NRC Response to Public Comments

Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors

NRC-2019-0062; RIN 3150-AK31

Volume #1 – Response to Comments on 10 CFR Part 53

U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
Office of Nuclear Security and Incident Response
Office of Nuclear Material Safety and Safeguards

March 2026

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Acronyms and Abbreviations

ACI	American Concrete Institute
ACRS	Advisory Committee on Reactor Safeguards
ADAMS	Agencywide Documents Access and Management System
ADVANCE Act	Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024
AEA	Atomic Energy Act of 1954, as amended
AERI	alternative evaluation of risk insights
AI	Artificial Intelligence
AIPT	adversary interference precluded time
AISC	American Institute of Steel Construction
ALARA	as low as (is) reasonably achievable
ANS	American Nuclear Society
ANSI	American National Standards Institute
AOO	anticipated operational occurrence
APA	Administrative Procedure Act
ARAR	Applicable or Relevant and Appropriate Requirements
ARCAP	Advanced Reactor Content of Application Project
ARDC	advanced reactor design criteria
ASCE	American Society of Civil Engineers
ASME	American Society of Mechanical Engineers
BDBE	beyond-design-basis event
BOP	behavioral observation program
C/TPA	consortia/third-party administrators
CAA	Clean Air Act
CAB	community advisory board
CCTV	closed-circuit television
CDF	core damage frequency
CER	cumulative effects of regulation
CFR	*Code of Federal Regulations*
COL	combined license (combined construction and operating license)
CP	construction permit
CRCPD	Conference of Radiation Control Program Directors
DANU	Division of Advanced Reactors and Non-Power Production or Utilization Facilities
DBA	design-basis accident
DBE	design-basis event
DBEHL	design-basis external hazard level
DBHL	design-basis hazard level
DBT	design-basis threat
DC	design certification
DECON	a phase of reactor decommissioning
DG	draft regulatory guide
DID	defense in depth
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation

DRO	Division of Reactor Oversight
EO	Executive Order
EA	environmental assessment
EAP	Employee Assistance Program
EBT	evidential breath testing device
ECA	Energy Communities Alliance
EIS	environmental impact statement
EP	emergency preparedness
EPA	U.S. Environmental Protection Agency
EPZ	emergency planning zone
ERDS	Emergency Response Data System
ESP	early site permit
FDA	U.S. Food and Drug Administration
FEMA	Federal Emergency Management Agency
FFD	fitness-for-duty
FIOP	Federal Interagency Operational Plan
FOAK	first-of-a-kind
FR	*Federal Register*
FRN	*Federal Register* notice
FSAR	final safety analysis report
GAO	U.S. Government Accountability Office
GDC	general design criteria
GEIS	generic environmental impact statement
GLRO	generally licensed reactor operator
HALEU	high-assay low-enriched uranium
HFE	human factors engineering
HHS	U.S. Department of Health and Human Services
HSI	human system interface
IAEA	International Atomic Energy Agency
IEEE	Institute of Electrical and Electronics Engineers
IEFR	individual early fatality risk
ILCFR	individual latent cancer fatality risk
ISG	interim staff guidance
ISI	inservice inspection
ISO	International Organization for Standardization
IST	inservice testing
ITAAC	inspections, tests, analyses, and acceptance criteria
LBE	licensing-basis event
LER	licensee event report
LERF	large early release frequency
LMP	Licensing Modernization Project
LNT	linear no-threshold
LWA	limited work authorization
LWR	light-water reactor
MC&A	material control and accounting
MD	management directive
ML	manufacturing license

MHA	maximum hypothetical accident
MRO	medical review officer
mSv	millisievert
NEI	Nuclear Energy Institute
NEIMA	Nuclear Energy Innovation and Modernization Act of 2019
NEPA	National Environmental Policy Act
NNAB	National Nuclear Accrediting Board
non-LWR	non-light-water reactor
NPS	National Preparedness System
NPUF	non-power production or utilization facility
NQA-1	Nuclear Quality Assurance-1 standard
NRC	U.S. Nuclear Regulatory Commission
NRF	National Response Framework
NRIA	Nuclear/Radiological Incident Annex
NSRSS	non-safety-related but safety-significant
NSS	Nuclear Security Series
NTIAP	Near-Term Implementation Action Plans
NTTAA	National Technology Transfer and Advancement Act of 1995
NUREG	NRC technical report designation
OAS	Organization of Agreement States
OCA	owner-controlled area
ODCM	offsite dose calculation manual
OL	operating license
OMB	Office of Management and Budget
PAG	protective action guide
PMRP	performance monitoring and review program
POCT	point of collection testing
POCTA	point of collection testing and assessment
PPS	performance-based physical security
PRA	probabilistic risk assessment
PSDAR	post-shutdown decommissioning activities report
QA	quality assurance
QHO	quantitative health objective
RA	regulatory analysis
rem	roentgen equivalent man
RE factor	relative effectiveness factor
RFC	request for comment
RG	regulatory guide
RHDRA	Rapid High-Volume Deployable Reactors in Remote Applications
RIDM	risk-informed decision-making
RIM	Reliability and Integrity Management
RO	reactor operator
ROWS	Remotely Operated Weapons System
SAE	substance abuse expert
SAFSTOR	nuclear decommissioning method
SAR	safety analysis report
SAT	systems approach to training

SBT	security bounding time
SDA	standard design approval
SDC	standard design certification
SECY	Commission
SGI	Safeguards Information
SMR	small modular reactor
SNM	special nuclear material
SR	safety related
SRE	systematic risk evaluation
SRM	staff requirements memorandum
SRMF	self-reliant mitigation facility
SRO	senior reactor operator
SRP	standard review plan
SSC	structure, system, and component
STA	shift technical advisor
TAG	EPA Technical Assistance Grant Program
TEDE	total effective dose equivalent
TI-RIPB	technology-inclusive, risk-informed, and performance-based
TNT	trinitrotoluene
U.S.C.	United States Code

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U.S. NUCLEAR REGULATORY COMMISSION
RESPONSE TO PUBLIC COMMENTS RECEIVED ON THE PROPOSED RULE RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR ADVANCED REACTORS

Introduction

This document presents the U.S. Nuclear Regulatory Commission's (NRC's) responses to written public comments received on the proposed rule, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" (Part 53). The NRC's review and response to these comments can be found in two documents. Volume 1, this document, addresses the comments received on the proposed Title 10 of the *Code of Federal Regulations* (10 CFR) Part 53 requirements, including specific questions on Part 53 that were asked in the *Federal Register* notice (FRN). Volume II addresses comments related to other sections of the 10 CFR (e.g., 10 CFR Part 26, 10 CFR Part 73) and supporting guidance (e.g., draft regulatory guides [DGs]), including specific questions on these topics that were asked in the FRN.

The NRC published the proposed rule in the *Federal Register* on October 30, 2024 (89 FR 86918), for public comment with a 60-day public comment period. On November 21, 2024 (89 FR 92609), the NRC extended the public comment period by an additional 60 days to allow more time for members of the public and other stakeholders to develop and submit their comments. The proposed rule is available from the Federal e-Rulemaking website at https://www.regulations.gov/ (Docket ID No. NRC-2019-0062).

In developing the final rule and supporting guidance, the NRC considered all the comments provided in response to the proposed rule. If, as a result of its review of a public comment, the NRC changed the rule or the supporting guidance, the NRC's response to the comment describes the change.

Comment Overview

The NRC received 152 unique comment submissions from individuals and organizations, with 915 identified comments within those comment submissions. In addition to providing feedback on the proposed rule, many commenters addressed the NRC specific requests for comment (RFCs) included in the proposed rule FRN. Table 1 identifies all unique comment submissions. The NRC reviewed and annotated the comment submissions to identify separate comments within each submission. Accordingly, a single submission may have several individual comments associated with it. The NRC gave each individual comment within a submission a unique identifier. The NRC's summaries include this unique identifier to identify which individual comments are addressed by each response.

