed rule, refer to Part IV.E.1.e. of this Summary of Comments and Explanation of Revisions, which describes the revisions to the proposed rules for substantiation of both electrode active materials and applicable critical minerals that are in these final regulations.

VI. Other Comments Received Regarding Ancillary Issues

In response to the Proposed Regulations, certain commenters responded concerning the application of sections 6417 and 6418. A commenter noted that the Proposed Regulations do not explain the process for making a section 6417 elective pay election for a section 45X credit and recommends the final regulations provide more details and guidance on the payment amount and potential considerations. Another commenter requested additional clarification on application procedures, methods, reporting items, refund/transfer periods, and other supplementary procedures relevant to the provisions of section 6417. Similar comments were received with respect to the transferability provisions of section 6418 that may apply to the section 45X credit. A separate commenter requested clarification regarding a transfer of tax credits from vessel manufacturer (shipyard) to vessel owner, and the possible effects of different ownership arrangements of related offshore wind vessels.

The comments related to sections 6417 and 6418 are outside the scope of these final regulations under section 45X, as the comments relate to rules under sections 6417 and 6418. Final regulations under sections 6417, 89 FR 17546 (March 11, 2024), corrected in 89 FR 26786 (April 16, 2024), and corrected in 89 FR 66562 (August 16, 2024) and 6418, 89 FR 34770 (April 30,

2024), corrected in 89 FR 67859 (August 22, 2024), are available and provide relevant information on the elective payment election under section 6417, making a transfer election under section 6418, and the impacts of various ownership structures on the ability and requirements when making an election under either section 6417 or section 6418.

A commenter suggested that the Proposed Regulations should have addressed whether the section 45X credit can be carried back to offset prior year tax liabilities or whether it can be transferred to other taxpayers. The commenter suggested that the final regulations allow the credit to be carried back for a reasonable period of time or to be transferred to other eligible taxpayers under certain conditions and limitations. This request is outside the scope of these final regulations, but as a clarification, section 39 of the Code describes rules related to the carryback and carryforward of unused credits, including section 39(a)(4) which provides a 3-year carryback period for any applicable credit (as defined in section 6417(b)). Section 1.6418-5(h) also provides a rule clarifying that a transferee of a specified credit portion under section 6418 can apply section 39(a)(4) to the extent the specified credit portion is described in section 6417(b) (list of applicable credits, taking into account any placed in service requirements in section 6417(b)(2), (3), and (5)).

A commenter requested that the final regulations define what constitutes a disposition or a cessation of eligibility for the purpose of recapturing the credit within five years of being placed in service. According to the commenter, the final rules should define the terms “disposition” and “cessation of eligibility” and provide examples and exceptions. As a clarification, the section 45X credit is not subject to the recapture provisions of section 50 of the Code because it is not an investment credit under section 46 of the Code. Further, there is no statutory authority under the provisions of section 45X to require recapture of the credit. Thus, these final regulations do not include any rules related to recapture.

A commenter noted that the Proposed Regulations do not address whether the section 45X credit can be specially allocated to certain partners or whether the credit can be modified by a partnership agreement for partnerships that produce and sell eligible components, possibly “creating inconsistencies or unfairness for some partners who may have different interests or expectations.” The

commenter requested that the final regulations include a rule allowing the section 45X credit to be specially allocated or modified by a partnership agreement. Because the commenter’s request is addressed under section 704 and § 1.704-1(b)(4)(ii) and does not relate to credit eligibility under section 45X, the Treasury Department and IRS decline to adopt a rule addressing partnership allocations in these final regulations.

VII. Severability

If any provision in this rulemaking is held to be invalid or unenforceable facially, or as applied to any person or circumstance, it shall be severable from the remainder of this rulemaking, and shall not affect the remainder thereof, and the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

Applicability Dates

These regulations apply to eligible components for which production is completed and sales occur after December 31, 2022, and during taxable years ending on or after October 28, 2024. Taxpayers may choose to apply these regulations to eligible components for which production is completed and sales occur after December 31, 2022, and during taxable years ending before October 28, 2024, provided that taxpayers follow these regulations in their entirety and in a consistent manner.

Effect on Other Documents

Section 5.05(2) of Notice 2023-18 and section 3 of Notice 2023-44, which relate to the interaction between sections 45X and 48C, are superseded for eligible components for which production is completed and sales occur after October 28, 2024.

Special Analyses

I. Regulatory Planning and Review

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6(b) of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (PRA) generally requires that a Federal agency obtain the approval of the Office of Management and Budget (OMB) before collecting information from the public, whether such collection of information is

mandatory, voluntary, or required to obtain or retain a benefit.

The collections of information in these final regulations contain reporting and recordkeeping requirements that are required to validate eligibility to claim a section 45X credit. These collections of information would generally be used by the IRS for tax compliance purposes and by taxpayers to facilitate proper reporting and compliance. The general recordkeeping requirements mentioned within these final regulations are considered general tax records under § 1.6001-1(e). Specific certification statements under § 1.45X-1(c)(3) and statements required in §§ 1.45X-3(e)(2)(iv)(C) and 1.45X-4(c)(4) are considered general tax records and are required for the IRS to validate the taxpayer that may claim a section 45X credit. For PRA purposes, general tax records are already approved by OMB under 1545-0074 for individuals, 1545-0123 for business entities, and under 1545-0092 for trust and estate filers.

These final regulations also provide reporting requirements related to making the Related Person Election as described in § 1.45X-2(d) and calculating the section 45X credit amount as described in § 1.45X-1. The Related Person Election will be made by taxpayers with Forms 1040, 1041, 1120-S, 1065, and 1120, on Form 7207, *Advanced Manufacturing Production Credit* (or any successor forms); and credit calculations will be made on Form 3800 and supporting forms including Form 7207 (and any successor forms). These forms are approved under 1545-0074 for individuals, 1545-0123 for business entities, 1545-2306 for trust and estate filers of Form 7207, and 1545-0895 for trust and estate filers of Form 3800. These final regulations are not changing or creating new collection requirements not already approved by OMB or will be approved under 5 CFR 1320.10 by OMB.

No public comments were received by the IRS directed specifically at the PRA or on the collection requirements, but commenters generally articulated the burdens associated with the documentation requirements contained in the Proposed Regulations. As described in the relevant portions of this preamble, the Treasury Department and the IRS have determined that the documentation requirements are necessary to administer the provisions of section 45X.

III. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the

notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency determines that a proposal is not likely to have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present a final regulatory flexibility analysis (FRFA) of the final regulations. The Treasury Department and the IRS have not determined whether the final regulations will likely have a significant economic impact on a substantial number of small entities. This determination requires further study. Because there is a possibility of significant economic impact on a substantial number of small entities, a FRFA is provided in these final regulations.

Pursuant to section 7805(f) of the Code, the Proposed Regulations were submitted to the Chief Counsel of the Office of Advocacy of the Small Business Administration for comment on its impact on small business, and no comments were received.

A. Need for and Objectives of the Rule

The final regulations provide greater clarity to taxpayers that intend to claim a section 45X credit. The final regulations provide necessary definitions, the time and manner to make the Related Person Election and rules regarding the determination of credit amounts. The Treasury Department and the IRS intend and expect that giving taxpayers guidance that allows them to claim the section 45X credit will beneficially impact various industries. In particular, the section 45X credit encourages the domestic production of eligible components and incentivizes taxpayers to invest in clean energy projects that generate eligible credits.

B. Affected Small Entities

The RFA directs agencies to provide a description of, and if feasible, an estimate of, the number of small entities that may be affected by the proposed rules, if adopted. The Small Business Administration Office of Advocacy (SBA) estimates in its 2023 Frequently Asked Questions that 99.9 percent of American businesses meet its definition of a small business. The applicability of these final regulations does not depend on the size of the business, as defined by the SBA.

As described more fully in the preamble to this final regulation and in this initial regulatory flexibility analysis (IRFA), section 45X and these final

regulations may affect a variety of different entities across several different clean energy industries as multiple types of eligible components are provided for under the statute and manufacturers may produce more than one type. Although there is uncertainty as to the exact number of small businesses within this group, the current estimated number of respondents to these final rules is 13,450 taxpayers. The estimated total annual reporting burden and estimated average annual burden per respondent will be computed when Form 7207 and the instructions to Form 7207 are updated to reflect these final regulations.

The Treasury Department and the IRS utilize tax data as the basis for its RFA analysis. Tax entities supply information on tax forms, which information is processed and recorded by the IRS. This data is then available to the IRS office of Research, Applied Analytics and Statistics and to the Treasury Department's Office of Tax Policy for use in estimating the impact of tax regulation on businesses. Tax data is the more appropriate data as it provides nearly universal coverage of the entities that are affected by these tax regulations. All taxpayers and many potential taxpayers are represented in the universe of tax data. Second, the tax data more accurately reflect the level of organization to which tax regulations are applicable because tax data is collected on the entity rather than the enterprise level. Overwhelmingly, business tax regulations apply to the entity level making tax data a natural fit for the analysis of regulatory impact. Further, with limited exceptions, tax regulations apply to all entities organized in a particular manner regardless of industry or size. Finally, analysis of the implications of tax regulations for the purposes of the PRA and any Special Analyses, including the Regulatory Impact Analysis, are carried out using tax data. Generally, restricting analysis for the RFA to tax data prevents difficulties in reconciling the different analyses within a given regulation.

Reliance on tax data has some drawbacks. In general, tax forms do not collect information unless it is directly relevant to the calculation of tax liability. The Northern American Industry Classification System (NAICS) codes referenced by the Office of Advocacy of the Small Business Administration are included on tax forms for informational purposes and may not be reliable. For example, past the first two-digits of the NAICS code, economic sector level, entries may be left blank in the raw data. In addition,

for a tax entity that is comprised of multiple different enterprises that each operate in a different industry, the NAICS code reported on a tax form may not reflect the appropriate industry for the regulation under analysis. Furthermore, most tax returns have no independent verification of the accuracy of NAICS codes. Notwithstanding this concern, tax data remains the most appropriate data for analysis of the implications of tax regulations.

The Treasury Department and the IRS have considered other data alternatives including Census data sources, such as the Statistics of U.S. Businesses (SUSB) suggested by SBA's Office of Advocacy. The 2020 SUSB includes only six million firms and eight million establishments while the proposed tax data includes approximately 18 million business entities. Unlike the SUSB data, the tax data includes more small businesses, not only ones with at least one employee. Tax data provides a more inclusive estimate of businesses affected by tax regulations. In conclusion, while tax data is an appropriate resource for evaluating the impact of tax regulations, this data does not permit some of the usual analysis presented to the SBA. Furthermore, since the NAICS codes reported on the tax return may not accurately reflect the industry of the entity, applying separate standards by industry is inadvisable.

Thus, the Treasury Department and the IRS have determined that reliance on NAICS codes would not accurately reflect the entities affected by these regulations. Further, the Treasury Department and the IRS currently do not have useable tax data that reflects the entities that will be affected by these regulations. While there is uncertainty as to the exact number of small businesses within this group, the Treasury Department and the IRS continue to estimate that approximately 13,450 taxpayers will be impacted.

The Treasury Department and the IRS expect to receive more information on the impact on small businesses after taxpayers start to claim the section 45X credit using the guidance and procedures provided in these final regulations.

C. Impact of the Rules

The final regulations provide rules for how taxpayers can claim the section 45X credit. Taxpayers that claim the section 45X credit will have administrative costs related to reading and understanding the rules as well as recordkeeping and reporting requirements because of the Related Person Election, computation of the section 45X credit and tax return

requirements. The costs will vary across different-sized entities and across the type of production activities in which such entities are engaged.

The Related Person Election allows a taxpayer to make an irrevocable election annually with their Federal income tax return by providing the information required on Form 7207 (or any successor form), including, for example, the name, EIN of the taxpayer; a description of the taxpayer's trade or business; the name, address and EINs of all related persons; a list of the eligible components that are sold, and the intended purpose of the eligible components sold by the related person. To make the Related Person Election and claim the section 45X credit, the taxpayer must file an annual Federal income tax return. The reporting and recordkeeping requirements for that Federal income tax return would be required for any taxpayer that is claiming a general business credit, regardless of whether the taxpayer was making a Related Person Election under section 45X.

D. Alternatives Considered

The Treasury Department and the IRS considered alternatives to these final regulations. For example, the Treasury Department and the IRS considered whether to impose certain pre-return filing requirements as a condition of making the Related Person Election as authorized in section 45X(a)(3)(B)(ii) to prevent duplication, fraud, or improper or excessive credits. These final regulations were designed to minimize burdens for taxpayers while ensuring that the IRS has sufficient information to determine eligibility for the section 45X credit. The Treasury Department and the IRS determined that requiring registration before a taxpayer makes the Related Person Election is unnecessary at this time. These final regulations would allow taxpayers to make an irrevocable Related Person Election annually with their Federal income tax return by providing the information required on Form 7207 (or any successor form), which would provide the IRS with sufficient information to assist in preventing duplication, fraud, or the claiming of improper or excessive credits if eligible components are produced and then sold to related persons.