Table 1. Unique Comment Submissions on Part 53 Proposed Rule

Submission No.	Commenter	Affiliation	Submission Abbreviation	Regulations.gov ID No.	ADAMS Accession No.
001	Marcus Nichol	Nuclear Energy Institute	NEI1	NRC-2019-0062-0331	ML24310A055
002	Patrick White	Nuclear Innovation Alliance	NIA1	NRC-2019-0062-0332	ML24312A204
003	Alyse Peterson	New York State Energy Research and Development Authority (NYSERDA)	NYS1	NRC-2019-0062-0333	ML24312A205
004	Michael Ravnitzky	Not Included	MR	NRC-2019-0062-0334	ML24312A206
005	Tom Gurdziel	Not Included	TG1	NRC-2019-0062-0335	ML24317A217
006	Tom Gurdziel	Not Included	TG2	NRC-2019-0062-0336	ML24317A219
007	Tom Gurdziel	Not Included	TG3	NRC-2019-0062-0339	ML24320A011
008	Cyril Draffin	United States Nuclear Industry Council (USNIC)	USNIC1	NRC-2019-0062-0338	ML24323A150
009	Tom Gurdziel	Not Included	TG4	NRC-2019-0062-0347	ML24323AA151
010	Michael F. Keller	Hybrid Power Technologies LLC	HPT1	NRC-2019-0062-0340	ML24324A030
011	Sarah Gibboney	Not Included	SG1	NRC-2019-0062-0341	ML24325A478
012	Sarah Gibboney	Not Included	SG2	NRC-2019-0062-0342	ML24325A479
013	Sarah Gibboney	Not Included	SG3	NRC-2019-0062-0343	ML24330A187
014	Benny Phillips	Not Included	BP1	NRC-2019-0062-0344	ML24330A188
015	Tom Gurdziel	Not Included	TG5	NRC-2019-0062-0348	ML24337A187
016	Tom Gurdziel	Not Included	TG6	NRC-2019-0062-0358	ML24337A188
017	Tom Gurdziel	Not Included	TG7	NRC-2019-0062-0359	ML24338A038
018	Tom Gurdziel	Not Included	TG8	NRC-2019-0062-0360	ML24339B734
019	Tom Gurdziel	Not Included	TG9	NRC-2019-0062-0361	ML24339B735
020	Tom Gurdziel	Not Included	TG10	NRC-2019-0062-0362	ML24340A108
021	Tom Gurdziel	Not Included	TG11	NRC-2019-0062-	ML24340A109

Submission No.	Commenter	Affiliation	Submission Abbreviation	Regulations.gov ID No.	ADAMS Accession No.
				0363	
022	Tom Gurdziel	Not Included	TG12	NRC-2019-0062-0376	ML24340A110
023	Tom Gurdziel	Not Included	TG13	NRC-2019-0062-0377	ML24340A111
024	Tom Gurdziel	Not Included	TG14	NRC-2019-0062-0378	ML24340A267
025	Tom Gurdziel	Not Included	TG15	NRC-2019-0062-0379	ML24344A021
026	Tom Gurdziel	Not Included	TG16	NRC-2019-0062-0380	ML24344A022
027	Tom Gurdziel	Not Included	TG17	NRC-2019-0062-0381	ML24344A023
028	Tom Gurdziel	Not Included	TG18	NRC-2019-0062-0382	ML24344A024
029	Tom Gurdziel	Not Included	TG19	NRC-2019-0062-0399	ML24345A025
030	Tom Gurdziel	Not Included	TG20	NRC-2019-0062-0388	ML24345A193
031	Michael F. Keller	Hybrid Power Technologies LLC	HPT2	NRC-2019-0062-0345	ML24351A014
032	Michael F. Keller	Hybrid Power Technologies LLC	HPT3	NRC-2019-0062-0346	ML24351A015
033	Tom Gurdziel	Not Included	TG21	NRC-2019-0062-0386	ML24353A258
034	Tom Gurdziel	Not Included	TG22	NRC-2019-0062-0387	ML24353A259
035	Tom Gurdziel	Not Included	TG23	NRC-2019-0062-0389	ML24353A298
036	Anonymous	Not Included	AN1	NRC-2019-0062-0349	ML24365A027
037	Douglas J. Hansen	State of Utah Department of Environmental Quality	UT1	NRC-2019-0062-0366	ML24366A095
038	Tom Gurdziel	Not Included	TG24	NRC-2019-0062-0390	ML24366A096
039	Herschell Specter	Mirco-Utilities, Inc.	MU1	NRC-2019-0062-0368	ML24366A097
040	Tom Gurdziel	Not Included	TG25	NRC-2019-0062-0365	ML25006A086
041	Ernie Kee	Not Included	EK	NRC-2019-0062-0350	ML25013A172
042	Michael Keller	Hybrid Power Technologies LLC	HPT4	NRC-2019-0062-0351	ML25013A173
043	Michael Keller	Hybrid Power Technologies LLC	HPT5	NRC-2019-0062-0352	ML25013A174
044	Michael Keller	Hybrid Power Technologies LLC	HPT6	NRC-2019-0062-0353	ML25013A175

Submission No.	Commenter	Affiliation	Submission Abbreviation	Regulations.gov ID No.	ADAMS Accession No.
045	Michael Keller	Hybrid Power Technologies LLC	HPT7	NRC-2019-0062-0354	ML25013A176
046	Michael Keller	Hybrid Power Technologies LLC	HPT8	NRC-2019-0062-0355	ML25013A177
047	Michael Keller	Hybrid Power Technologies LLC	HPT9	NRC-2019-0062-0356	ML25013A178
048	Michael Keller	Hybrid Power Technologies LLC	HPT10	NRC-2019-0062-0357	ML25013A17Q
049	Tom Gurdziel	Not Included	TG26	NRC-2019-0062-0364	ML25015A103
050	Lisa Davis	Not Included	LD	NRC-2019-0062-0372	ML25023A177
051	Anonymous	Not Included	AN2	NRC-2019-0062-0373	ML25021A303
052	Michael Keller	Hybrid Power Technologies LLC	HPT11	NRC-2019-0062-0371	ML25027A422
053	Tom Gurdziel	Not Included	TG27	NRC-2019-0062-0383	ML25024A196
054	Michael Keller	Hybrid Power Technologies LLC	HPT12	NRC-2019-0062-0384	ML25024A197
055	Michael Keller	Hybrid Power Technologies LLC	HPT13	NRC-2019-0062-0385	ML25024A198
056	Michael Keller	Hybrid Power Technologies LLC	HPT14	NRC-2019-0062-0375	ML25027A422
057	Michael Keller	Hybrid Power Technologies LLC	HPT15	NRC-2019-0062-0374	ML25027A423
058	Michael Keller	Hybrid Power Technologies LLC	HPT16	NRC-2019-0062-0396	ML25027A424
059	Michael Keller	Hybrid Power Technologies LLC	HPT17	NRC-2019-0062-0369	ML25027A452
060	Michael Keller	Hybrid Power Technologies LLC	HPT18	NRC-2019-0062-0395	ML25027A453
061	Michael Keller	Hybrid Power Technologies LLC	HPT19	NRC-2019-0062-0370	ML25027A454
062	Michael Keller	Hybrid Power Technologies LLC	HPT20	NRC-2019-0062-0400	ML25030A375
063	Romney Duffey	Not Included	RD	NRC-2019-0062-0398	ML25034A063
064	Anonymous	Not Included	AN3	NRC-2019-0062-0401	ML25036A184

Submission No.	Commenter	Affiliation	Submission Abbreviation	Regulations.gov ID No.	ADAMS Accession No.
065	Anonymous	Not Included	AN4	NRC-2019-0062-0402	ML25036A185
066	Michael Keller	Hybrid Power Technologies LLC	HPT21	NRC-2019-0062-0403	ML25036A186
067	Michael Keller	Hybrid Power Technologies LLC	HPT22	NRC-2019-0062-0404	ML25036A187
069	Michael Keller	Hybrid Power Technologies LLC	HPT23	NRC-2019-0062-0406	ML25037A344
070	Michael Keller	Hybrid Power Technologies LLC	HPT24	NRC-2019-0062-0407	ML25037A345
071	Michael Keller	Hybrid Power Technologies LLC	HPT25	NRC-2019-0062-0408	ML25037A346
072	Rani Franovich	Not Included	RF	NRC-2019-0062-0397	ML25037A347
073	Michael Keller	Hybrid Power Technologies LLC	HPT26	NRC-2019-0062-0437	ML25042A549
075	Lizzie McFee	Not Included	LM	NRC-2019-0062-0409	ML25044A419
076	Herschel Specter	Micro-Utilities Inc	MU2	NRC-2019-0062-0416	ML25044A420
077	Michael Keller	Hybrid Power Technologies LLC	HPT27	NRC-2019-0062-0410	ML25050A259
078	Michael Keller	Hybrid Power Technologies LLC	HPT28	NRC-2019-0062-0411	ML25050A260
079	Michael Keller	Hybrid Power Technologies LLC	HPT29	NRC-2019-0062-0412	ML25050A262
080	Michael Keller	Hybrid Power Technologies LLC	HPT30	NRC-2019-0062-0414	ML25050A263
081	Michael Keller	Hybrid Power Technologies LLC	HPT31	NRC-2019-0062-0413	ML25050A264
082	Michael Keller	Hybrid Power Technologies LLC	HPT32	NRC-2019-0062-0415	ML25050A265
083	Michael Keller	Hybrid Power Technologies LLC	HPT33	NRC-2019-0062-0417	ML25050A266
084	Douglas True	Nuclear Energy Institute	NEI2	NRC-2019-0062-0418	ML25051A092
085	Michael Keller	Hybrid Power Technologies LLC	HPT34	NRC-2019-0062-0435	ML25051A154
086	Michael	Hybrid Power	HPT35	NRC-2019-0062-	ML25051A155

Submission No.	Commenter	Affiliation	Submission Abbreviation	Regulations.gov ID No.	ADAMS Accession No.
	Keller	Technologies LLC		0436	
087	Sarah Campbell	Not Included	SC	NRC-2019-0062-0432	ML25051A156
088	Nathan Padilla	Not Included	NP	NRC-2019-0062-0433	ML25051A157
089	Michael Keller	Hybrid Power Technologies LLC	HPT36	NRC-2019-0062-0434	ML25051A158
090	Michael Keller	Hybrid Power Technologies LLC	HPT37	NRC-2019-0062-0431	ML25051A159
091	Nevada Caldwell	Not Included	NA	NRC-2019-0062-0428	ML25051A160
092	Michael Keller	Hybrid Power Technologies LLC	HPT38	NRC-2019-0062-0430	ML25051A162
093	Jesse Seymour	Not Included	JSE	NRC-2019-0062-0429	ML25051A163
094	Michael Keller	Hybrid Power Technologies LLC	HPT39	NRC-2019-0062-0438	ML25056A004
095	Michael Keller	Hybrid Power Technologies LLC	HPT40	NRC-2019-0062-0439	ML25056A005
096	Michael Keller	Hybrid Power Technologies LLC	HPT41	NRC-2019-0062-0440	ML25056A006
097	Michael Keller	Hybrid Power Technologies LLC	HPT42	NRC-2019-0062-0441	ML25056A007
098	Anonymous	Not Included	AN5	NRC-2019-0062-0442	ML22040A354
099	Michael Keller	Hybrid Power Technologies LLC	HPT43	NRC-2019-0062-0443	ML25056A009
100	Adam Stein	Stakeholder Consensus Working Group	SCWG	NRC-2019-0062-0444	ML25056A010
101	Tom Gurdziel	Not Included	TG28	NRC-2019-0062-0488	ML25057A451
102	Cyril Draffin	United States Nuclear Industry Council	USNIC2	NRC-2019-0062-0492	ML25058A180
103	James E. Holloway	Dominion Energy Services	DOM	NRC-2019-0062-0490	ML25058A244
104	Jason A. Christensen	Idaho National Laboratory	IDNL	NRC-2019-0062-0493	ML25062A131
105	Kenneth Mack	NextEra Energy	NEX	NRC-2019-0062-0494	ML25062A132
106	Steven P.	LMNT	LMNT	NRC-2019-0062-	ML25062A134

Submission No.	Commenter	Affiliation	Submission Abbreviation	Regulations.gov ID No.	ADAMS Accession No.
	Nesbit	Consulting		0495	
107	Edwin Lyman	Union of Concerned Scientists	UCS	NRC-2019-0062-0491	ML25062A134
108	W. Grover Hettel	Energy Northwest	ENW	NRC-2019-0062-0489	ML25063A073
109	Alyse Peterson	NYSERDA	NYS2	NRC-2019-0062-0445	ML25066A024
110	Peter Hastings	Kairos Power LLC	KAP	NRC-2019-0062-0446	ML25066A025
111	Melinda Alankar	The Anthropocene Institute	ANI	NRC-2019-0062-0447	ML25066A026
112	Micholas McMurray	ClearPath	CP	NRC-2019-0062-0448	ML25066A027
113	Cheryl Gayheart	Southern Nuclear Operating Company	SOU	NRC-2019-0062-0449	ML25066A028
114	Joe Miller	BWXT Advanced Technologies	BWXT	NRC-2019-0062-0450	ML25066A029
115	Malcolm Thompson	Deep Fission, Inc.	DP	NRC-2019-0062-0451	ML25066A030
116	Andrew Sowder, Ph.D.	American Nuclear Society Standards Committee	ANS	NRC-2019-0062-0452	ML25066A031
117	Eric Meyer	Generation Atomic	GA	NRC-2019-0062-0453	ML25066A032
118	James Smith	Not Included	JSM	NRC-2019-0062-0454	ML25066A033
119	Jon Facemire	Nuclear Energy Institute	NEI3	NRC-2019-0062-0455	ML25066A034
120	Tim Williamson	Shepherd Power LLC	SHP	NRC-2019-0062-0456	ML25066A035
121	Rod Adams	Nucleation Capital	NUC	NRC-2019-0062-0468	ML25066A036
122	Anthony Schoedel	Westinghouse Electric Company LLC	WEST1	NRC-2019-0062-0469	ML25066A037
123	Ismael Garcia	Not Included	IG	NRC-2019-0062-0470	ML25066A038
124	Mark Shaver	NuScale Power	NUS1	NRC-2019-0062-0471	ML25066A039
125	Vincent D'Aco	Not Included	VD	NRC-2019-0062-0472	ML25066A040
126	Phil Couture	Entergy Operations Inc	ENT	NRC-2019-0062-0473	ML25066A041
127	Fernando Fonseca	Not Included	FF	NRC-2019-0062-0474	ML25066A042
128	Frans Kopp	Not Included	FK	NRC-2019-0062-	ML25066A043

Submission No.	Commenter	Affiliation	Submission Abbreviation	Regulations.gov ID No.	ADAMS Accession No.
				0475	
129	Ruth Hollander	Not Included	RH	NRC-2019-0062-0476	ML25066A044
130	John Parillo	Not Included	JP	NRC-2019-0062-0466	ML25066A045
131	Michael McLean	Not Included	MM	NRC-2019-0062-0465	ML25066A046
132	Michael Keller	Hybrid Power Technologies LLC	HPT44	NRC-2019-0062-0478	ML25066A047
133	Anonymous	Not Included	AN6	NRC-2019-0062-0477	ML25066A048
134	Michael Keller	Hybrid Power Technologies LLC	HPT45	NRC-2019-0062-0467	ML25066A049
135	Stephen G. Burns, John Cornwell, Judi Greenwald, Nicholas McMurray, Malwina Qvist, Dr. Adam Stein	BTI, CATF, ClearPath, GEC, NIA, and Third Way	NGO	NRC-2019-0062-0483	ML25069A162
136	Patrick White	Nuclear Innovation Alliance (NIA)	NIA2	NRC-2019-0062-0480	ML25069A163
137	Eric Ingersoll	Terra Praxis	TP	NRC-2019-0062-0484	ML25069A164
138	Carl Wurtz	Fission Transition Inc.	FTI	NRC-2019-0062-0485	ML25069A165
139	Dietmar Detering, PhD	Nuclear New York, Inc.	NNY	NRC-2019-0062-0486	ML25069A166
140	Rani Franovich and N. Prasad Kadambi	Nuclear ROSE Consulting, LLC, and Kadambi Engineering Consultants	ROSE	NRC-2019-0062-0479	ML25069A167
141	Carrie Fosaaen	NuScale Power	NUS2	NRC-2019-0062-0481	ML25069A168
142	Anonymous	Not Included	AN7	NRC-2019-0062-0487	ML25069A169
143	Anonymous	Not Included	AN8	NRC-2019-0062-0482	ML25069A170
144	Anonymous	Not Included	AN9	NRC-2019-0062-0457	ML25069A171
145	Anonymous	Not Included	AN10	NRC-2019-0062-0458	ML25069A172
146	Anonymous	Not Included	AN11	NRC-2019-0062-0460	ML25069A173
147	Anonymous	Not Included	AN12	NRC-2019-0062-	ML25069A174

Submission No.	Commenter	Affiliation	Submission Abbreviation	Regulations.gov ID No.	ADAMS Accession No.
				0459	
148	Chanson Yang	Radiant	RAD	NRC-2019-0062-0461	ML25069A175
149	Joseph Hunt	Not Included	JH	NRC-2019-0062-0464	ML25069A176
150	Arden Rowell	University of Illinois	UL	NRC-2019-0062-0462	ML25069A177
151	Adam Stein	Breakthrough Institute	BI1	NRC-2019-0062-0463	ML25069A179
152	Michael D. DiLorenzo	Arizona Public Service	APS	NRC-2019-0062-0500	ML25072A162
153	Anonymous	Not Included	AN13	NRC-2019-0062-0501	ML25072A163
154	Herschel Specter	Micro-Utilities Inc	MU3	NRC-2019-0062-0502	ML25094A080
APSR-003*	Anthony Schoedel	Westinghouse Electric Company	WEST2	NRC-2017-0227-0045	ML24295A034
APSR-004*	Charlie	Blue Energy	BE1	NRC-2017-0227-0046	ML24295A035
APSR-006*	Christopher P. Chwasz	Advanced Reactor Regulatory Coordination and Integration Group	ARRC	NRC-2017-0227-0052	ML24297A426
APSR-007*	Mark Shaver	NuScale Power	NUS3	NRC-2017-0227-0047	ML24298A062
APSR-010*	Kati R. Austgen	Nuclear Energy Institute	NEI4	NRC-2017-0227-0050	ML24298A065
APSR-011*	Edwin Lyman	Union of Concerned Scientists	UCS1	NRC-2017-0227-0053	ML24298A066
APSR-014*	Spencer Toohill	Breakthrough Institute	BI2	NRC-2017-0227-0057	ML24312A335

*Submission Nos. APSR-003, APSR-004, APSR-006, APSR-007, APSR-010, APSR-011, and APSR-014 were originally submitted in response to the Alternative Physical Security Requirements for Advanced Reactors proposed rule (89 FR 65226) under Docket ID NRC-2017-0227.