E. Duplicative, Overlapping, or Conflicting Federal Rules

The final rule would not duplicate, overlap, or conflict with any relevant Federal rules. As discussed previously, the final rule would merely provide procedures and definitions to allow

taxpayers to claim the section 45X credit. The Treasury Department and the IRS invite input from interested members of the public about identifying and avoiding overlapping, duplicative, or conflicting requirements.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of \$100 million (updated annually for inflation). These final regulations do not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. These final regulations do not have federalism implications and do not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

VI. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (Consultation and Coordination with Indian Tribal governments) prohibits an agency from publishing any rule that has Tribal implications if the rule either imposes substantial, direct compliance costs on Indian Tribal governments, and is not required by statute, or preempts Tribal law, unless the agency meets the consultation and funding requirements of section 5 of the Executive order. This final rule does not have substantial direct effects on one or more federally recognized Indian tribes and does not impose substantial direct compliance costs on Indian Tribal governments within the meaning of the Executive order.

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs

designated this rule as a major rule as defined by 5 U.S.C. 804(2).

Statement of Availability of IRS Documents

IRS notices and other guidance cited in this preamble are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at <https://www.irs.gov>.

Drafting Information

The principal authors of these final regulations are Mindy Chou, John Deininger, Derek Gimbel, John Lovelace, and Alexander Scott. However, other personnel from the Office of Chief Counsel, the Treasury Department, and the IRS participated in the development of these regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, the Treasury Department and the IRS amend 26 CFR part 1 as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order for §§ 1.45X–1 through 1.45X–4 to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.45X–1 also issued under 26 U.S.C. 45X, 6001, 6417(h) and 6418(h).

Section 1.45X–2 also issued under 26 U.S.C. 45X and 1502.

Section 1.45X–3 also issued under 26 U.S.C. 6001.

Section 1.45X–4 also issued under 26 U.S.C. 6001.

* * * * *

■ **Par. 2.** Sections 1.45X–0 through 1.45X–4 are added to read as follows:

Sec.

* * * * *

1.45X–0 Table of contents.

1.45X–1 General rules applicable to the advanced manufacturing production credit.

1.45X–2 Sale to unrelated person.

1.45X–3 Eligible components.

1.45X–4 Applicable critical minerals.

* * * * *

§ 1.45X–0 Table of contents.

This section lists the major captions contained in §§ 1.45X–1 through 1.45X–4.
§ 1.45X–1 General rules applicable to the advanced manufacturing production credit.

- (a) Overview.
- (b) Credit amount.
- (c) Definition of produced by the taxpayer.
- (d) Produced in the United States.
- (e) Production and sale in a trade or business.

(f) Sale of integrated components.
 (g) Interaction between sections 45X and 48C.

- (h) [Reserved]
- (i) Anti-abuse rule.
- (j) Applicability date.

§ 1.45X–2 Sale to unrelated person.

- (a) In general.
- (b) Definitions.
- (c) Special rule for sale to related person.
- (d) Related person election.
- (e) Sales of integrated components to related person.

(f) Applicability date.

§ 1.45X–3 Eligible components.

- (a) In general.
- (b) Solar energy components.
- (c) Wind energy components.
- (d) Inverters.
- (e) Qualifying battery component.
- (f) Phase out rule.
- (g) Applicability date.

§ 1.45X–4 Applicable critical minerals.

- (a) In general.
- (b) Definitions.
- (c) Credit amount.
- (d) Applicability date.

§ 1.45X–1 General rules applicable to the advanced manufacturing production credit.

(a) *Overview*—(1) *In general*. This section provides general rules regarding the advanced manufacturing production credit determined under section 45X of the Code (section 45X credit). Paragraph (a)(2) of this section provides definitions of certain terms that apply for purposes of section 45X and the section 45X regulations (as defined in paragraph (a)(2)(xv) of this section). Paragraphs (b) through (j) of this section provide the basic rules regarding the section 45X credit, including the definition of the term *produced by the taxpayer*, and rules to determine the taxpayer that produces an eligible component and whether such taxpayer is entitled to claim a section 45X credit in contract manufacturing arrangements; where the production of eligible components must occur; the treatment of integrated, incorporated or assembled eligible components; and the interaction between sections 45X and 48C of the Code. See § 1.45X–2 for rules regarding sales to unrelated persons, sales to related persons, and the related person election (Related Person Election), including rules regarding the time, place, and manner of making the Related Person Election. See § 1.45X–3 for the definitions of all eligible components (except applicable critical minerals) and the credit amounts available for each of these eligible components, including certain phase-

out percentages. See § 1.45X–4 for the definitions of applicable critical minerals and the rules regarding the determination of the credit amount for applicable critical minerals.

(2) *Generally applicable definitions*. This paragraph (a)(2) provides definitions of terms that apply for purposes of section 45X and the section 45X regulations.

(i) *Applicable critical mineral*. The term *applicable critical mineral* means any of the minerals that are listed in section 45X(c)(6) and defined in § 1.45X–4(b).

(ii) *Code*. The term *Code* means the Internal Revenue Code.

(iii) *Contract manufacturing arrangement*. The term *contract manufacturing arrangement* is defined in paragraph (c)(3)(ii)(B) of this section.

(iv) *Electrode active materials*. The term *electrode active materials* is defined in section 45X(c)(5)(B)(i) and described in § 1.45X–3(e)(2).

(v) *Eligible component*. The term *eligible component* is defined in section 45X(c)(1)(A) and described in §§ 1.45X–3 and 1.45X–4.

(vi) *Eligible taxpayer*. The term *eligible taxpayer* is defined in paragraph (c)(3) of this section.

(vii) *Extraction*. The term *extraction* is defined in § 1.45X–3(e)(2)(iv)(B).

(viii) *Guidance*. The term *guidance* means guidance published in the **Federal Register** or Internal Revenue Bulletin, as well as administrative guidance such as forms, instructions, publications, or other guidance on the IRS.gov website. See §§ 601.601 and 601.602 of this chapter.

(ix) *IRA*. The term *IRA* means Public Law 117–169, commonly known as the Inflation Reduction Act of 2022.

(x) *IRS*. The term *IRS* means the Internal Revenue Service.

(xi) *Produced by the taxpayer*. The term *produced by the taxpayer* is defined in paragraph (c) of this section, and the related terms *production activities* and *production process* have the meaning given those terms in paragraph (c) of this section.

(xii) *Related person*. The term *related person* is defined in § 1.45X–2(b)(2).

(xiii) *Related Person Election*. The term *Related Person Election* is defined in § 1.45X–2(d)(1).

(xiv) *Secretary*. The term *Secretary* means the Secretary of the Treasury or her delegate.

(xv) *Section 45X regulations*. The term *section 45X regulations* means the provisions of this section, §§ 1.45X–2 through 1.45X–4, and the regulations in this chapter under sections 6417 and 6418 of the Code that relate to the section 45X credit.

(xvi) *Unrelated person*. The term *unrelated person* is defined in section 45X(a)(3) and described in § 1.45X–2(b)(3).

(b) *Credit amount*. Except as otherwise provided in section 45X(b)(3) and § 1.45X–3(f), for purposes of section 38 of the Code, the amount of the section 45X credit for any taxable year is equal to the sum of the credit amounts provided under section 45X(b) and described in §§ 1.45X–3 and 1.45X–4 with respect to each eligible component that is produced by the taxpayer and, within the taxable year, sold by the taxpayer to an unrelated person. See § 1.45X–2 for rules regarding sales of eligible components to related persons that may be treated as if sold to unrelated persons for purposes of section 45X(a).

(c) *Definition of produced by the taxpayer*—(1) *In general*. The term *produced by the taxpayer* means a process conducted by the taxpayer that substantially transforms constituent elements, materials, or subcomponents into a complete and distinct eligible component that is functionally different from that which would result from minor assembly or superficial modification of the elements, materials, or subcomponents, and includes both primary and secondary production. Primary production involves producing an eligible component using non-recycled materials while secondary production involves producing an eligible component using recycled materials.

(i) *Partial transformation*. The term *produced by the taxpayer* does not include partial transformation that does not result in substantial transformation of constituent elements, materials, or subcomponents into a complete and distinct eligible component as described in this paragraph (c)(1).

(ii) *Minor assembly or superficial modification*. The term *produced by the taxpayer* does not include minor assembly of two or more constituent elements, materials, or subcomponents, or superficial modification of the final eligible component, if the taxpayer does not also engage in the process resulting in a substantial transformation described in paragraph (c)(1) or (2) of this section.

(iii) *Examples*. The following examples illustrate the application of this paragraph (c)(1).

(A) *Example 1*. Taxpayers X, Y, and Z each produce one of three sections of a wind tower that together make up the wind tower. No taxpayer has produced an eligible component within the meaning of section 45X(a)(1)(A) because

no taxpayer has produced all sections of the wind tower.

(B) *Example 2.* Same facts as paragraph (c)(1)(iii)(A) of this section (*Example 1*), but taxpayers X, Y, and Z instead form Partnership XYZ. Partnership XYZ produces all three sections of the wind tower. Partnership XYZ has produced an eligible component within the meaning of section 45X(a)(1)(A).

(C) *Example 3.* Taxpayer V puts the external casing on a battery module (within the meaning of § 1.45X-3(e)(4)(i)(A)) that already had cells, battery management systems, and other components integrated into it. Taxpayer V has engaged in minor assembly and has not produced an eligible component within the meaning of section 45X(a)(1)(A).

(D) *Example 4.* Taxpayer U purchases two finished halves of a wind turbine nacelle and combines them into a single nacelle. Taxpayer U has engaged in minor assembly and has not produced an eligible component within the meaning of section 45X(a)(1)(A).

(E) *Example 5.* Taxpayer T purchases a dry cell battery and fills the electrolyte of the battery. Taxpayer T has engaged in minor assembly and has not produced an eligible component within the meaning of section 45X(a)(1)(A).

(F) *Example 6.* Taxpayer W purchases a prefabricated wind turbine blade and applies paint and finishes. Taxpayer W has engaged in superficial modification of the blade and has not produced an eligible component within the meaning of section 45X(a)(1)(A).

(2) *Special rule for certain eligible components—(i) In general.* For solar grade polysilicon, electrode active materials, and applicable critical minerals, the term *produced by the taxpayer* means processing, converting, refining, or purifying source materials, such as brines, ores, or waste streams, to substantially transform the source materials to derive a distinct eligible component, and includes both primary and secondary production. For the production process for electrode active materials and applicable critical minerals, the term *conversion* is defined in § 1.45X-3(e)(2)(ii)(A) or § 1.45X-4(c)(2)(i), respectively, and the term *purification* is defined in § 1.45X-3(e)(2)(ii)(B) or § 1.45X-4(c)(2)(ii), respectively.

(ii) *Example.* Taxpayers X, Y and Z are unrelated C corporations that have calendar year taxable years. In 2024, X extracts raw lithium from natural mineral deposits and purifies the extracted material to 90% lithium by mass. X subsequently hires Y to further purify the lithium material furnished by

X to a purity of no less than 99.9% lithium by mass as required by section 45X(c)(6)(P) and § 1.45X-4(b)(16)(ii). In 2025, Y purifies the material to 99.9% lithium by mass (qualifying lithium). X subsequently sells the qualifying lithium to Z in 2026. X may not claim a section 45X credit for the qualifying lithium sold to Z because the qualifying lithium was not produced by X within the meaning of this paragraph (c)(2) of this section, given that X did not transform the lithium material to derive a distinct eligible component (*i.e.*, lithium which satisfies the minimum purity of 99.9% lithium by mass prescribed by section 45X(c)(6)(P)).

(3) *Eligible taxpayer—(i) In general.* Except as otherwise provided in paragraph (c)(3)(iii) of this section, a taxpayer claiming a section 45X credit with respect to an eligible component must be the taxpayer that directly performs the production activities that bring about a substantial transformation resulting in the eligible component and must sell such eligible component to an unrelated person.

(ii) *Contract manufacturing arrangement—(A) In general.* If the production of an eligible component is performed in whole or in part pursuant to a contract that is a contract manufacturing arrangement, then, provided the other requirements of section 45X are met, the party to such contract that may claim the section 45X credit with respect to such eligible component is the party that performs the actual production activities that bring about a substantial transformation resulting in the eligible component.

(B) *Contract manufacturing arrangement defined.* The term *contract manufacturing arrangement* means any agreement (or agreements) providing for the production of an eligible component if the agreement is entered into before the production of the eligible component to be delivered under the contract is completed. A routine purchase order for off-the-shelf property is not treated as a contract manufacturing arrangement for purposes of this paragraph (c)(3). An agreement will be treated as a routine purchase order for off-the-shelf property if the contractor is required to make no more than de minimis modifications to the property to tailor it to the customer's specific needs, or if at the time the agreement is entered into, the contractor knows or has reason to know that the contractor can satisfy the agreement out of existing stocks or normal production of finished goods.