Public Meetings

On November 19-21, 2024, and January 8, 2025, the NRC held public meetings to discuss the proposed rule with external stakeholders. The NRC's goal for conducting these meetings was to promote stakeholder understanding of the proposed rule. The staff discussed the structure and content of the proposed rule and answered questions to facilitate the submission of meaningful comments on the proposed rule.

Comment Categorization

This comment response document separates the comments into the 11 categories identified below. Within each category, the NRC summarizes comments and responds to them. In general, the NRC addresses each individual comment. However, when similar comments can be readily grouped together, the NRC has binned those comments and treated them as a single comment bin. The NRC's response addresses the binned comments. The annotated comment number or numbers appear in a parenthetical list at the end of each comment summary to provide a cross-reference aid to the reader. The comment summaries are grouped in the following volumes and categories:

<u>Volume #1 – Response to Comments on 10 CFR Part 53</u>

1. General Feedback on the Proposed Rule
2. Background and Need for Rulemaking/Purpose and Scope of the Proposed Rule (e.g., historic issues with existing regulatory framework, need for regulatory certainty for advanced reactors)
3. Major Provisions of the Proposal—10 CFR Part 53 (Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants)

<u>Volume #2 – Response to Comments on 10 CFR Part 26, 10 CFR Part 73, Guidance, and Other Topics</u>

4. Major Provisions of the Proposal – 10 CFR Part 26 (Fitness-for-Duty Programs)
5. Major Provisions of the Proposal – 10 CFR Part 73 (Physical Protection of Plants and Materials)
6. Changes to Other Parts of 10 CFR Chapter I
7. Other Comments on the Proposed Rule
8. Accompanying Guidance
9. Procedural Matters and Other Supporting Documents
10. Rulemaking Timeline and Implementation (e.g., requests to extend comment period, public engagement/stakeholder outreach, rulemaking/implementation timeline)
11. Out of Scope

1. General Feedback on the Proposed Rule

1.1 General support for the proposed rule

Comment Bin 1.1.A: Several commenters expressed support for the proposed rule (SC-0001, FF-0001, NP-0001, NP-0005, RH-0001, MR-0001, RH-0004). One commenter said the proposed rule promotes nuclear innovation by using a flexible, faster, and simple approach to regulation, and it is a vital change to existing nuclear licensing frameworks (SC-0001). Another commenter said that they trust that NRC will take the time to look for ways to efficiently approve advanced reactors while maintaining safety standards (GA-0002). Similarly, two commenters said that the proposed rule is necessary for improvements to the health and wellness of nuclear reactor workers (NP-0001, NP-0005). Another commenter said that through implementation of a risk-informed approach, the proposed rule effectively balances risk reduction and cost increases (RH-0004).

NRC Response: The NRC agrees with the comments.

The comments support the proposed rule and suggest no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to these comments.

1.2. General opposition to the proposed rule

Comment Bin 1.2.A: A commenter said that NRC's approach is overly conservative with arbitrary and complex performance requirements (NNY-0003).

NRC Response: The NRC disagrees with the comment.

The final rule's technology-inclusive, performance-based approach provides a set of requirements that provide an equivalent level of safety to existing regulatory frameworks that ensure the reasonable assurance of adequate protection of public health and safety. Extensive input from all stakeholders has significantly contributed to the efficacy of the performance requirements.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 1.2.B: A commenter criticized the idea of a "flexible" regulatory framework where safety is a secondary concern and said that there was a lack of transparency when it came to public safety and environmental impact (AN3-0001). Another commenter discussed the history of the Federal Government's regulations for aircraft and nuclear reactors generally in contrast to the new proposed regulations. The commenter said that the regulations are not sufficiently protective of the public (TG1-0001).

NRC Response: The NRC disagrees with the comments.

The NRC's mission is to license and regulate the civilian use of nuclear power to provide reasonable assurance of adequate protection of public health and safety, promote the common defense and security by enabling the safe and secure use and deployment of civilian nuclear energy technologies, and protect the environment. This rulemaking is consistent with the agency's mission. While 10 CFR Part 53 may provide additional flexibilities to licensees beyond those contained in the existing regulations, licensees will have to provide an adequate safety evaluation to justify greater operational flexibility. The NRC is not reducing the current safety, environmental, or transparency requirements through this rulemaking.

Moreover, the NRC disagrees with the suggestion that this rulemaking was insufficiently transparent. The NRC held dozens of public meetings, published many drafts of the regulations, and provided an extensive discussion of 10 CFR Part 53 in this rulemaking and through accompanying guidance.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 1.2.C: A commenter wrote that the proposed 10 CFR Part 53 is not the correct approach due to the lack of operating experience with advanced reactors. The commenter explained that a process is needed that primarily makes use of a small panel of experts in the specific type of reactor being considered until that type of reactor has been manufactured and has 5 to 7 years of operating experience, at which point the commenter would be comfortable with the proposed rule being applied to that specific type of reactor (TG27-0001).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that applications for first-of-a-kind reactor technologies and designs will be challenging to prepare and review.

The NRC disagrees that the lack of operating experience with advanced reactors is an issue with 10 CFR Part 53. The suggestions in the comment can largely be addressed as part of the preapplication interactions and reviews for such first-of-a-kind applications and the subsequent inspection and oversight programs during construction and operations. The framework provided by 10 CFR Part 53 is sufficiently flexible to address the licensing of first-of-a-kind reactor designs and, if pursued, to provide the benefits of licensing and deploying standardized reactors incorporating lessons learned from the initial operations of the first commercial nuclear reactor.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 1.2.D: A commenter requested that the proposed rule be withdrawn (without providing supporting rationale) while also stating that the rule is a positive step towards the development of regulations for advanced nuclear reactors and that the commenter has many goals that are consistent with the rule (NA-0001).

NRC Response: The NRC disagrees with the comment.

Based on the context in which this comment was provided, the NRC understands this comment to mean that the commenter would like to see suggested changes between the proposed rule and the final rule and would therefore request that the proposed rule be "withdrawn." See the NRC's responses to Comment Bins 3.9.1.H, 7.A, 9.3.A, and 11.H. This comment did not provide an overall basis for withdrawing the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

1.3. Legal issues raised by comments (e.g., statutory authority, APA comments)

Comment Bin 1.3.A: A commenter discussed legal concerns with the NRC's use of guidance documents. The commenter said that there are serious flaws associated with the use of guidance documents, and that the NRC staff must use CFR compliance as the acceptance standard, not the staff's guidance documents (HPT9-0001, HPT29-0001).

The commenter suggested that NRC reviews utilizing guidance documents are insufficiently risk-informed and proposed adding a new section to 10 CFR Part 53 requiring NRC reviews to be commensurate with risk. The commenter also stated that the NRC may rely on industry codes and standards even if the CFR does not approve or endorse the standards or if the standards are not endorsed in guidance documents. The commenter asserted that consensus codes/standards are inherently acceptable for use, pointing to language in the Nuclear Energy Innovation and Modernization Act (NEIMA). The commenter also asserted that "well established law does not allow guidance documents to create requirements outside of Congressional Acts" and that no Congressional Acts "sanction NRC approval, endorsement or acceptance of industry codes/standards."

The commenter further stated that there is a requirement for the NRC to collaborate with industry in the development of consensus codes/standards and to incorporate such codes/standards into the regulatory framework. The commenter questioned why industry has not previously objected to regulatory guide use of NRC approval, endorsement, or acceptance, and explained that the recent Supreme Court case overruling *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*. now grants the opportunity for legal recourse. The commenter stated that they intend to legally challenge the guidance document approach as they have legal standing and are developing a patented advanced reactor approach (HPT32-0001).

NRC Response: The NRC disagrees with the comments.