(iii) *Special rule for contract manufacturing arrangements.* If an eligible component is produced by a

taxpayer pursuant to a contract manufacturing arrangement, the parties to such agreement may determine by agreement the party that may claim the section 45X credit. If a taxpayer enters into contract manufacturing arrangements with multiple fabricators to produce an eligible component, the parties to such agreements may determine by agreement the party that may claim the section 45X credit. The IRS will not challenge the agreement of the parties provided all the parties submit signed certification statements in the manner required in Form 7207, *Advanced Manufacturing Production Credit*, or its instructions (as described in paragraph (c)(3)(iv) of this section) indicating that all parties agree as to the party that may claim the section 45X credit.

(iv) *Certification statement requirements.* A certification statement indicating that all parties to a contract manufacturing arrangement agree as to the party that will claim the section 45X credit must include—

(A) All required information set forth in guidance; and

(B) A properly signed penalty of perjury statement that includes the following: under penalties of perjury, I declare that I have examined this statement, including accompanying documents, and to the best of my knowledge and belief, the facts presented in support of this statement are true, correct, and complete.

(v) *Examples.* The following examples illustrate the application of this paragraph (c)(3).

(A) *Example 1: Contract manufacturing with sale.* Taxpayers X, Y and Z are unrelated C corporations that have calendar year taxable years. In 2024, pursuant to a contract manufacturing arrangement as described in paragraph (c)(3)(ii)(B) of this section, X hires Y to produce a solar module. The contract is a tolling arrangement and provides that Y will produce the solar module according to X's designs and specifications and using the materials and subcomponents that X provides. X and Y enter an agreement providing that X is the sole party that may claim a section 45X credit for the production and sale of the solar module, and X and Y each sign a certification statement as described in paragraph (c)(3)(iv) of this section reflecting this agreement. In 2025, Y produces and delivers the solar module to X, and in 2026, X sells the solar module to Z. X may claim a section 45X credit in taxable year 2026 for the solar module it sold to Z provided all other requirements of section 45X are met and the certification statements signed by X

and Y meet the requirements described in paragraph (c)(3)(iv) of this section and are properly submitted by X. Y could claim a section 45X credit if the agreement between X and Y had designated Y as the sole party that could claim a section 45X credit for the production and sale of the solar module provided all other requirements of section 45X are met and the certification statements signed by X and Y meet the requirements described in paragraph (c)(3)(iv) of this section and are properly submitted by Y.

(B) *Example 2: Contract manufacturing with no sale.* Assume the facts are the same as in paragraph (c)(3)(v)(A) of this section (*Example 1*), except that X does not sell the solar module and instead X uses it to generate electricity for use in X's trade or business. Because there has been no sale, neither X nor Y may claim a section 45X credit for the solar module regardless of whether X and Y submit signed certification statements described in paragraph (c)(3)(iv) of this section.

(C) *Example 3: Multiple contract manufacturing arrangements.* Taxpayers V, W, X, Y, and Z are unrelated C corporations that have calendar year taxable years. In 2024, pursuant to three separate contract manufacturing arrangements as described in paragraph (c)(3)(ii)(B) of this section, V hires W, X, and Y to produce the bottom, middle and top segments, respectively, of a single wind tower that V designed. W, X, Y, and V enter into an agreement providing that V is the sole party that may claim a section 45X credit for the production and sale of the wind tower, and W, X, Y, and V each sign a certification statement as described in paragraph (c)(3)(iv) of this section reflecting this agreement. In 2024, W and X both produce and deliver their respective wind tower segments to the installation site, and in 2025, Y produces and delivers its wind tower segment to the installation site. In 2026, V sells the completed wind tower to Z. V may claim a section 45X credit in taxable year 2026 for the wind tower it sold to Z provided all other requirements of section 45X are met and the certification statements signed by V, W, X, and Y meet the requirements described in paragraph (c)(3)(iv) of this section and are properly submitted by V. W or X or Y could be the party that could claim a section 45X credit if the agreement between V, W, X and Y had designated W or X or Y as the sole party that could claim a section 45X credit for the production and sale of the wind tower provided all other requirements of section 45X are met and the certification

statements signed by V, W, X, and Y meet the requirements described in paragraph (c)(3)(iv) of this section and are properly submitted by the party designated as the sole party that could claim a section 45X credit.

(D) *Example 4: Applicable Critical Mineral Processing with Certification.* Taxpayers X, Y, and Z are unrelated C corporations that have calendar year taxable years. In 2024, X extracts raw lithium from natural mineral deposits and purifies the extracted material to 90% lithium by mass. X subsequently hires Y to further process the lithium material pursuant to a contract manufacturing arrangement as described in paragraph (c)(3)(ii)(B) of this section. Specifically, the contract is a tolling arrangement and provides that X remains the owner for Federal income tax purposes throughout the purification process and that Y will further purify the lithium material furnished by X to a purity of no less than 99.9% lithium by mass as required by section 45X(c)(6)(P) and § 1.45X-4(b)(16)(ii). X and Y enter an agreement providing that X is the sole party that may claim a section 45X credit for the production and sale of the applicable critical mineral, and X and Y each sign a certification statement as described in paragraph (c)(3)(iv) of this section reflecting this agreement. In 2025, Y purifies the material to 99.9% lithium by mass (qualifying lithium) and delivers it to X. X subsequently sells the qualifying lithium to Z in 2026. X may claim a section 45X credit in taxable year 2026 for the qualifying lithium sold to Z, provided that all other requirements of section 45X are met, and the certification statements signed by X and Y meet the requirements described in paragraph (c)(3)(iv) of this section and are properly submitted by X. Y could claim a section 45X credit if the agreement between X and Y had designated Y as the sole party that could claim a section 45X credit for the qualifying lithium, provided that all other requirements of section 45X are met, and the certification statements signed by X and Y meet the requirements described in paragraph (c)(3)(iv) of this section and are properly submitted by Y. Neither X nor Y could claim a section 45X credit in the absence of a designating agreement and certification statement (described in paragraphs (c)(3)(iii) and (iv) of this section, respectively) for the reasons stated in paragraph (c)(2)(i) of this section.

(4) *Timing of production and sale—(i) In general.* Production of eligible components for which a taxpayer is claiming a section 45X credit may begin

before December 31, 2022. Production of eligible components must be completed, and sales of eligible components must occur, after December 31, 2022.

(ii) *Example.* Taxpayer X has a calendar year taxable year. Taxpayer X begins production of a related offshore wind vessel (as defined in section 45X(4)(B)(iv) and described in § 1.45X-3(c)(4)) in January 2022. Production is completed in December 2024 and the sale to an unrelated person occurs in 2025. Taxpayer X is eligible to claim the section 45X credit in 2025, assuming that all other requirements of section 45X are met.

(d) *Produced in the United States—(1) In general.* Sales are taken into account for purposes of the section 45X credit only for eligible components that are produced within the United States, as defined in section 638(1) of the Code, or a United States territory, which for purposes of section 45X and the section 45X regulations has the meaning of the term *possession* provided in section 638(2).

(2) *Subcomponents.* Constituent elements, materials, and subcomponents used in the production of eligible components are not subject to the domestic production requirement provided in paragraph (d)(1) of this section.

(e) *Production and sale in a trade or business.* An eligible component produced and sold by the taxpayer is taken into account for purposes of the section 45X credit only if the production and sale are in a trade or business (within the meaning of section 162 of the Code) of the taxpayer.

(f) *Sale of integrated components—(1) In general.* For purposes of the section 45X credit, section 45X(d)(4) provides that a taxpayer that produces an eligible component is treated as having sold such eligible component to an unrelated person if such component is integrated, incorporated, or assembled into another eligible component that is then sold to an unrelated person.

(i) *Integrated, incorporated, or assembled.* The term *integrated*, *incorporated*, or *assembled* means the production activities by which an eligible component that is a constituent element, material, or subcomponent is substantially transformed into another complete and distinct eligible component that is not solar grade polysilicon, an electrode active material, or an applicable critical mineral. The term *integrated*, *incorporated*, or *assembled* does not mean the minor assembly or superficial modification of an eligible component used as an element, material, or subcomponent and other elements, materials, or

subcomponents that results in a distinct product.

(ii) *Special rule for eligible components resulting in solar grade polysilicon, electrode active materials, or applicable critical minerals.* For solar grade polysilicon, electrode active materials, and applicable critical minerals, the term *integrated, incorporated, or assembled* means the production activities in which an eligible component is processed, converted, refined, or purified to derive a distinct eligible component that is solar grade polysilicon, an electrode active material, or an applicable critical mineral. The term *integrated, incorporated, or assembled* does not mean minor assembly or superficial modification of an eligible component used as an element, material, or subcomponent and other elements, materials, or subcomponents that results in a distinct product.

(2) *Application—(i) In general.* A taxpayer may claim a section 45X credit for each eligible component the taxpayer produces and sells to an unrelated person, including any eligible component the taxpayer produces that was used as a constituent element, material, or subcomponent and integrated, incorporated, or assembled into another complete and distinct eligible component or another complete and distinct product (that is not itself an eligible component) that the taxpayer also produces and sells to an unrelated person.

(ii) *Example: Sale of product with incorporated eligible components to unrelated person.* In 2022, X, a domestic corporation that has a calendar year taxable year, begins production of electrode active materials (EAMs) that are completed in 2023 and incorporated into battery cells that X also produces. In 2024, X incorporates those battery cells into battery modules (within the meaning of § 1.45X-3(e)(4)(i)(A)) and integrates the battery modules into electric vehicles. X sells the electric vehicles to Z, an unrelated person, in 2024. X may claim a section 45X credit for the EAMs, the battery cells, and the battery modules in 2024.

(g) *Interaction between sections 45X and 48C—(1) In general.* For purposes of the section 45X credit, consistent with section 45X(c)(1)(B), property that would otherwise qualify as an eligible component (otherwise qualified property) is only an eligible component if the property is produced at a section 45X facility (as defined in paragraph (g)(2) of this section) and no part of that section 45X facility is also a section 48C facility (as defined in paragraph (g)(3) of this section).

(2) *Section 45X facility—(i) In general.* A section 45X facility comprises the independently functioning tangible property used by the taxpayer that is necessary to be considered the producer of the otherwise qualified property within the meaning of paragraph (c)(1) or (2) of this section, as applicable. The tangible property that comprises a section 45X facility may be in more than one location.

(ii) *Special rule for contract manufacturing arrangement.* In the case of a contract manufacturing arrangement where the parties have agreed to who can claim a section 45X credit under paragraph (c)(3)(iii) of this section, the section 45X facility under paragraph (g)(2)(i) of this section is determined by taking into account the tangible property used to produce the otherwise qualified property, regardless of which party to the arrangement claims the credit.

(3) *Section 48C facility—(i) In general.* A section 48C facility includes all eligible property included in a qualifying advanced energy project for which a taxpayer receives an allocation of section 48C credits under the allocation program established under section 48C(e) and claims such credits after August 16, 2022.

(ii) *Eligible property.* *Eligible property* is property that—

(A) Is necessary for the production or recycling of property described in section 48C(c)(1)(A)(i), re-equipping an industrial or manufacturing facility described in section 48C(c)(1)(A)(ii), or re-equipping, expanding, or establishing an industrial facility described in section 48C(c)(1)(A)(iii);

(B) Is tangible personal property, or other tangible property (not including a building or its structural components), but only if such property is used as an integral part of the qualified investment credit facility; and

(C) With respect to which depreciation (or amortization in lieu of depreciation) is allowable.

(4) *Examples.* The following examples illustrate the application of this paragraph (g), and assume any other requirements of section 45X that are not described have been met:

(i) *Example 1: Two independent section 45X facilities—(A) Facts.* Taxpayer owns and operates a manufacturing site that contains tangible property made up of Equipment A and Equipment B, each set of which functions independently and which is arranged in serial fashion. Equipment A is used by the taxpayer to produce otherwise qualified property 1. Equipment B is used to produce otherwise qualified property 2, a

different type of product than otherwise qualified property 1. Taxpayer was allocated a section 48C credit under the section 48C(e) program for a section 48C facility that includes Equipment A and subsequently placed the section 48C facility and Equipment A in service in taxable year 2026. Taxpayer claimed a section 48C credit related to Equipment A for taxable year 2026.

(B) *Analysis.* The section 45X facility with respect to otherwise qualified property 1 is the tangible property made up of Equipment A, which is the independently functioning tangible property used by the taxpayer that is necessary to be considered the producer of the otherwise qualified property within the meaning of paragraph (c)(1) or (2) of this section. However, Equipment A is also eligible property that is considered part of a section 48C facility as defined in paragraph (g)(3) of this section. Therefore, otherwise qualified property 1 is not an eligible component under paragraph (g)(1) of this section because part (all in this case) of the section 45X facility where otherwise qualified property 1 was produced is also considered a section 48C facility. There is a separate section 45X facility with respect to otherwise qualified property 2. That section 45X facility is the tangible property made up of Equipment B. Equipment A is not included in the section 45X facility as it is not used to produce otherwise qualified property 2. None of the tangible property comprising the section 45X facility with respect to otherwise qualified property 2 is considered part of a section 48C facility. Thus, otherwise qualified property 2 is an eligible component under paragraph (g)(1) of this section.