The Atomic Energy Act of 1954, as amended (AEA), gives the NRC authority to issue regulations governing a variety of topics. The NRC is not aware of anything in the AEA, or any other law, exempting the use of codes and industry standards from the NRC's regulatory authority. Regulatory guides (RGs) and other guidance documents issued by the NRC are not regulations. Their primary purpose is to provide guidance on methods that are acceptable to the NRC for demonstrating compliance with NRC requirements. These documents are not mandatory unless a licensee has incorporated a specific RG into its license. Therefore, issuing guidance documents, such as RGs, including those endorsing codes and standards, is legal under the AEA. As such, the NRC can rely on compliance with 10 CFR and the use of guidance documents as acceptable methods to satisfy regulatory requirements and endorse industry codes and standards.

Nonetheless, applicants may always refer to an industry code or standard that has not been previously endorsed by the NRC, either in guidance or in a regulation, and the NRC will consider the referenced industry code or standard on an application-specific basis. Further, contrary to the suggestion that NRC reviews are not risk-informed, the NRC seeks to focus on the most risk-significant portions of applications in its safety reviews. As explained in the final rule, the enhanced use of risk insights from the approach taken in 10 CFR Part 53 will provide a significant advancement in these efforts.

Finally, the comment asserted that the NRC "must collaborate with industry in the development of consensus codes/standards and incorporate such codes/standard into the regulatory framework." This assertion appears to be based on language in section 103(b)(4)(B)(iii) of NEIMA. That language, however, does not create a substantive collaboration requirement. Rather, it instructs the NRC to submit a report to Congress evaluating, among other things, options for licensing commercial advanced nuclear reactors under 10 CFR, including collaboration with standards-setting organizations to identify specific technical areas for which new and updated standards are needed and providing assistance, if appropriate, to ensure the new or updated standards are developed and finalized in a timely fashion.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 1.3.B: Two commenters expressed concern that multiple legal changes that occurred over the last year have either not been addressed or not sufficiently addressed in the proposed rulemaking. These include (UL-0001, UL-0002, UL-0003, UL-0004, BI1-0025, UL-0006):

- the *Loper Bright Enterprises v. Raimondo* decision
- the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act)
- Executive Order (EO) 14215, "Ensuring Accountability for All Agencies," dated February 18, 2025.

One of the commenters discussed that reversals of Federal actions by courts or the President wastes time for agencies and increases uncertainty for industry (UL-0001). The commenter said that in order to reduce unnecessary waste and uncertainty, the NRC should reconsider its analysis for 10 CFR Part 53 in light of these recent actions (UL-0001, UL-0002, UL-0003, UL-0004).

The commenter wrote that this should include addressing new statutory requirements in the ADVANCE Act, and a cost-benefit analysis that helps establish that the rule is efficient and does not unnecessarily limit benefits to society and the environment. The commenter also said that this cost-benefit analysis would provide critical support when presenting the rule to the Office of Information and Regulatory Affairs should EO 14215 prove to be constitutional (UL-0007).

Commenters also discussed the impact of the ADVANCE Act and the NRC's need to comply with new statutory directives. The commenters said that the ADVANCE Act requires the NRC to establish a significantly more risk-informed and efficient licensing and regulatory environment for nuclear reactors (BI1-0011, BI1-0015, UL-0005). One of the commenters said that the NRC's current approach does not define "adequate protection" required under the AEA; rather, 10 CFR Part 53 enables the NRC to make its required findings under the AEA by providing sufficient performance standards, safety criteria, and related requirements on how applicants must demonstrate compliance with Subpart B and other subparts. The commenter said that this approach is arbitrary and capricious because the NRC has not defined a standard for "adequate protection" (BI1-0015).

The commenter went on to state that the other flaw in the NRC's interpretation is that it implies that Congress had no intention for what constitutes "adequate protection to the health and safety of the public" in the context of radionuclide emissions. The commenter said that Congress has spoken directly about this question in the 1990 amendments to the Clean Air Act (CAA), which established the "ample margin of safety" metric to measure the health-protectiveness of NRC's regulations. The commenter said that the U.S. Environmental Protection Agency (EPA) determined that the NRC regulated its facilities at a far more stringent metric than what Congress intended (BI1-0025). The commenter remarked that insisting on further demonstration of safety beyond the already conservative "ample margin of safety" standards goes far beyond the authority to protect public safety delegated to the NRC by Congress. Therefore, the commenter said that if the NRC seeks to establish a new comprehensive risk standard, it will need to make modifications to the proposed rule to avoid exceeding its authority granted by Congress (BI1-0027).

A commenter also discussed the *Loper Bright Enterprises v. Raimondo* decision and said it makes clear that a reviewing court may not simply defer to any "reasonable" interpretation by the agency, but the court must independently interpret the statute and "effectuate the will of Congress" and "fix the boundaries" of the delegation. The commenter said that the NRC appears to believe that it is insulated from the impacts of *Loper Bright Enterprises v. Raimondo* due to a long history of wide deference from the courts. The commenter said that any court reviewing NRC's interpretation of "adequate protection of public health and safety" will not interpret the silence in the AEA as a delegation to the NRC to come up with its own approach, and will engage in a search for any statement from Congress about what it intends to be the yardstick for protection of public health from radionuclide emissions from nuclear plants, which will lead to the 1990 CAA amendments (BI1-0026). Another commenter said the *Loper Bright Enterprises v. Raimondo* decision reinforces the need for NRC regulations to adhere strictly to statutory mandates (NNY-0006).

A commenter discussed the new EO 14215 that purports to exert executive control over independent agencies, including the NRC. The commenter said that this EO is inconsistent with longstanding Supreme Court precedent in *Humphrey's Executor v. U.S.*, which clearly allows Congress to create agencies who are independent of direct executive control. The commenter said that the NRC could theoretically wait to comply with the order until Federal courts have time to rule on its constitutionality, but waiting to perform a thorough cost-benefit analysis would mean trying to retrofit a cost-benefit analysis to justify the agency's decisions. The commenter suggested that, with such a tight statutory deadline, the agency would do better to revisit the analysis now (UL-0006).

NRC Response: The NRC disagrees with the comments.

These comments all suggest that the NRC lacks statutory authority to proceed with the Part 53 rulemaking. However, the NRC has clear statutory authority to promulgate regulations governing the licensing of nuclear reactors. For example, several sections of the AEA, including sections 161 and 182, explicitly authorize the NRC to issue regulations for licensing nuclear reactors, such as 10 CFR Part 53. Moreover, as noted by many of the comments, Congress explicitly authorized the NRC to promulgate 10 CFR Part 53 in section 103(a)(4) of NEIMA. While many of the circumstances cited by the comments represent significant legal developments, none of them, individually or collectively, erode these authorities or otherwise require the NRC to adopt a specific approach when selecting a viable regulatory option.

Many comments question whether promulgating 10 CFR Part 53 in its current form remains lawful following passage of the ADVANCE Act. Specifically, comments point to section 501 of the ADVANCE Act, which required the NRC to update its mission statement to explicitly incorporate efficiency and avoid unnecessary limitations on nuclear energy. The comments contend that in light of these changes, the NRC must further evaluate and revise 10 CFR Part 53 to ensure that it does not unduly hamper nuclear development. The NRC has updated its mission statement in response to the ADVANCE Act and remained mindful of the ADVANCE Act while it finalized this rule. Additionally, the NRC further considered its mission statement following promulgation of EO 14300, “Ordering the Reform of the Nuclear Regulatory Commission,” dated May 23, 2025. Moreover, as one comment observes, efficiency has long been an element of the NRC’s Principles of Good Regulation.

Nonetheless, neither section 501 nor any other section of the ADVANCE Act amended the NRC’s statutory authority to promulgate regulations for licensing nuclear power plants under the AEA or NEIMA. Thus, the NRC disagrees with the suggestion that the changes to the mission statement required by the ADVANCE Act somehow diminished the NRC’s legal authority to promulgate 10 CFR Part 53 under the AEA. Rather, section 501 specifically required the Commission to update the mission statement “while remaining consistent with the policies” in the AEA. Moreover, while section 501 of the ADVANCE Act provides an important statement from Congress on how the Commission should exercise its legal authorities under the AEA, language providing Congressional expectations, such as precatory language, normally does not override clear language in substantive portions of a statutory scheme, such as sections 161 and 182 of the AEA. Thus, the NRC concludes that the ADVANCE Act does not occasion a reevaluation of whether 10 CFR Part 53 is beyond the agency’s authority.

Similarly, one comment points to the 1990 amendments to the CAA, which in the comment’s view established a standard for radiological safety inconsistent with the NRC’s standard. However, like the ADVANCE Act, those amendments did not change any of the substantive provisions of the AEA, and predated NEIMA and the ADVANCE Act itself by several decades. Therefore, the NRC does not find that the 1990 amendments to the CAA impinged on its regulatory authority to promulgate 10 CFR Part 53 under the AEA.

The comments also propose that the Supreme Court’s decision in *Loper Bright Enterprises v. Raimondo* further limited the NRC’s statutory basis for promulgating 10 CFR Part 53. The NRC agrees with the comment’s description of the case, which held that courts will no longer defer to an agency’s interpretation of statutory language as long as it is reasonable and will instead conduct their own examination of a statute to determine if the agency adopted the best interpretation. However, as noted above, the AEA plainly authorizes the NRC to promulgate regulations governing reactor licensing. Therefore, the NRC concludes that the Court’s holding in *Loper Bright Enterprises v. Raimondo* does not impact the statutory basis for 10 CFR Part 53 because the NRC’s authority to promulgate these regulations rests on a clear reading of the underlying statutes and is therefore the best interpretation of them.

Several comments also pointed to recent EOs, which may introduce additional steps into the rulemaking process for 10 CFR Part 53, including a more rigorous cost-benefit analysis. The NRC is assessing the impact of these EOs on the agency’s rulemaking process and will take all appropriate steps to engage in the processes those orders describe. Nonetheless, the EOs provide direction to Federal agencies and are not intended to create enforceable rights. Moreover, the agency’s existing regulatory analysis for the proposed rule demonstrated that 10 CFR Part 53 was cost-effective. Because that analysis rested on very conservative assumptions (such as only one applicant using 10 CFR Part 53 during the period studied), the NRC does not anticipate that a more refined cost-benefit analysis would have led to significant changes in the rule. Additionally, to the extent the comment implies that the NRC should separately evaluate the cost-effectiveness of each portion of the rule to establish efficiency, the

NRC concludes that such an analysis would be of limited value and potentially misleading because the majority of provisions in 10 CFR Part 53 are intended to function in concert. Indeed, for the regulatory analysis for the final rule, the NRC has used more realistic assumptions with respect to the assumed numbers of applicants; the results of that analysis show that 10 CFR Part 53 will likely be significantly cost-beneficial.

Lastly, one comment suggests that 10 CFR Part 53 is arbitrary and capricious because it does not define a specific level of safety needed to achieve “adequate protection.” As explained in Section IV, Subpart B—Technology-Inclusive Safety Requirements of the final rule, the regulations in 10 CFR Part 53 are not intended to define a specific level of “adequate protection,” consistent with longstanding Commission policy. Rather like the current set of regulations in 10 CFR Part 50 and 10 CFR Part 52, 10 CFR Part 53 contains requirements needed to provide reasonable assurance of adequate protection as well as those the Commission has found desirable to promote the common defense and security or to protect health or to minimize danger to life or property. Thus, this rulemaking would not benefit from a specific definition of “adequate protection.”

Accordingly, the NRC did not change the rule language in response to these comments.

1.4. Other general comments on the proposed rule

Comment Bin 1.4.A: A commenter said that as currently written, the proposed regulation will not enable the deployment of advanced reactors, and Part 53 should be more flexible to facilitate a range of different approaches to design, licensing, and operation; meet stakeholder needs; and provide for predictable, performance-based, technology-inclusive, and risk-informed regulation of advanced reactors (NIA2-0001).

NRC Response: The NRC disagrees with the comment.

The final rule’s technology-inclusive, performance-based approach provides reasonable assurance of adequate protection of public health and safety and was developed with input from all stakeholders. As stated in the proposed and final rules, the new alternative requirements and implementing guidance would adopt technology-inclusive approaches and use risk-informed and performance-based techniques to ensure an equivalent level of safety to that of operating commercial nuclear plants while providing flexibility for licensing and regulating a variety of technologies and designs for commercial nuclear reactors. However, while the NRC’s mission is to enable the safe and secure use and deployment of civilian nuclear energy technologies, the NRC must balance that objective with the protection of public health and safety and advancing the Nation’s common defense and security, which usually involve additional costs, and the approach to licensing in 10 CFR Part 53 reflects that balance.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 1.4.B: Several commenters provided general comments on the rule that were appreciative of the NRC’s efforts on the proposed rulemaking and said that additional modifications to the proposed rule were necessary to fully align with NEIMA’s intent to provide a sufficiently flexible licensing framework to accommodate emerging technologies (SCWG-0026, NGO-0001, KAP-0001, BI1-0013, BWXT-0001).

NRC Response: The NRC disagrees with the comments.

NEIMA Section 2, “Purpose” states in part that, “The purpose of this Act is to provide—(1) a program to develop the expertise and regulatory processes necessary to allow innovation and the commercialization of advanced nuclear reactors;” The final rule’s technology-inclusive, performance-based approach provides reasonable assurance of adequate protection of the public health and safety and was developed with input from all stakeholders. The final rule provides a reliable regulatory framework that allows for the innovation and the commercialization of advanced nuclear reactors.

Accordingly, the NRC did not change the rule language in response to these comments. However, the NRC notes that it has made a number of changes elsewhere in the rule in response to specific comments that will make the 10 CFR Part 53 rule more flexible, and some of these changes may facilitate the licensing process for technologies described in the comments.

Comment Bin 1.4.C: A few commenters stated that NRC’s incorporation of the Commission’s directive is a step in the right direction, but the proposed rulemaking is still not in alignment with the Commission’s directions, and issues remain that must be addressed prior to the final rule (CP-0001, SOU-0001, APS-0001, ENW-0001, WEST1-0002). One commenter specifically stated that changes are needed to meet NEIMA and the ADVANCE Act (WEST1-0002).

A commenter said that the NRC cannot have both flexibility and predictability unless it builds two different sets of procedures: one that is flexible and not predictable and one that is predictable but not flexible (TG17-0007). Another commenter said that the proposed regulations do not recognize that the actual risk of operating a facility that uses nuclear fuel is significantly less than perceived risk, and the Part 53 rule needs to acknowledge this reality (NEX-0001).

A commenter expressed support for the recommendation of another commenter to pursue more aggressive changes throughout 10 CFR Part 53, including limiting regulatory burden for advanced reactors that present a low level of hazard and impact to the public by establishing graded, performance-based requirements (ENW-0001).

NRC Response: The NRC disagrees with the comments.

The 10 CFR Part 53 proposed rule was approved by the Commission for publication, so the proposed rule was in alignment with Commission direction. The NRC also disagrees that the proposed rule did not meet the statutory requirements of NEIMA (see response to Comment Bin 1.4.B) and the ADVANCE Act (see response to Comment Bin 1.3.B). However, the NRC notes that it has adopted a number of changes to the final rule, including the probabilistic risk assessment (PRA) requirements, that will provide applicants with greater flexibility.

For the final rule, the NRC has made appropriate changes in response to the public comments received on the proposed rule. The NRC disagrees that an appropriate balance cannot be struck between flexibility and predictability and therefore the NRC must create multiple regulatory frameworks; the NRC has strived to achieve this balance in 10 CFR Part 53 but notes that applicants may also use the existing licensing framework in 10 CFR Part 50 and 10 CFR Part 52, which reflects an alternate approach to balancing flexibility and predictability.

The NRC also disagrees that the proposed rule is not tailored to the actual risk of a nuclear power facility. The final rule's technology-inclusive, performance-based approach provides reasonable assurance of adequate protection of public health and safety. It was developed with input from all stakeholders and reflects long-standing Commission policy to ensure that new reactors present a similar or lower risk profile than the operating fleet.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 1.4.D: Commenting on the historical implementation of the policy statement, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" (PRA Policy Statement), dated August 16, 1995 (60 FR 42622), a commenter stated that while the expanded use of PRA is longstanding NRC policy, the policy has not been updated since the ADVANCE Act was passed, which includes provisions for microreactors (NEI3-0005).

NRC Response: The NRC acknowledges the statement that the NRC has not updated its PRA Policy Statement since the ADVANCE Act was passed. However, the current PRA Policy Statement recognizes the need to select PRA methods that are appropriate to the technology being assessed and to develop new and improved PRA methods, including industry initiatives. 10 CFR Part 53 provides flexibility by allowing the use of other systematic risk evaluation methods in combination with traditional PRA methods based on event tree and fault tree logic models.

The NRC is working to meet the ADVANCE Act's various deadlines for completing appropriate revisions to agency regulations or guidance. With respect to ADVANCE Act provisions related to microreactors, the NRC has engaged its external stakeholders on several occasions on ADVANCE Act section 208 activities. In addition, the NRC has initiated development of an additional rulemaking to expedite licensing of microreactors and other low safety-consequence reactors, consistent with the ADVANCE Act and EOs issued in 2025.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 1.4.E: Several commenters said that the 10 CFR Part 53 rulemaking can help meet clean energy demands and support a robust and reliable electric grid (NNY-0009; SOU-0004, NEI2-0007, ENT-0005, DOM-0003, APS-0003, KAP-0005, ENW-0003).

NRC Response: The NRC agrees with the comments. The comments support the proposed rule and suggest no specific changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to these comments.