(ii) *Example 2: Single section 45X facility at different locations—(A) Facts.* Taxpayer owns and operates two manufacturing sites at different locations. The tangible property at manufacturing site 1 is Equipment A, which is used to continue and finish the first part of the production process for otherwise qualified property. The tangible property at manufacturing site 2 is Equipment B, which is used to complete the production process of the same otherwise qualified property. Taxpayer was allocated a section 48C credit under the section 48C(e) program for Equipment A.

(B) *Analysis.* Equipment A and B comprise a single section 45X facility regardless of location under paragraph (g)(2)(i) of this section because both Equipment A and B were used to produce the otherwise qualified property and the use of Equipment A and B are necessary to consider the

taxpayer the producer, consistent with the meaning of produced by the taxpayer in paragraph (c)(1) or (2) of this section. However, part of the property comprising the section 45X facility is also a section 48C facility under paragraph (g)(3) of this section because Equipment A is eligible property that is part of a section 48C facility. As a result, the otherwise qualified property is not considered an eligible component, and the sale of the otherwise qualified property will not generate a section 45X credit.

(iii) *Example 3: Independent tangible property and production of component*—(A) *Facts.* Taxpayer owns and operates two manufacturing sites. Manufacturing Site 1 contains tangible property that is Equipment A, which is used to produce photovoltaic cells. Manufacturing Site 2 contains tangible property that is Equipment B and tangible property that is Equipment C, which are arranged in serial fashion. Equipment B is used to produce photovoltaic cells. Equipment C is used to produce solar modules, in part, by combining the photovoltaic cells produced by Equipment A and Equipment B. Taxpayer was allocated a section 48C credit under the section 48C(e) program for a section 48C facility that includes Equipment B. Subsequently, Taxpayer places the section 48C facility and Equipment B in service in taxable year 2026. Taxpayer claimed a section 48C credit for Equipment B in taxable year 2026.

(B) *Analysis.* Equipment A and Equipment B each comprise a section 45X facility since each independently functions to produce otherwise qualified property, photovoltaic cells. No part of the section 45X facility comprised of Equipment A is eligible property that is included in a section 48C facility. Thus, the photovoltaic cells produced in the section 45X facility comprised of Equipment A are eligible components. The photovoltaic cells that are produced in the section 45X facility comprised of Equipment B are otherwise qualified property that cannot qualify as eligible components because part (all in this case) of the section 45X facility comprised of Equipment B where the photovoltaic cells are produced is also considered a section 48C facility. Solar modules, a different otherwise qualified property, are produced in using Equipment C, which is itself a separate section 45X facility. Equipment C does not have to include any of the tangible property included in Production Unit A or B under paragraph (g)(2)(i) of this section because it is not necessary for the Taxpayer to use that equipment to be considered the

producer of the solar modules for purposes of section 45X. As a result, no part of section 45X facility comprised of Equipment C where the solar modules are produced is considered a section 48C facility, and the solar modules are considered an eligible component for purposes of section 45X.

(iv) *Example 4: Manufacturing under a contract manufacturing arrangement*—(A) *Facts.* X is hired by Y to manufacture photovoltaic cells, but X and Y agree under paragraph (c)(3)(iii) of this section that Y will be the party to claim any section 45X credit resulting from the sale of the photovoltaic cells. X owns and operates a manufacturing site that contains equipment that is tangible property used to produce the photovoltaic cells. X was allocated a section 48C credit under the section 48C(e) program for a section 48C facility that includes the equipment used to produce the photovoltaic cells. The equipment is eligible property that is part of the section 48C facility that was placed in service in taxable year 2026. X claimed a section 48C credit for the equipment in taxable year 2026.

(B) *Analysis.* Under paragraph (g)(2)(ii) of this section, in determining the section 45X facility related to the photovoltaic cells (the otherwise qualified property), Y must consider the equipment that X used in producing the photovoltaic cells. In this case, that means that part of the section 45X facility is also considered a section 48C facility, as the equipment used to produce the photovoltaic cells is also eligible property that is part of a section 48C facility. Therefore, the photovoltaic cells are not eligible components for purposes of section 45X to X or Y, and there is no section 45X credit generated if the photovoltaic cells are sold.

(v) *Example 5: Two independent production units manufacturing under a contract manufacturing arrangement*—(A) *Facts.* Assume the facts are the same as in paragraph (g)(4)(iv) of this section (*Example 4*), except that Y and X also agreed for X to produce photovoltaic wafers using other equipment that is tangible property that is different than the equipment X uses to produce the photovoltaic cells.

(B) *Analysis.* While Y must consider the equipment that X uses to produce the photovoltaic wafers (the otherwise qualified property) under paragraph (g)(2)(ii) of this section to determine the section 45X facility associated with the photovoltaic wafer production, Y is not required to include any of the equipment used by X to produce the photovoltaic cells because it was not necessary to use that equipment to be considered the producer of the

photovoltaic wafers. As a result, no part of the section 45X facility related to photovoltaic wafers is part of a section 48C facility. Therefore, the photovoltaic wafers are eligible components for purposes of section 45X and Y will be entitled to claim a section 45X credit upon the sale.

(h) [Reserved]

(i) *Anti-abuse rule*—(1) *In general.* The rules of section 45X and the section 45X regulations must be applied in a manner consistent with the purposes of section 45X and the section 45X regulations (and the regulations in this chapter under sections 6417 and 6418 related to the section 45X credit). A purpose of section 45X and the section 45X regulations (and the regulations in this chapter under sections 6417 and 6418 related to the section 45X credit) is to provide taxpayers an incentive to produce eligible components in a manner that contributes to the development of secure and resilient supply chains. Accordingly, the section 45X credit is not allowable if the primary purpose of the production and sale of an eligible component is to obtain the benefit of the section 45X credit in a manner that is wasteful, such as discarding, disposing of, or destroying the eligible component without putting it to a productive use. A determination of whether the production and sale of an eligible component is inconsistent with the purposes of section 45X and the section 45X regulations (and the regulations in this chapter under sections 6417 and 6418 related to the section 45X credit) is based on all facts and circumstances.

(2) *Example*—(i) *Facts.* Taxpayer is engaged in the activity of producing and selling multiple units of Eligible Component 1 (EC1). Taxpayer engages in no other activities. The cost of producing each unit of EC1 is less than the amount of the section 45X credit that would be available if each EC1 qualified for the section 45X credit. Taxpayer sells some of its units of EC1 to related persons and makes a Related Person Election pursuant to section 45X(a)(3)(B)(i). Taxpayer also sells some of its units of EC1 to unrelated persons. Taxpayer sells all units of EC1 at an amount equal to cost plus a markup to reflect an anticipated accommodation fee and establishes corresponding accounts receivable at the time of the respective sales. In addition, Taxpayer knows or reasonably expects that after acquiring the units of EC1, the related and unrelated transferees will not resell the units of EC1 or use them in their trades or businesses. Taxpayer intends to obtain the benefit from the section 45X credit by claiming such credits

itself or monetizing such credits through an election under section 6417 or section 6418. Taxpayer eliminates the aforementioned accounts receivable at the time it claims the section 45X credit or receives related payments attributable to the section 45X credit, and further makes payments to the related and unrelated transferees as accommodation fees computed as a percentage of such benefits.

(ii) *Analysis.* Based on all of the facts and circumstances in paragraph (i)(2)(i) of this section, the primary purpose of Taxpayer's production and sale of EC1 is to obtain the benefit of the section 45X credit in a manner that is wasteful and will not be treated as the production and sale of eligible components in a trade or business of Taxpayer for purposes of section 45X(a)(1) and (2). Taxpayer is not eligible for the section 45X credit with respect to units of EC1 that it produced and sold. See sections 6417(d)(6) (excessive payments) and 6418(g)(2) (excessive credit transfer).

(j) *Applicability date.* This section applies to eligible components for which production is completed and sales occur after December 31, 2022, and during a taxable year ending on or after October 28, 2024.

§ 1.45X-2 Sale to unrelated person.

(a) *In general.* The amount of the section 45X credit for any taxable year is equal to the sum of the credit amounts determined under section 45X(b) (and described in §§ 1.45X-3 and 1.45X-4) with respect to each eligible component that is produced by the taxpayer and, during the taxable year, sold by the taxpayer to an unrelated person. Applicable Federal income tax principles apply to determine whether a transaction is in substance a sale (or the provision of a service, or some other disposition). See § 1.45X-1(d) and (e) for additional requirements relating to sales.

(b) *Definitions.* This paragraph (b) provides definitions of terms that apply for purposes of this section.

(1) *Person.* The term *person* means an individual, a trust, estate, partnership, association, company, or corporation, as provided in section 7701(a)(1) of the Code. For purposes of this section, an entity disregarded as separate from a person (for example, under § 301.7701-3 of this chapter) is not a person.

(2) *Related person.* The term *related person* means a person who is related to another person if such persons would be treated as a single employer under the regulations in this chapter under section 52(b) of the Code.

(3) *Unrelated person.* The term *unrelated person* means a person who is not a related person as defined in paragraph (b)(2) of this section.

(c) *Special rule for sale to related person—(1) In general.* For purposes of section 45X(a), a taxpayer is treated as selling an eligible component to an unrelated person if such component is sold to such person by a person who is a related person with respect to the taxpayer.

(2) *Example.* X and Y are members of a group of trades or businesses under common control under section 52(b), and thus are related persons under section 45X(d)(1). Each of X and Y has a calendar year taxable year. Z is an unrelated person. X is in the trade or business of producing and selling solar modules. X produces and sells solar modules to Y in 2023. Y sells the solar modules to Z in 2024. X may claim a section 45X credit for the sale of the solar modules in 2024, the taxable year of X in which Y sells the solar modules to Z.

(d) *Related person election—(1) Availability of election—(i) In general.* In such form and manner as the Secretary may prescribe, a taxpayer may make an election under section 45X(a)(3)(B) (Related Person Election), to treat a sale of eligible components by such taxpayer to a related person as if made to an unrelated person. As a condition of, and prior to, a taxpayer making a Related Person Election (as described in paragraph (d)(2) of this section), the Secretary may require such information or registration as the Secretary deems necessary for purposes of preventing duplication, fraud, or any improper or excessive credit amount determined under section 45X(a)(1).

(ii) *Members of a consolidated group.* A Related Person Election is made by a member of a consolidated group (as defined in § 1.1502-1(h)) in the manner described in paragraph (d)(3)(ii) of this section. A member of a consolidated group that sells eligible components in an intercompany transaction (as defined in § 1.1502-13(b)(1)) may make the Related Person Election to claim the section 45X credit in the year of the intercompany sale. For the treatment of the selling member's gain or loss from that sale, see § 1.1502-13.

(2) *Time and manner of making election—(i) In general.* A taxpayer must make an affirmative Related Person Election annually on the taxpayer's timely filed original Federal income tax return, including extensions in such form and in such manner as may be prescribed in guidance. The Related Person Election will be applicable to all sales of eligible components to related

persons by the taxpayer for each trade or business that the taxpayer engages in during the taxable year that resulted in a credit claim and for which the taxpayer has made the Related Person Election.

(ii) *Required information.* For all sales of eligible components to related persons, the taxpayer must provide all required information set forth in guidance. Such information may include, for example, the taxpayer's name, employer identification number (EIN), a description of the taxpayer's trade or business (including principal business activity code); the name(s) and EINs of all related persons; a listing of the eligible components that are sold; and the intended purpose of any sales of eligible components to or from related persons.

(3) *Scope and effect of election—(i) In general.* A separate Related Person Election must be made with respect to related person sales made by a taxpayer for each eligible trade or business of the taxpayer. The election applies only to such trade or business for which the Related Person Election is made. An election under this section applies to all sales to related persons (including between members of the same consolidated group) of eligible components produced by the taxpayer during the taxable year with respect to each trade or business for which the Related Person Election is made and is irrevocable for the taxable year for which the election is made. An election under paragraph (d)(2)(i) of this section applies solely for purposes of the section 45X credit and the section 45X regulations (and the regulations in this chapter under sections 6417 and 6418 related to the section 45X credit).

(ii) *Application to consolidated groups.* For a trade or business of a consolidated group, a Related Person Election must be made by the agent for the group on behalf of the members claiming the section 45X credit and filed with the group's timely filed original Federal income tax return, including extensions, with respect to each trade or business that the consolidated group conducts. See § 1.1502-77 (providing rules regarding the status of the common parent as agent for its members). A separate election must be filed on behalf of each member claiming the section 45X credit, and each election must include the name and EIN of the agent for the group and the member on whose behalf the election is being made.

(iii) *Application to partnerships.* The Related Person Election for a partnership must be made on the partnership's timely filed original

Federal income tax return, including extensions, with respect to each trade or business that the partnership conducts. The election applies only to such trade or business for which the Related Person Election is made. An election by a partnership does not apply to any trade or business conducted by a partner outside the partnership.