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2. <u>Background and Need for Rulemaking/Purpose and Scope of the Proposed Rule</u>

Comment Bin 2.A: Several commenters expressed support for the NRC's stated need for and purpose of the proposed rulemaking (NEI1-0002, FK-0002, NIA1-0002, USNIC1-0002, IDNL-0001, IDNL-0003, TP-0001, NYS2-0003, NNY-0001).

NRC Response: The NRC agrees with the comments. The comments support the need for the proposed rule and suggest no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 2.B: One commenter expressed opposition to the NRC's stated need for the proposed regulations and disagreed that 10 CFR Part 53 met the NRC's stated goals. The commenter said that the NRC staff is apparently unable to "move on" from the overly prescriptive approaches of the past and accept Congress's direction for modernization and increased regulatory efficiency. The commenter also said that the proposed regulation is more complex and burdensome than 10 CFR Part 50, and many of the proposed requirements are not supported by law. Finally, the commenter said that the development of 10 CFR Part 53 has been an inefficient use of NRC industry, and public resources (HPT2-0001).

The same commenter also stated that 10 CFR Part 53 introduces many new elements, largely related to human factors, that are not in the current 10 CFR Part 50, and that 10 CFR Part 53 subjects applicants to costly and unnecessary burdens (HPT20-0002).

NRC Response: The NRC disagrees with the comments.

The need for Part 53 rulemaking is still valid, and the final rule meets the stated goals and purpose of the rulemaking effort and the direction by Congress. The final rule's technology-inclusive, risk-informed, and performance-based approach provides reasonable assurance of adequate protection of the public health and safety and was developed with input from stakeholders. Additionally, 10 CFR Part 53, while being technology-inclusive, is equivalent to the existing licensing frameworks in 10 CFR Part 50 and 10 CFR Part 52. Moreover, because 10 CFR Part 53 is an optional licensing framework, it does not increase burden on regulated entities as they can choose to use the current licensing framework in 10 CFR Part 50 or 10 CFR Part 52.

Finally, many of the human factor's regulations in 10 CFR Part 53 either have a corresponding regulation in 10 CFR Part 50, 10 CFR Part 55, or are necessary due to the different frameworks used for 10 CFR Part 50 and 10 CFR Part 53. For example, there is no requirement under 10 CFR Part 50 to submit a staffing plan because this information is prescriptive and located in 10 CFR 50.54. Because of the flexibilities built into 10 CFR Part 53, a new staffing plan requirement was added in place of the prescriptive staffing requirement.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 2.C: A commenter highlighted the importance of creating a new regulatory framework for advanced reactors that can enable the licensing of diverse reactor technologies, be risk-informed and performance-based, and address the needs of diverse stakeholders. According to the commenter, meeting these criteria would enable the effective, efficient, and predictable licensing of advanced reactors, which aligns with the initial Congressional direction in NEIMA and subsequent direction from Congress and the Commission (NIA2-0006). Another commenter stated that they understand that the proposed Part 53 framework is a voluntary alternative and is intended to offer future applicants flexibility of advanced reactor technologies and innovative designs (NYS2-0001).

Another commenter said that there are two themes presented by all stakeholders commenting on the proposed rule: (1) that the rule needs to be very open to avoid unforeseen future limitations, or (2) that the rule should be more specific on performance requirements to reduce uncertainty of what will be acceptable and therefore streamline the regulatory process. The commenter said that it is possible to satisfy both of these requirements in this rulemaking process (BI1-0003).

NRC Response: The NRC agrees with the comments.

The organization and content of 10 CFR Part 53 reflect a systems-engineering style approach to the design, licensing, operation, and ultimately decommissioning of future commercial nuclear plants. 10 CFR Part 53 also incorporates a performance-based approach to regulation by specifying high-level safety requirements and providing considerable flexibility in how applicants and licensees can meet the requirements through combinations of design features, programmatic controls, and human actions. The requirements in 10 CFR Part 53 are also structured to allow applicants and licensees to use a flexible and graded approach to the performance of safety functions based on the role of a particular structure, system, and component (SSC), human action, or program in limiting the overall risks to the public below accepted standards through balanced measures to prevent and mitigate possible events.

Accordingly, the NRC did not change the rule language in response to these comments.

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3. Major Provisions of the Proposal – 10 CFR Part 53

3.1. Subpart A: General Provisions (§§ 53.015-53.120)

3.1.1 Definitions (§ 53.020)

Comment Bin 3.1.1.A: A commenter said that the rule should discuss the definition of “functional design criteria” for 10 CFR Part 53 in the context of principal design criteria, a closely related concept under 10 CFR Part 50 and 10 CFR Part 52 (NEI2-0014). The commenter wrote that “functional design criteria” under 10 CFR Part 53 serves a similar purpose as "principal design criteria" under 10 CFR Part 50 and 10 CFR Part 52, and that they appreciate the effort to limit functional design criteria appropriately and relegate special treatments to other requirements. The commenter noted that while the definition of principal design criteria focuses on the criteria being met by SSCs alone, principal design criteria may in fact be met by SSCs, human actions, programs, or a combination thereof. The commenter suggested revising the definition of “functional design criteria” by (1) adding “programs and operator actions” as means by which functional design criteria may be met, (2) changing the first instance of “SSCs” to read “functions supported by SSCs” and replacing subsequent instances of “SSCs” with “functions,” and (3) adding cross-references to the safety criteria in 10 CFR 53.260 and 53.270 (NEI2-0033, NEI2-0045).

NRC Response: The NRC disagrees with the comments.

There are significant differences between the concepts of “principal design criteria” from 10 CFR Part 50 and “functional design criteria” used in 10 CFR Part 53. Principal design criteria are a key part of a largely deterministic methodology and define specific design requirements and design rules against which the NRC reviews proposed reactor designs. Functional design criteria within 10 CFR Part 53 are derived as part of a risk-informed and performance-based methodology and an overall hierarchy that covers: (1) plant-level safety criteria; (2) safety functions needed to demonstrate compliance with the safety criteria; (3) design features, human actions, and programmatic controls needed to fulfill the safety functions; and (4) functional design criteria defined for each design feature relied on to demonstrate the safety criteria are met. In terms of specificity of requirements for individual design features, functional design criteria would align more closely with the definition of "design bases" in 10 CFR 50.2.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.1.1.B: A commenter supported some aspects of the definition of "commercial nuclear plant" while seeking changes to other aspects. The commenter supported excluding the phrase "in a self-supporting chain reaction" (which appears in the definition of "nuclear reactor" in 10 CFR 50.2) from the definition of "commercial nuclear reactor" that is referenced in the definition of "commercial nuclear plant." The commenter also supported the second sentence of the definition: "For the purposes of requirements in this part that reference requirements in part 50 of this chapter, a commercial nuclear plant is equivalent to a nuclear power plant." However, the commenter objected to creating the new term "commercial nuclear plant" for 10 CFR Part 53 instead of using the existing term "production and utilization facility" from 10 CFR Part 50 and 10 CFR Part 52, saying this will lead to confusion as to how 10 CFR Part 53 is an optional alternative to 10 CFR Part 50 and 10 CFR Part 52. The commenter also stated that including a separate definition of "utilization facility" only added to the confusion—they suggested deleting that definition and modifying the definition of "commercial nuclear plant" to make 10 CFR Part 53 applicable to all production and utilization facilities licensed under section 103 or 104 of the AEA (NEI2-0025).

Another commenter expressed concerns that the proposed rule restricts the definition of new and advanced reactor to evolutionary light-water reactor (LWR) and non-LWR technologies and recommended that the agency specify and define what "advanced" means in practical terms and for any change in safety significance (RD-0007).

Another commenter said that the NRC's expansion of the applicability of the proposed rule from "advanced nuclear reactors" to all "commercial reactors" violates both the letter and spirit of NEIMA. The commenter said that the NRC's excuse is that NEIMA did not define "advanced reactors" with enough specificity to implement in the NRC regulations, which the commenter said is false as NEIMA listed a number of characteristics that it considered "significant improvements". The commenter said that it is arbitrary and capricious for the NRC to conclude that because NEIMA was not specific enough, the NRC can completely jettison any consideration of improvements compared to current reactors to determine eligibility for 10 CFR Part 53. The commenter also questioned why the NRC did not just use its own definition of "advanced reactors" (UCS-0003).

Arguing that some proposed terms and definitions are tied to existing regulations for large LWRs, another commenter stated that the rule instead should apply terms and definitions in a modern, risk-informed manner that reflects the reduced risk-profiles and dose consequences of advanced reactors. Specifically, the commenter took issue with the proposed definitions of "commercial nuclear plant," "commercial nuclear reactor," and "utilization facility," reasoning that while they may accommodate some deployment models involving stationary reactors deployed to a final place of operation, they limit other deployment models involving fuel loading and physics testing at a manufacturing facility, or rapid, high-volume deployment of small and mobile advanced reactors to multiple sites in series. The commenter suggested that the NRC should work with stakeholders to adopt terms and definitions for the regulation of advanced reactors (including microreactors) that are more appropriate and risk-informed, in line with NEIMA (RAD-0014).