(4) *Anti-abuse rule*—(i) *In general.* A Related Person Election may not be made if, with respect to the eligible components relevant to such election, the taxpayer fails to provide the information described in paragraph (d)(2) of this section, provides information described in paragraph (d)(2) of this section that shows that such components are described in paragraph (d)(4)(ii) or (iii) of this section, or such components are described in paragraph (d)(4)(ii) or (iii) of this section.

(ii) *Improper use.* For purposes of this paragraph (d)(4) the term *improper use* means a use that is wasteful, such as discarding, disposing of, or destroying the eligible component without putting it to a productive use by the related person to which the eligible component is sold.

(iii) *Defective components.* The term *defective component* means a component that does not meet the requirements of section 45X and the section 45X regulations.

(e) *Sales of integrated components to related person*—(1) *In general.* For purposes of section 45X and the section 45X regulations (and the regulations in this chapter under sections 6417 and 6418 related to the section 45X credit), a taxpayer that produces and then sells an eligible component to a related person, who then integrates, incorporates, or assembles the taxpayer's eligible component into another complete and distinct eligible component that is subsequently sold to an unrelated person, may claim a section 45X credit (or make an election under section 6417 or section 6418) with respect to the taxable year in which the related person's sale to the unrelated person occurs.

(2) *Examples.* The following examples illustrate the rules provided in paragraph (e)(1) of this section.

(i) *Example 1: Sales of multiple incorporated eligible components to related persons.* X and Y are C corporations that are members of a group of trades or businesses under common control under section 52(b), and thus are related persons under section 45X(d)(1) and paragraph (b)(2) of this section. Each of X and Y has a calendar year taxable year. Z is an unrelated person. X and Y are in the

trade or business of producing and selling photovoltaic wafers and cells. X produces and sells photovoltaic wafers to Y in 2023. Y incorporates the photovoltaic wafers into photovoltaic cells and sells the photovoltaic cells to Z in 2024. X may claim a section 45X credit for the sale of the photovoltaic wafers in 2024, the taxable year of X in which Y sells the photovoltaic cells to Z.

(ii) *Example 2: Sales of multiple incorporated eligible components to related and unrelated persons.* W, X, and Y are domestic C corporations that are members of a group of trades or businesses under common control under section 52(b), and thus are related persons under section 45X(d)(1) and paragraph (b)(2) of this section. Each of W, X, and Y has a calendar year taxable year. W produces electrode active materials (EAMs) and sells the EAMs to X in 2023. In 2024, X incorporates the EAMs into battery cells that it produces and sells the battery cells to Y. In 2025, Y incorporates the battery cells into battery modules (within the meaning of § 1.45X-3(e)(4)(i)(A)) that it produces and sells the battery modules to Z, an unrelated person. W may claim a section 45X credit for EAMs sold to X, X may claim a section 45X credit for the battery cells sold to Y, and Y may claim a section 45X credit for the battery modules sold to Z in 2025, the taxable year of each of W, X, and Y in which the battery modules are sold to Z.

(3) *Special rules applicable to related person election*—(i) *In general.* If a taxpayer makes a valid Related Person Election under section 45X(a)(3)(B)(i) and paragraph (d)(1) of this section, and the taxpayer produces and then sells an eligible component to a related person, who then integrates, incorporates, or assembles the taxpayer's eligible component into another complete and distinct eligible component that is subsequently sold to an unrelated person, the taxpayer's sale of the eligible component to the related person is treated (solely for purposes of the section 45X credit and the section 45X regulations, and the regulations in this chapter under sections 6417 and 6418 related to the section 45X credit) as if made to an unrelated person in the taxable year in which the sale to the related person occurs.

(ii) *Example: Sales of multiple integrated eligible components to related and unrelated persons with a related person election.* W, X, and Y are domestic C corporations that are members of a group of trades or businesses under common control and thus are related persons under section 45X(d)(1) and paragraph (b)(2) of this

section. Each of W, X, and Y has a calendar year taxable year. W produces electrode active materials (EAMs) and sells the EAMs to X in 2023. W makes a valid Related Person Election under paragraph (d)(1) of this section in 2023 with regard to the sale. In 2024, X incorporates the EAMs into battery cells that it produces and sells the battery cells to Y. X makes a valid Related Person Election under paragraph (d)(1) of this section in 2024 with regard to the sale. In 2025, Y incorporates the battery cells into battery modules that it produces and sells the battery modules to Z, an unrelated person. W may claim a section 45X credit for the sale of the EAMs in 2023 because the sale to X is treated as if made to an unrelated person solely for purposes of section 45X(a). X may claim a section 45X credit for the sale of the battery cells in 2024 because the sale to Y is treated as if made to an unrelated person solely for purposes of section 45X(a). Y may claim a section 45X credit for the sale of battery modules in 2025 because Z is an unrelated person.

(f) *Applicability date.* This section applies to eligible components for which production is completed and sales occur after December 31, 2022, and during a taxable year ending on or after October 28, 2024.

§ 1.45X-3 Eligible components.

(a) *In general.* For purposes of the section 45X credit, *eligible component* means any solar energy component (as defined in paragraph (b) of this section), any wind energy component (as defined in paragraph (c) of this section), any inverter (as defined in paragraph (d) of this section), any qualifying battery component (as defined in paragraph (e) of this section), and any applicable critical mineral (as defined in § 1.45X-4(b)). See paragraph (f) of this section for certain phase-out rules applicable to eligible components other than applicable critical minerals.

(b) *Solar energy components.* *Solar energy component* means a solar module, photovoltaic cell, photovoltaic wafer, solar grade polysilicon, torque tube, structural fastener, or polymeric backsheet, each as defined in this paragraph (b).

(1) *Photovoltaic cell*—(i) *Definition.* *Photovoltaic cell* means the smallest semiconductor element of a solar module that performs the immediate conversion of light into electricity that is either a thin film photovoltaic cell or a crystalline photovoltaic cell.

(ii) *Credit amount.* For a photovoltaic cell, the credit amount is equal to the product of 4 cents multiplied by the capacity of such photovoltaic cell. The

capacity of each photovoltaic cell is expressed on a direct current watt basis. Capacity is the nameplate capacity in direct current watts using Standard Test Conditions (STC), as defined by the International Electrotechnical Commission (IEC). In the case of a tandem technology produced in serial fashion, such as a monolithic multijunction cell composed of two or more sub-cells, capacity must be measured at the point of sale at the end of the single cell production unit. In the case of a four-terminal tandem technology produced by mechanically stacking two distinct cells or interconnected layers, capacity must be measured for each cell at each point of sale. If a cell is sold to a customer who will use it as the bottom cell in a tandem module, its capacity should be measured with the customer's intended top cell placed between the bottom cell and the one-sun light source.

(iii) *Substantiation*. The taxpayer must document the capacity of a photovoltaic cell in a bill of sale or design documentation, such as an IEC certification (for example, IEC 61215 or IEC 60904).

(2) *Photovoltaic wafer*—(i) *Definition*. *Photovoltaic wafer* means a thin slice, sheet, or layer of semiconductor material of at least 240 square centimeters that comprises the substrate or absorber layer of one or more photovoltaic cells. A photovoltaic wafer must be produced by a single manufacturer by forming an ingot from molten polysilicon (for example, Czochralski method) and then subsequently slicing it into wafers, forming molten or evaporated polysilicon into a sheet or layer, or depositing a thin-film semiconductor photon absorber into a sheet or layer (that is, thin-film deposition).

(ii) *Credit amount*. For a photovoltaic wafer, the credit amount is \$12 per square meter.

(3) *Polymeric backsheet*—(i) *Definition*. *Polymeric backsheet* means a sheet on the back of a solar module, composed, at least in part, of a polymer, that acts as an electric insulator and protects the inner components of such module from the surrounding environment.

(ii) *Credit amount*. For a polymeric backsheet, the credit amount is 40 cents per square meter.

(4) *Solar grade polysilicon*—(i) *Definition*. *Solar grade polysilicon* means silicon that is suitable for use in photovoltaic manufacturing and purified to a minimum purity of 99.999999 percent silicon by mass. Satisfaction of the minimum purity requirement will be determined in

accordance with the standards provided in SEMI Specification PV17–1012, Category 1.

(ii) *Credit amount*. For solar grade polysilicon, the credit amount is \$3 per kilogram.

(5) *Solar module*—(i) *Definition*. *Solar module* means the connection and lamination of photovoltaic cells into an environmentally protected final assembly that is—

(A) Suitable to generate electricity when exposed to sunlight; and

(B) Ready for installation without an additional manufacturing process.

(ii) *Credit amount*. For a solar module, the credit amount is equal to the product of 7 cents multiplied by the capacity of such module. The capacity of each solar module is expressed on a direct current watt basis. Capacity is the nameplate capacity in direct current watts using STC, as defined by the IEC.

(iii) *Substantiation*. The taxpayer must document the capacity of a solar module in a bill of sale or design documentation, such as an IEC certification (for example, IEC 61215 or IEC 61646).

(6) *Solar tracker*. *Solar tracker* means a mechanical system that moves solar modules according to the position of the sun and to increase energy output. A torque tube (as defined in paragraph (b)(7) of this section) or structural fastener (as defined in paragraph (b)(8) of this section) are solar tracker components that are eligible components for purposes of the section 45X credit.

(7) *Torque tube*—(i) *Definition*. *Torque tube* means a structural steel support element (including longitudinal purlins) that—

(A) Is part of a solar tracker;

(B) Is of any cross-sectional shape;

(C) May be assembled from individually manufactured segments;

(D) Spans longitudinally between foundation posts;

(E) Supports solar panels and is connected to a mounting attachment for solar panels (with or without separate module interface rails); and

(F) Is rotated by means of a drive system.

(ii) *Credit amount*. For a torque tube, the credit amount is 87 cents per kilogram.

(iii) *Substantiation*. The taxpayer must document that a torque tube is part of a solar tracker with a specification sheet, bill of sale, or other similar documentation that explicitly describes its application as part of a solar tracker.

(8) *Structural fastener*—(i) *Definition*. *Structural fastener* means a component that is used—

(A) To connect the mechanical and drive system components of a solar

tracker to the foundation of such solar tracker;

(B) To connect torque tubes to drive assemblies; or

(C) To connect segments of torque tubes to one another.

(ii) *Credit amount*. For a structural fastener, the credit amount is \$2.28 per kilogram.

(iii) *Substantiation*. The taxpayer must document that a structural fastener is used in a manner described in paragraph (b)(8)(i)(A), (B), or (C) of this section with a bill of sale or other similar documentation that explicitly describes such use.

(c) *Wind energy components*. *Wind energy component* means a blade, nacelle, tower, offshore wind foundation, or related offshore wind vessel, each as defined in this paragraph (c).

(1) *Blade*—(i) *Definition*. *Blade* means an airfoil-shaped blade that is responsible for converting wind energy to low-speed rotational energy.

(ii) *Credit amount*. For a blade, the credit amount is equal to the product of 2 cents multiplied by the total rated capacity of the completed wind turbine for which the blade is designed.

(2) *Offshore wind foundation*—(i) *Definition*. *Offshore wind foundation* means the component (including transition piece) that secures an offshore wind tower and any above-water turbine components to the seafloor using—

(A) Fixed platforms, such as offshore wind monopiles, jackets, or gravity-based foundations; or

(B) Floating platforms and associated mooring systems.

(ii) *Credit amount*. For a fixed offshore wind foundation platform, the credit amount is equal to the product of 2 cents multiplied by the total rated capacity of the completed wind turbine for which the fixed offshore wind foundation platform is designed. For a floating offshore wind foundation platform, the credit amount is equal to the product of 4 cents multiplied by the total rated capacity of the completed wind turbine for which the floating offshore wind foundation platform is designed.

(3) *Nacelle*—(i) *Definition*. *Nacelle* means the assembly of the drivetrain and other tower-top components of a wind turbine (with the exception of the blades and the hub) within their cover housing.

(ii) *Credit amount*. For a nacelle, the credit amount is equal to the product of 5 cents multiplied by the total rated capacity of the completed wind turbine for which the nacelle is designed.

(4) *Related offshore wind vessel*—(i) *Definition*. *Related offshore wind vessel*

means any vessel that is purpose-built or retrofitted for purposes of the development, transport, installation, operation, or maintenance of offshore wind energy components. A vessel is purpose-built for development, transport, installation, operation, or maintenance of offshore wind energy components if it is built to be capable of performing such functions and it is of a type that is commonly used in the offshore wind industry. A vessel is retrofitted for development, transport, installation, operation, or maintenance of offshore wind energy components if such vessel was incapable of performing such functions prior to being retrofitted, the retrofit causes the vessel to be capable of performing such functions, and the retrofitted vessel is of a type that is commonly used in the offshore wind industry.

(ii) *Credit amount.* For a related offshore wind vessel, the credit amount is equal to 10 percent of the sales price of the vessel. The sales price of the vessel, determined under Federal income tax principles, does not include the price of maintenance, services, or other similar items that may be sold with the vessel. For a related offshore wind vessel with respect to which an election under section 45X(a)(3)(B)(i) has been made, such election will not cause the sale price of such vessel to be treated as having been determined with respect to a transaction between uncontrolled taxpayers for purposes of section 482 of the Code and the regulations in this chapter.

(5) *Tower*—(i) *Definition.* *Tower* means a tubular or lattice structure that supports the nacelle and rotor of a wind turbine.

(ii) *Credit amount.* For a tower, the credit amount is equal to the product of 3 cents multiplied by the total rated capacity of the completed wind turbine for which the tower is designed.

(6) *Total rated capacity of the completed wind turbine.* For purposes of this section, *total rated capacity of the completed wind turbine* means, for the completed wind turbine for which a blade, nacelle, offshore wind foundation, or tower was manufactured and sold, the nameplate capacity at the time of sale as certified to the relevant national or international standards, such as IEC 61400, or ANSI/ACP 101-1-2021, the Small Wind Turbine Standard (Standard). Certification of the turbine to such Standards must be documented by a certificate issued by an accredited certification body. The total rated capacity of a wind turbine must be expressed in watts.

(7) *Substantiation.* Taxpayers must maintain specific documentation

regarding wind energy components for which a section 45X credit is claimed. For blades, nacelles, offshore wind foundations, or towers, a taxpayer must document the turbine model for which such component is designed and the total rated capacity of the completed wind turbine in technical documentation associated with the sale of such component. For related offshore wind vessel, such documentation could include the contract to construct or retrofit (along with retrofit plans), sales contract, U.S. Coast Guard bill of sale, U.S. Coast Guard Certificate of Documentation (COD), and U.S. Coast Guard Certificate of Inspection (COI).

(d) *Inverters*—(1) *In general.* *Inverter* means an end product that is suitable to convert direct current (DC) electricity from one or more solar modules or certified distributed wind energy systems into alternating current electricity. An end product is suitable to convert DC electricity from one or more solar modules or certified distributed wind energy systems into alternating current electricity if, in the form sold by the manufacturer, it is able to connect with such modules or systems and convert DC electricity to alternating current electricity from such connected source. The term inverter includes a central inverter, commercial inverter, distributed wind inverter, microinverter, or residential inverter. Only an inverter that meets at least one of the requirements in paragraphs (d)(2) through (7) of this section is an eligible component for purposes of the section 45X credit.

(2) *Central inverter*—(i) *Definition.* *Central inverter* means an inverter that is suitable for large utility-scale systems and has a capacity that is greater than 1,000 kilowatts. The capacity of a central inverter is expressed on an alternating current watt basis. An inverter is suitable for large utility-scale systems if, in the form sold by the manufacturer, it is capable of serving as a component in a large utility-scale system and meets the core engineering specifications for such application.

(ii) *Credit amount.* For a central inverter the total rated capacity of which is expressed on an alternating current watt basis, the credit amount is equal to the product of 0.25 cents multiplied by the total rated capacity of the central inverter.

(iii) *Substantiation.* The taxpayer must document that a central inverter meets the core engineering specifications for use in a large utility-scale system and has a capacity that is greater than 1,000 kilowatts with a specification sheet, bill of sale, or other similar documentation that explicitly

describes such specifications and capacity.

(3) *Commercial inverter*—(i) *Definition.* *Commercial inverter* means an inverter that—

(A) Is suitable for commercial or utility-scale applications;

(B) Has a rated output of 208, 480, 600, or 800 volt three-phase power; and

(C) Has a capacity expressed on an alternating current watt basis that is not less than 20 kilowatts and not greater than 125 kilowatts.

(ii) *Suitable for commercial or utility-scale applications.* An inverter is suitable for commercial or utility-scale applications if, in the form sold by the manufacturer, it is capable of serving as a component in commercial or utility-scale systems and meets the core engineering specifications for such application.

(iii) *Credit amount.* For a commercial inverter the total rated capacity of which is expressed on an alternating current watt basis, the credit amount is equal to the product of 2 cents multiplied by the total rated capacity of the commercial inverter.

(iv) *Substantiation.* The taxpayer must document that a commercial inverter meets the core engineering specifications for use in commercial or utility-scale applications, the inverter's rated output, and the inverter's capacity in a specification sheet, bill of sale, or other similar documentation.

(4) *Distributed wind inverter*—(i) *In general.* *Distributed wind inverter* means an inverter that is used in a residential or non-residential system that utilizes one or more certified distributed wind energy systems and has a total rated output, expressed on an alternating current watt basis, of not greater than 150 kilowatts.

(ii) *Certified distributed wind energy system.* *Certified distributed wind energy system* means a wind energy system that is certified by an accredited certification agency to meet Standard 9.1-2009 of the American Wind Energy Association; IEC 61400-1, 61400-2, 61400-11, 61400-12; or ANSI/ACP 101-1-2021, the Standard, including any subsequent revisions to or modifications of such Standard that have been approved by ANSI.

(iii) *Credit amount.* For a distributed wind inverter the total rated capacity of which is expressed on an alternating current watt basis, the credit amount is equal to the product of 11 cents multiplied by the total rated capacity of the distributed wind inverter.

(iv) *Substantiation.* The taxpayer must document that a distributed wind inverter is used in a residential or non-residential system that utilizes one or

more certified distributed wind energy systems with a specification sheet, bill of sale, or other similar documentation that explicitly describes such use and the total rated output of the inverter on an alternating current watt basis.

(5) *Microinverter*—(i) *Definition*. *Microinverter* means an inverter that—

(A) Is suitable to connect with one solar module;

(B) Has a rated output described in paragraph (d)(5)(ii) of this section; and

(C) Has a capacity, expressed on an alternating current watt basis, that is not greater than 650 watts.

(ii) *Rated output*. For purposes of

paragraph (d)(5)(i)(B) of this section, for an inverter to be a microinverter, the inverter must have a rated output of—

(A) 120 or 240 volt single-phase power; or

(B) 208 or 480 volt three-phase power.

(iii) *Suitable to connect to one solar module*—(A) *In general*. An inverter is suitable to connect to one solar module if, in the form sold by the manufacturer, it is capable of connecting to one or more solar modules and regulating the DC electricity from each module independently before that electricity is converted into alternating current electricity.

(B) *Application to direct current (DC) optimized inverter systems*. A DC optimized inverter system means an inverter that is comprised of an inverter connected to multiple DC optimizers that are each designed to connect to one solar module. A DC optimized inverter system is suitable to connect with one solar module if, in the form sold by the manufacturer, it is capable of connecting to one or more solar modules and regulating the DC electricity from each module independently before that electricity is converted into alternating current electricity.

(C) *Application to multi-module inverters*. A multi-module inverter means an inverter that is comprised of an inverter with independent connections and DC optimizing components for two or more modules. A multi-module microinverter is suitable to connect with one solar module if it is capable of connecting to one or more solar modules and regulating the DC electricity from each module independently before that electricity is converted into alternating current electricity.

(iv) *Credit amount*—(A) *In general*. For a microinverter the total rated capacity of which is expressed on an alternating current watt basis, the credit amount is equal to the product of 11 cents multiplied by the total rated capacity of the microinverter.

(B) *DC optimized inverter systems*. A DC optimized inverter system qualifies as a microinverter if it meets the requirements of paragraph (d)(5)(i) of this section. For purposes of paragraph (d)(5)(i)(C) of this section, a DC optimized inverter system's capacity is determined separately for each DC optimizer paired with the inverter in a DC optimized inverter system. If each DC optimizer paired with the inverter in a DC optimized inverter system meets the requirements of paragraph (d)(5)(i) of this section, then the DC optimized inverter system qualifies as a microinverter. The credit amount for a DC optimized inverter system that qualifies as a microinverter is equal to the product of 11 cents multiplied by the lesser of the sum of the alternating current capacity of each DC optimizer when paired with the inverter in the DC optimized inverter system or the alternating current capacity of the inverter in the DC optimized inverter system. For purposes of this paragraph (d)(5)(iv)(B), capacity must be measured in watts of alternating current converted from DC electricity by the inverter in a DC optimized inverter system. For a DC optimized inverter system to qualify as a microinverter, a taxpayer must produce and sell the inverter and the DC optimizers in the DC optimized inverter system together as a combined end product.

(C) *Multi-module inverters*. A multi-module inverter qualifies as a microinverter if it meets the requirements of paragraph (d)(5)(i) of this section. For purposes of paragraph (d)(5)(i)(C) of this section, a multi-module inverter's capacity is determined separately for each internal DC optimizer paired with the inverter. The credit amount for a multi-module inverter is equal to the product of 11 cents multiplied by the total alternating current capacity of the DC optimizers in the multi-module inverter when paired with the inverter in the system. For purposes of this paragraph (d)(5)(iv)(C), capacity must be measured in watts of alternating current converted from DC electricity by the inverter in a multi-module microinverter.

(v) *Substantiation*. The taxpayer must document that a microinverter meets the core engineering specifications to be suitable to connect with one solar module, the inverter's rated output, and the inverter's capacity in a specification sheet, bill of sale, or other similar documentation. In the case of a DC optimized inverter system, the taxpayer must also document that the DC optimizers and the inverter in such system were sold as a combined end product.

(6) *Residential inverter*—(i) *Definition*. *Residential inverter* means an inverter that—

(A) Is suitable for a residence;

(B) Has a rated output of 120 or 240 volt single-phase power; and

(C) Has a capacity expressed on an alternating current watt basis that is not greater than 20 kilowatts.

(ii) *Suitable for a residence*. An inverter is suitable for a residence if, in the form sold by the manufacturer, it is capable of serving as a component in a residential system and meets the core engineering specifications for such application.

(iii) *Credit amount*. For a residential inverter the total rated capacity of which is expressed on an alternating current watt basis, the credit amount is equal to the product of 6.5 cents multiplied by the total rated capacity of the residential inverter.

(iv) *Substantiation*. The taxpayer must document that a residential inverter meets the core engineering specifications for use in a residence, the inverter's rated output, and the inverter's capacity in a specification sheet, bill of sale, or other similar documentation.

(7) *Utility inverter*—(i) *Definition*. *Utility inverter* means an inverter that—

(A) Is suitable for commercial or utility-scale systems;

(B) Has a rated output of not less than 600 volt three-phase power; and

(C) Has a capacity expressed on an alternating current watt basis that is greater than 125 kilowatts and not greater than 1000 kilowatts.

(ii) *Suitable for commercial or utility-scale systems*. An inverter is suitable for commercial or utility-scale systems if, in the form sold by the manufacturer, it is capable of serving as a component in such systems and meets the core engineering specifications for such application.

(iii) *Credit amount*. For a utility inverter the total rated capacity of which is expressed on an alternating current watt basis, the credit amount is equal to the product of 1.5 cents multiplied by the total rated capacity of the utility inverter.

(iv) *Substantiation*. The taxpayer must document that a utility inverter meets the core engineering specifications for use in commercial or utility-scale systems, the inverter's rated output, and the inverter's capacity in a specification sheet, bill of sale, or other similar documentation.

(e) *Qualifying battery component*—(1) *In general*. *Qualifying battery component* means electrode active materials, battery cells, or battery

modules, each as defined in this paragraph (e).

(2) *Electrode active materials*—(i) *Definitions*—(A) *Electrode active materials*. *Electrode active materials* means cathode electrode materials, anode electrode materials, and electrochemically active materials that contribute to the electrochemical processes necessary for energy storage. Electrode active materials do not include battery management systems, terminal assemblies, cell containments, gas release valves, module containments, module connectors, compression plates, straps, pack terminals, bus bars, thermal management systems, and pack jackets.

(B) *Cathode electrode materials*. *Cathode electrode materials* means the materials that comprise the cathode of a commercial battery technology, such as binders, and current collectors (for example, cathode foils).

(C) *Anode electrode materials*. *Anode electrode materials* means the materials that comprise the anode of a commercial battery technology, including anode foils.

(D) *Electrochemically active materials*. *Electrochemically active materials* that contribute to the electrochemical processes necessary for energy storage means battery-grade materials that enable the electrochemical storage within a commercial battery technology. In addition to solvents, additives, and electrolyte salts, electrochemically active materials that contribute to the electrochemical processes necessary for energy storage may include electrolytes, catholytes, anolytes, separators, and metal salts and oxides.

(E) *Example*. A commercial battery technology contains Cathode Active Material (CAM), which is a powder used in the battery that is made by processing and combining Battery-Grade Materials A and B. Battery-Grade Material A is a derivative of Material C, which has been refined to the necessary level to enable electrochemical storage. The production costs for CAM and its direct inputs (Battery-Grade Material A and Battery-Grade Material B) are eligible for the section 45X credit for electrode active materials, but the unrefined Material C is not.

(F) *Battery-grade materials*. *Battery-grade materials* means the processed materials found in a final battery cell or an analogous unit, or the direct battery-grade precursors to those processed materials.

(ii) *Credit amount*. For an electrode active material, the credit amount is equal to 10 percent of the costs incurred

by the taxpayer with respect to production of such materials.

(iii) *Production processes for electrode active materials*—(A) *Conversion*. For purposes of section 45X, the term *conversion* means a chemical transformation from one species to another.

(B) *Purification*. For purposes of section 45X, the term *purification* means increasing the mass fraction of a certain element.

(iv) *Production costs incurred*—(A) *In general*—(1) *Definition of production costs incurred*. Costs incurred by the taxpayer with respect to production of an electrode active material includes all costs as defined in § 1.263A-1(e) that are paid or incurred within the meaning of section 461 of the Code by the taxpayer for the production of such electrode active material including direct materials costs as defined in § 1.263A-1(e)(2)(i)(A), or indirect materials costs as defined in § 1.263A-1(e)(3)(ii)(E), but does not include direct or indirect materials costs that relate to the purchase of materials that are an eligible component at the time of acquisition (for example, an electrode active material as defined in paragraph (e)(2)(i) of this section or applicable critical mineral as defined in § 1.45X-4(b)). This definition of production costs incurred also includes any costs incurred by the taxpayer related to the extraction, as defined in paragraph (e)(2)(iv)(B) of this section, of raw materials in the United States or a United States territory, but only if those costs are paid or incurred by the taxpayer that claims the section 45X credit with respect to the relevant electrode active material. Section 263A of the Code and the regulations in this chapter under section 263A apply solely to identify the types of costs that are includible in production costs incurred for purposes of computing the amount of the section 45X credit, but do not apply for any other purpose, such as to determine whether a taxpayer is engaged in production activities.

(2) *Production costs for production of incorporated eligible components*. The production costs that a taxpayer pays or incurs in the production of an eligible component (whether produced domestically or not) that the taxpayer then incorporates into a further distinct electrode active material within the meaning of § 1.45X-1(f)(1) are not included in the costs incurred by the taxpayer in producing the further distinct electrode active material. A taxpayer may not include the same production costs in the calculation of the credit amount for more than one eligible component. For example, if the

taxpayer pays or incurs production costs of \$50X for eligible component 1 and an additional \$100X of production costs for eligible component 2 that included integrating eligible component 1 within the meaning of § 1.45X-1(f)(1), then the production costs for eligible component 1 equal \$50X and the production costs for eligible component 2 equal \$100X.

(3) *Examples*. The following examples illustrate the rules of this section:

(i) *Example 1*. Taxpayers X, Y and Z are unrelated C corporations that have calendar year taxable years. In 2024, X extracts raw nickel from natural mineral deposits located in the United States and purifies the extracted material to 99% nickel by mass (qualifying nickel) as required by section 45X(c)(6)(S) and § 1.45X-4(b)(19)(ii). Y subsequently purchases the qualifying nickel and uses the material to produce battery-grade nickel salts which qualify as electrode active materials within the meaning of paragraph (e)(2) of this section. Y sells the battery-grade nickel salts to Z in tax year 2026. Y may claim a section 45X credit for the battery-grade nickel salts in tax year 2026 because Y produced, within the meaning of § 1.45X-1(c)(2), an eligible component. In calculating its production costs with respect to such credit, Y may not include the purchase price it paid to X for the qualifying nickel because the qualifying nickel met the minimum purity requirement prescribed by section 45X(c)(6)(S) such that the material constituted an applicable critical mineral (and, accordingly, an eligible component) at the time at which Y acquired the qualifying nickel.

(ii) *Example 2*. Assume the facts are the same as in paragraph (e)(2)(iv)(A)(2)(i) of this section (*Example 1*), except that X purifies the extracted raw nickel material to a purity of 90% nickel by mass, rather than 99% nickel by mass as required by section 45X(c)(6)(S) and § 1.45X-4(b)(19)(ii). Y may claim a section 45X credit for the battery-grade nickel salts in tax year 2026 because Y produced, within the meaning of § 1.45X-1(c)(2), an eligible component. In calculating its production costs with respect to such credit, Y may include the purchase price of the 90% nickel material among its production costs, provided that Y satisfies the substantiation requirements described in paragraph (e)(2)(iv)(C) of this section, because, at the time at which Y acquired such material, the material did not meet the minimum purity as required by section 45X(c)(6)(S) to constitute an applicable critical mineral.

(B) *Definition of extraction*. The term *extraction* means the activities

performed to harvest minerals or natural resources from the ground or from a body of water. Extraction includes, but is not limited to, operating equipment to harvest minerals or natural resources from mines and wells and the physical processes involved in refining.

Extraction also includes operating equipment to extract minerals or natural resources from the waste or residue of prior extraction, including crude oil extraction to the extent that processes applied to that crude oil yield an applicable critical mineral or an electrode active material as a byproduct. Extraction concludes when activities are performed to convert raw mined or harvested products or raw well effluent to substances that can be readily transported or stored for direct use in critical mineral or electrode active material processing. Extraction does not include activities that begin with a recyclable commodity (as such activities are recycling). Extraction does not include the chemical and thermal processes involved in refining.

(C) *Substantiation.* In order to include direct or indirect materials costs as defined in § 1.263A-1(e)(2)(i)(A) and (e)(3)(ii)(E) as production costs when calculating a section 45X credit for the production and sale of an electrode active material, a taxpayer, as part of filing an annual tax return (or a return for a short year within the meaning of section 443 of the Code), must include the information in paragraph (e)(2)(iv)(C)(1) of this section as an attachment to that return, prepare the information required in paragraphs (e)(2)(iv)(C)(2) through (4) of this section and maintain that information in the taxpayer's books and records under section 6001, and comply with directions for the information required in paragraph (e)(2)(iv)(C)(5) of this section as specified in guidance:

(1) Certifications from any supplier, including the supplier's employer identification number and that is signed under penalties of perjury, from which the taxpayer purchased any constituent elements, materials, or subcomponents of the taxpayer's electrode active material, stating that the supplier is not claiming the section 45X credit with respect to any of the material acquired by the taxpayer, nor is the supplier aware that any prior supplier in the chain of production of that material claimed a section 45X credit for the material.

(2) A document that provides an analysis of any constituent elements, materials, or subcomponents that concludes the material did not meet the definition of an eligible component (for example, did not meet the definition of

applicable critical mineral or electrode active material) at the time of acquisition by the taxpayer. The document may be prepared by the taxpayer or ideally by an independent third-party.

(3) A list of all direct and indirect material costs and the amount of such costs that were included within the taxpayer's total production cost for each electrode active material.

(4) A document related to the taxpayer's production activities with respect to the direct and indirect material costs that establishes the materials were used in the production of the electrode active material. The document may be prepared by the taxpayer or ideally by an independent third-party.

(5) Any other information related to the direct or indirect materials specified in guidance.

(D) Failure to provide the documentation described in paragraph (e)(2)(iv)(C) of this section with the return filing, or providing an available upon request statement, will constitute a failure to substantiate the claim.

(v) *Materials that are both electrode active materials and applicable critical minerals—(A) In general.* A material that qualifies as an electrode active material and an applicable critical material is eligible for the section 45X credit. A taxpayer may claim the section 45X credit with respect to such material either as an electrode active material or an applicable critical material, but not both.

(B) *Example.* Lithium carbonate is an electrode active material because it is a direct battery-grade precursor to electrolyte salts, which are processed materials found in a final battery cell. Lithium carbonate is also eligible for the 45X critical minerals credit. A taxpayer who produces and sells lithium carbonate may claim either the electrode active material credit or the critical mineral credit for its production and sale of lithium carbonate but may not take both credits.

(3) *Battery cells—(i) Definition.* *Battery cell* means an electrochemical cell—

(A) Comprised of one or more positive electrodes and one or more negative electrodes;

(B) With a volumetric energy density of not less than 100 watt-hours per liter; and

(C) Capable of storing at least 12 watt-hours of energy.

(ii) *Capacity measurement.* Taxpayers must measure the capacity of a battery cell in accordance with a national or international standard, such as IEC 60086-1 (Primary Batteries), or an

equivalent standard. Taxpayers can reference the United States Advanced Battery Consortium (USABC) Battery Test Manual for additional guidance.

(iii) *Credit amount.* For a battery cell, the credit amount is equal to the product of \$35 multiplied by the capacity of such battery cell, subject to the limitation provided in paragraph (e)(5) of this section. The capacity of a battery cell is expressed on a kilowatt-hour basis.

(4) *Battery module definitions and applicable rules—(i) Battery module defined.* The term *battery module* means a module described in paragraph (e)(4)(i)(A) or (B) of this section with an aggregate capacity of not less than 7 kilowatt-hours (or, in the case of a module for a hydrogen fuel cell vehicle, not less than 1 kilowatt-hour).

(A) *Modules using battery cells.* A module using battery cells, is a module with two or more battery cells that are configured electrically, in series or parallel, to create voltage or current, as appropriate, to a specified end use, meaning an end-use configuration of battery technologies. An end-use configuration is the product that combines cells into a module such that any subsequent manufacturing is done to the module rather than to the cells individually. Where multiple points in a supply chain may be eligible under this section, the first module produced and sold that meets the requirements of this section and the kilowatt-hour requirement in paragraph (e)(4)(i) of this section will be the only module eligible.

(B) *Modules with no battery cells.* A *module with no battery cells* means a product with a standardized manufacturing process and form that is capable of storing and dispatching useful energy, that contains an energy storage medium that remains in the module (for example, it is not consumed through combustion), and that is not a custom-built electricity generation or storage facility. For example, neither standalone fuel storage tanks nor fuel tanks connected to engines or generation systems qualify as modules with no battery cells.

(ii) *Capacity measurement—(A) Modules using battery cells.* Taxpayers must measure the capacity of a module using battery cells with a testing procedure that complies with a national or international standard published by a recognized standard setting organization. The capacity of a battery module may not exceed the total nameplate capacity of the battery cells in the module. Taxpayers must measure the capacity of a battery cell in accordance with a national or international standard, such as IEC

60086–1 (Primary Batteries), or an equivalent standard. Taxpayers can reference the USABC Battery Test Manual for additional guidance.

(B) *Modules with no battery cells.* Taxpayers must measure the capacity of a module with no battery cells with a testing procedure that complies with a national or international standard published by a recognized standard setting organization. Taxpayers producing thermal and thermochemical battery modules described in paragraph (e)(4)(i)(B) of this section must convert the energy storage to a kilowatt-hour basis and provide both methodology and testing regarding this conversion. Such conversion of the kilowatt-hour basis cannot exceed the total direct conversion of the total nameplate capacity of the thermal battery module to kilowatt-hours.

(C) *Substantiation of capacity measurement.* Taxpayers must maintain the testing standard and methodology with respect to the capacity measurement described in paragraphs (e)(4)(ii)(A) and (B) of this section as part of books and records under section 6001 and § 1.6001–1. The testing procedure and methodology must consistently be used, subject to any updated standard of the same methodology and testing, for battery modules (with or without cells) sold in the taxpayer's trade or business.

(iii) *Credit amount—(A) Modules using battery cells.* For a battery module with cells, the credit amount is equal to the product of \$10 multiplied by the capacity of such battery module, subject to the limitation provided in paragraph (e)(5) of this section. The capacity of each battery module is expressed on a kilowatt-hour basis.

(B) *Modules with no battery cells.* For a battery module without cells, the credit amount is equal to the product of \$45 multiplied by the capacity of such battery module, subject to the limitation provided in paragraph (e)(5) of this section. The capacity of each battery module is expressed on a kilowatt-hour basis.

(5) *Limitation on capacity of battery cells and battery modules—(i) In general.* For purposes of paragraphs (e)(3)(iii) and (e)(4)(iii) of this section, the capacity determined with respect to a battery cell or battery module must not exceed a capacity-to-power ratio of 100:1.

(ii) *Capacity to power ratio.* For purposes of paragraph (e)(5)(i) of this section, *capacity-to-power ratio* means, with respect to a battery cell or battery module, the ratio of the capacity of such cell or module to the maximum

discharge amount of such cell or module.

(f) *Phase out rule—(1) In general.* Except as provided in paragraph (f)(3) of this section, in the case of any eligible component sold after December 31, 2029, the amount of the section 45X credit determined with respect to such eligible component must be equal to the product of—

(i) The amount determined under this section with respect to such eligible component, multiplied by

(ii) The phase out percentage under paragraph (f)(2) of this section.

(2) *Phase out percentages.* The phase out percentage is equal to—

(i) 75 percent for eligible components sold during calendar year 2030;

(ii) 50 percent for eligible components sold during calendar year 2031;

(iii) 25 percent for eligible components sold during calendar year 2032, and

(iv) Zero percent for eligible components sold after calendar year 2032.

(3) *Exception for applicable critical minerals.* The phase out rules described in paragraphs (f)(1) and (2) of this section apply to all eligible components except applicable critical minerals.

(g) *Applicability date.* This section applies to eligible components for which production is completed and sales occur after December 31, 2022, and during a taxable year ending on or after October 28, 2024.

§ 1.45X–4 Applicable critical minerals.

(a) *In general.* The term *applicable critical mineral* means any of the minerals that are listed in section 45X(c)(6) and defined in paragraph (b) of this section.

(b) *Definitions.* The following definitions apply for the purpose of this section—

(1) [Reserved]

(2) *Antimony.* The term *antimony* means antimony that is—

(i) Converted to antimony trisulfide concentrate with a minimum purity of 90 percent antimony trisulfide by mass; or

(ii) Purified to a minimum purity of 99.65 percent antimony by mass.

(3) *Barite.* The term *barite* means barite that is barium sulfate purified to a minimum purity of 80 percent barite by mass.

(4) *Beryllium.* The term *beryllium* means beryllium that is—

(i) Converted to copper-beryllium master alloy; or

(ii) Purified to a minimum purity of 99 percent beryllium by mass.

(5) *Cerium.* The term *cerium* means cerium that is—

(i) Converted to cerium oxide that is purified to a minimum purity of 99.9 percent cerium oxide by mass; or

(ii) Purified to a minimum purity of 99 percent cerium by mass.

(6) *Cesium.* The term *cesium* means cesium that is—

(i) Converted to cesium formate or cesium carbonate; or

(ii) Purified to a minimum purity of 99 percent cesium by mass.

(7) *Chromium.* The term *chromium* means chromium that is—

(i) Converted to ferrocromium consisting of not less than 60 percent chromium by mass; or

(ii) Purified to a minimum purity of 99 percent chromium by mass.

(8) *Cobalt.* The term *cobalt* means cobalt that is—

(i) Converted to cobalt sulfate; or

(ii) Purified to a minimum purity of 99.6 percent cobalt by mass.

(9) *Dysprosium.* The term *dysprosium* means dysprosium that is—

(i) Converted to not less than 99 percent pure dysprosium iron alloy by mass; or

(ii) Purified to a minimum purity of 99 percent dysprosium by mass.

(10) *Europium.* The term *europium* means europium that is—

(i) Converted to europium oxide that is purified to a minimum purity of 99.9 percent europium oxide by mass; or

(ii) Purified to a minimum purity of 99 percent of europium by mass.

(11) *Fluorspar.* The term *fluorspar* means fluorspar that is—

(i) Converted to fluorspar that is purified to a minimum purity of 97 percent calcium fluoride by mass; or

(ii) Purified to a minimum purity of 99 percent fluorspar by mass.

(12) *Gadolinium.* The term *gadolinium* means gadolinium that is—

(i) Converted to gadolinium oxide that is purified to a minimum purity of 99.9 percent gadolinium oxide by mass; or

(ii) Purified to a minimum purity of 99 percent gadolinium by mass.

(13) *Germanium.* The term *germanium* means germanium that is—

(i) Converted to germanium tetrachloride; or

(ii) Purified to a minimum purity of 99.99 percent germanium by mass.

(14) *Graphite.* The term *graphite* means natural or synthetic graphite that is purified to a minimum purity of 99.9 percent graphitic carbon by mass. The term *99.9 percent graphitic carbon by mass* means graphite that is 99.9 percent carbon by mass.

(15) *Indium.* The term *indium* means indium that is—

(i) Converted to—

(A) Indium tin oxide; or

(B) Indium oxide that is purified to a minimum purity of 99.9 percent indium oxide by mass; or

(ii) Purified to a minimum purity of 99 percent indium by mass.

(16) *Lithium*. The term *lithium* means lithium that is—

(i) Converted to lithium carbonate or lithium hydroxide; or

(ii) Purified to a minimum purity of 99.9 percent lithium by mass.

(17) *Manganese*. The term *manganese* means manganese that is—

(i) Converted to manganese sulphate; or

(ii) Purified to a minimum purity of 99.7 percent manganese by mass.

(18) *Neodymium*. The term *neodymium* means neodymium that is—

(i) Converted to neodymium-praseodymium oxide that is purified to a minimum purity of 99 percent neodymium-praseodymium oxide by mass;

(ii) Converted to neodymium oxide that is purified to a minimum purity of 99.5 percent neodymium oxide by mass; or

(iii) Purified to a minimum purity of 99.9 percent neodymium by mass.

(19) *Nickel*. The term *nickel* means nickel that is—

(i) Converted to nickel sulphate; or

(ii) Purified to a minimum purity of 99 percent nickel by mass.

(20) *Niobium*. The term *niobium* means niobium that is—

(i) Converted to ferroniobium; or

(ii) Purified to a minimum purity of 99 percent niobium by mass.

(21) *Tellurium*. The term *tellurium* means tellurium that is—

(i) Converted to cadmium telluride; or

(ii) Purified to a minimum purity of 99 percent tellurium by mass.

(22) *Tin*. The term *tin* means tin that purified to low alpha emitting tin that—

(i) Has a purity of greater than 99.99 percent by mass; and

(ii) Possesses an alpha emission rate of not greater than 0.01 counts per hour per centimeter square.

(23) *Tungsten*. The term *tungsten* means tungsten that is converted to ammonium paratungstate or ferrotungsten.

(24) *Vanadium*. The term *vanadium* means vanadium that is converted to ferrovanadium or vanadium pentoxide.

(25) *Yttrium*. The term *yttrium* means yttrium that is—

(i) Converted to yttrium oxide that is purified to a minimum purity of 99.999 percent yttrium oxide by mass; or

(ii) Purified to a minimum purity of 99.9 percent yttrium by mass.

(26) *Other minerals*. The following minerals are also applicable critical minerals provided that such mineral is purified to a minimum purity of 99 percent by mass:

(i) Arsenic.

(ii) Bismuth.

(iii) Erbium.

(iv) Gallium.

(v) Hafnium.

(vi) Holmium.

(vii) Iridium.

(viii) Lanthanum.

(ix) Lutetium.

(x) Magnesium.

(xi) Palladium.

(xii) Platinum.

(xiii) Praseodymium.

(xiv) Rhodium.

(xv) Rubidium.

(xvi) Ruthenium.

(xvii) Samarium.

(xviii) Scandium.

(xix) Tantalum.

(xx) Terbium.

(xxi) Thulium.

(xxii) Titanium.

(xxiii) Ytterbium.

(xxiv) Zinc.

(xxv) Zirconium.

(c) *Credit amount*—(1) *In general*. For any applicable critical mineral, the credit amount is equal to 10 percent of the costs incurred by the taxpayer with respect to production of such mineral.

(2) *Production processes for applicable critical minerals*—(i) *Conversion*. For purposes of section 45X, the term *conversion* means a chemical transformation from one species to another.

(ii) *Purification*. For purposes of section 45X, the term *purification* means increasing the mass fraction of a certain element.

(3) *Production costs incurred*—(i) *In general*. Costs incurred by the taxpayer with respect to the production of applicable critical minerals includes all costs as defined in § 1.263A-1(e) that are paid or incurred within the meaning of section 461 of the Code by the taxpayer for the production of an applicable critical mineral, including direct or indirect materials costs as defined in § 1.263A-1(e)(2)(i)(A) and (e)(3)(ii)(E), respectively, but only if those direct or indirect material costs do not relate to the purchase of materials that are an eligible component at the time of acquisition (for example, an electrode active material as defined in § 1.45X-3(e)(2)(i) or applicable critical mineral as defined in paragraph (b) of this section). This definition of production costs incurred would include any costs incurred by the taxpayer related to the extraction of raw materials in the United States or a United States territory, but only if those costs are paid or incurred by the taxpayer that claims the section 45X credit with respect to the relevant applicable critical mineral. Section 263A of the Code and the regulations in

this chapter under section 263A apply solely to identify the types of costs that are includible in production costs incurred for purposes of computing the amount of the section 45X credit, but do not apply for any other purpose, such as to determine whether a taxpayer is engaged in production activities.

(ii) *Production costs for production of incorporated eligible components*. The production costs that a taxpayer pays or incurs in the production of an eligible component (whether produced domestically or not) that the taxpayer then incorporates into a further distinct applicable critical mineral within the meaning of § 1.45X-1(f)(1) are not included in the costs incurred by the taxpayer in producing the further distinct applicable critical mineral. A taxpayer may not include the same production costs in the calculation of the credit amount for more than one eligible component. For example, if the taxpayer pays or incurs production costs of \$50X for eligible component 1 and an additional \$100X of production costs for eligible component 2 that included integrating eligible component 1 within the meaning of § 1.45X-1(f)(1), then the production costs for eligible component 1 equal \$50X and the production costs for eligible component 2 equal \$100X.

(4) *Substantiation*. In order to include direct or indirect materials costs as defined in § 1.263A-1(e)(2)(i)(A) and (e)(3)(ii)(E) as production costs when calculating a section 45X credit for the production and sale of an applicable critical mineral, a taxpayer, as part of filing an annual tax return (or a return for a short year within the meaning of section 443 of the Code), must include the information in paragraph (c)(4)(i) of this section as an attachment to that return, prepare the information required in paragraph (c)(4)(ii) through (iv) of this section and maintain that information in the taxpayer's books and records under section 6001, and comply with directions for the information required in paragraph (c)(4)(v) of this section as specified in guidance:

(i) Certification from any supplier, including the supplier's employer identification number and that is signed under penalties of perjury, from which the taxpayer purchased any constituent elements, materials, or subcomponents of the taxpayer's applicable critical mineral, stating that the supplier is not claiming the section 45X credit with respect to any of the material acquired by the taxpayer, nor is the supplier aware that any prior supplier in the chain of production of that material claimed a section 45X credit for the material.

(ii) A document that provides an analysis of any constituent elements, materials, or subcomponents that concludes the material did not meet the definition of an eligible component (for example, an applicable critical mineral or electrode active material) at the time of acquisition by the taxpayer. The document may be prepared by the taxpayer or ideally by an independent third-party.

(iii) A list of all direct and indirect material costs and the amount of such costs that were included within the taxpayer's total production cost for each applicable critical mineral.

(iv) A document related to the taxpayer's production activities with respect to the direct and indirect material costs that establishes the materials were used in the production of the applicable critical mineral. The document may be prepared by the taxpayer or ideally by an independent third-party.

(v) Any other information related to the direct or indirect materials specified in guidance.

(5) Failure to provide the documentation described in paragraph (c)(4) of this section with the return filing, or providing an available upon

request statement, will constitute a failure to substantiate the claim.

(d) *Applicability date.* This section applies to eligible components for which production is completed and sales occur after December 31, 2022, and during a taxable year ending on or after October 28, 2024.

Douglas W. O'Donnell,

Deputy Commissioner.

Approved: October 17, 2024.

Aviva R. Aron-Dine,

Deputy Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2024-24840 Filed 10-24-24; 8:45 am]

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FEDERAL REGISTER

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October 28, 2024

Part VI

The President

Notice of October 25, 2024—Continuation of the National Emergency With Respect to Sudan

Presidential Documents

Title 3—**Notice of October 25, 2024****The President****Continuation of the National Emergency With Respect to Sudan**

On November 3, 1997, by Executive Order 13067, the President declared a national emergency with respect to Sudan pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) and took related steps to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States posed by the actions and policies of the Government of Sudan. On April 26, 2006, by Executive Order 13400, the President determined that the conflict in Sudan's Darfur region posed an unusual and extraordinary threat to the national security and foreign policy of the United States, expanded the scope of the national emergency declared in Executive Order 13067, and ordered the blocking of property of certain persons connected to the Darfur region. On October 13, 2006, by Executive Order 13412, the President took additional steps with respect to the national emergency declared in Executive Order 13067 and expanded in Executive Order 13400. In Executive Order 13412, the President also took steps to implement the Darfur Peace and Accountability Act of 2006 (Public Law 109–344).

On January 13, 2017, by Executive Order 13761, the President found that positive efforts by the Government of Sudan between July 2016 and January 2017 improved certain conditions that Executive Orders 13067 and 13412 were intended to address. Given these developments, and in order to encourage the Government of Sudan to sustain and enhance these efforts, section 1 of Executive Order 13761 provided that sections 1 and 2 of Executive Order 13067 and the entirety of Executive Order 13412 would be revoked as of July 12, 2017, provided that the criteria in section 12(b) of Executive Order 13761 had been met.

On July 11, 2017, by Executive Order 13804, the President amended Executive Order 13761, extending until October 12, 2017, the effective date in section 1 of Executive Order 13761. On October 12, 2017, pursuant to Executive Order 13761, as amended by Executive Order 13804, sections 1 and 2 of Executive Order 13067 and the entirety of Executive Order 13412 were revoked.

On May 4, 2023, by Executive Order 14098, I further expanded the scope of the national emergency declared in Executive Order 13067, finding that the situation in Sudan, including the military's seizure of power in October 2021 and the outbreak of inter-service fighting in April 2023, constituted an unusual and extraordinary threat to the national security and foreign policy of the United States.

The crisis that led to the declaration of a national emergency in Executive Order 13067 of November 3, 1997; the expansion of the scope of that emergency in Executive Order 13400 of April 26, 2006; the taking of additional steps with respect to that emergency in Executive Order 13412 of October 13, 2006, Executive Order 13761 of January 13, 2017, and Executive Order 13804 of July 11, 2017; and the further expansion of the scope of that emergency in Executive Order 14098 of May 4, 2023, has not been resolved. The policies and actions of the Government of Sudan, and the situation in Sudan and Darfur, continue to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared in Executive Order 13067,

as expanded by Executive Orders 13400 and 14098, must continue in effect beyond November 3, 2024.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
October 25, 2024.

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