NRC Response: The NRC disagrees with the comments.

The scope of 10 CFR Part 53 is intentionally limited to utilization facilities licensed under section 103 of the AEA. The regulations in 10 CFR Part 53 do not address the unique requirements and distinctions that are associated with production facilities under section 103 of the AEA or uses for medical therapy and research and development under section 104 of the AEA. As explained in Section IV, Subpart A—General Provisions of the final rule, defining the scope of the rule using the term "advanced reactors" from NEIMA proved to be problematic and the term "commercial nuclear plant" was chosen.

Therefore, a new term is used to reflect the differences from the definition of "nuclear reactor" in 10 CFR Part 50. Because the definition of "commercial nuclear plant" is more expansive than the definition of "advanced reactor" under NEIMA – and would include all reactors encompassed in that term, 10 CFR Part 53 fulfills the statutory requirements of NEIMA. While 10 CFR Part 53 also covers reactors beyond those described in the definition of "advanced reactor" under NEIMA, the NRC has expansive authority to promulgate regulations governing the licensing of new reactors under the AEA as explained in response to Comment Bin 1.3.B. Including these reactors within the scope of 10 CFR Part 53 is appropriate because 10 CFR Part 53's safety standards are sufficient to ensure that any reactor licensed under that part poses no undue risk to public health safety. As a result, the NRC disagrees with the assessment that the definition of "commercial nuclear" plant is "arbitrary and capricious."

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.1.1.C: A commenter suggested removing the definition of "consensus code or standard," writing that it is incomplete because it lacks some elements of the American National Standards Institute (ANSI) requirements for development of consensus standards and arguing that the NRC should not attempt to develop and enshrine in Federal regulations its own definition that is inconsistent with the nationally recognized process (NEI2-0026). Another commenter echoed this recommendation, stating that it would be consistent with recommendations from the February 11, 2025, NRC public meeting (USNIC2-0020).

NRC Response: The NRC agrees with the comments.

Defining the term "consensus code or standard" in 10 CFR Part 53 is not essential for the framework and could introduce possible issues given alternative definitions for these terms by standards development organizations, international organizations, and other forums.

Accordingly, the NRC revised the rule language in response to these comments to remove the definition of "consensus code or standard".

Comment Bin 3.1.1.D: A commenter characterized the definition of "programmatic controls" as vague and subjective, arguing that it offers no clarity or predictability as to what would constitute acceptable programmatic controls and effectively duplicates the longstanding concept of "programs." The commenter suggested removing the definition of "programmatic controls" and replacing that term throughout 10 CFR Part 53 with the term "programs," to be defined as follows (NEI2-0027):

> *Programs* are the administrative measures and controls that are relied upon by the NRC to provide reasonable assurance that plant design, construction, maintenance and operation meet the safety criteria in 53.210 and 53.220 for the lifetime of the plant. Programs may apply to design features and/or credited human actions. Programs that require NRC approval are specified in the regulations for various technical areas (e.g., QA).

NRC Response: The NRC agrees, in part, with the comment.

The term programmatic controls as used in 10 CFR Part 53 provides flexibility for applicants and licensees to address risks posed by commercial nuclear plants using a combination of design features and programmatic controls involving procedures for human actions and programs for specific technical areas (e.g., radiation protection, quality assurance [QA]). Programmatic controls are therefore broader than the program documents addressed in Subpart F. The NRC has incorporated minor changes to the definition of "programmatic controls" from that included in the proposed rule to clarify how the term is used throughout 10 CFR Part 53; the relationship with the higher-level requirements for programs that are included in Subpart F; and, as suggested by the comment, distinguish between SSCs classified as safety-related (SR) or non-safety-related but safety significant (NSRSS).

Accordingly, the NRC revised the rule language in response to this comment to make minor clarifying changes to the definition of *programmatic controls*.

Comment Bin 3.1.1.E: A commenter suggested that the NRC align the definition of PRA in 10 CFR 53.020 with the definition on the NRC website to address inconsistencies between the two definitions (NEI2-0246).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees there is inconsistency between the definition of the term probabilistic risk assessment (PRA) on the NRC's public website and the definition of that term in the 10 CFR Part 53 proposed rule. The NRC disagrees that codifying a definition of "probabilistic risk assessment" is necessary. Instead, the NRC deleted the definition of "probabilistic risk assessment."

Accordingly, the NRC revised the rule language to remove the term "probabilistic risk assessment" in 10 CFR 53.020 in response to this comment.

Comment Bin 3.1.1.F: A commenter stated that the 10 CFR Part 53 definition of "small modular reactor" (SMR), like the definition in 10 CFR 50.2, includes an upper limit on electric power generation of 1,000 megawatts thermal (around 300 megawatts electric) per module, which also features in early definitions of SMR by bodies such as the U.S. Department of Energy and the International Atomic Energy Agency. The commenter stated that while those power levels may be suitable for some regulatory purposes (e.g., setting fees), a reactor power level by itself does not determine the safety, security, and accident consequence characteristics of a given design. The commenter thus asked the NRC to remove the power level criterion from the definition of SMR (NEI2-0028).

NRC Response: The NRC disagrees with the comment.

The definition of SMR included in 10 CFR Part 53 is consistent with other uses of the term in NRC regulations in 10 CFR Part 50 and 10 CFR Part 171. The NRC disagrees with introducing an inconsistency between 10 CFR Part 53 and 10 CFR Parts 50 and 171. The primary reference to SMRs within 10 CFR Part 53 relates to references to the final rulemaking on ‘‘Emergency Preparedness for Small Modular Reactors and Other New Technologies’’ (88 FR 80050; November 16, 2023) (the EP for SMR and the Other New Technology [ONT] rule) by including references to 10 CFR 50.160, ‘‘Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities,’’ and by making conforming changes within 10 CFR 50.160.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.1.1.G: Stating that the rule provides for special treatment of NSRSS SSCs and SR SSCs, a commenter asserted that the definition of “special treatment” provides no clarity or regulatory stability. The commenter described how 10 CFR Part 50 and 10 CFR Part 52 instead state within specific requirements whether they apply to SR or risk-significant SSCs and reasoned that the same can be done in 10 CFR Part 53. Urging that there must be a clear distinction among special treatment requirements for SR and NSRSS SSCs, the commenter suggested clearly defining the phrase “risk-significant functions” as it applies in the definitions of special treatment and NSRSS SSCs (NEI2-0029).

NRC Response: The NRC agrees, in part, with the comment.

The regulations within 10 CFR Part 53 require applicants and licensees to identify appropriate special treatments for SSCs to fulfill functional design requirements associated with either design-basis accidents or licensing-basis events other than design-basis accidents. This provides both a technology-inclusive approach and provides flexibility to applicants and licensees in defining the role of various SSCs and programmatic controls to meet safety criteria in Subpart B. The NRC disagrees with making the definition of the term “special treatment” more prescriptive or deterministic as it could reduce the flexibility that could be allowed for identifying appropriate special treatments.

Accordingly, while not going so far as being more prescriptive or deterministic as mentioned in this comment, the NRC did revise the definition of the term “special treatment” in response to this comment and made corresponding changes throughout 10 CFR Part 53 to distinguish between SR SSCs and NSRSS SSCs.

Comment Bin 3.1.1.H: Arguing that the definition of “defense in depth” is not needed and could create unintended consequences by making the definition prescriptive in nature, a commenter suggested either deleting the definition or defining it as follows (NEI2-0030):

> *Defense in depth* is a design philosophy that provides reasonable assurance that the design meets the safety criteria in 53.210 over the life of plant by addressing uncertainties in the performance of safety functions through measures such as increased safety margin and multiple layers of protection.

NRC Response: The NRC disagrees with the comment.

The philosophy of defense in depth (DID) included in the comment is implemented in 10 CFR Part 50 and 10 CFR Part 52 by including various deterministic and prescriptive requirements such as those in design requirements and design rules included in Appendix A, "General Design Criteria for Nuclear Power Plants" to 10 CFR Part 50. In contrast, the 10 CFR Part 53 framework includes a hierarchy that begins with the high-level safety requirements in Subpart B and provides for a flexible, performance-based approach on how applicants and licensees meet those high-level safety requirements. The need to provide DID is included as one of the specific safety requirements in Subpart B and the related definition therefore needs to go beyond the philosophical background included in the comment.

The definition used in 10 CFR Part 53 is consistent with available guidance documents such as RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors," issued June 2020 (Agencywide Documents Access and Management System Accession No. ML20091L698), and International Atomic Energy Agency Specific Safety Requirements No. SSR-2/1, Revision 1, "Safety of Nuclear Power Plants: Design," issued 2016.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.1.1.I: A commenter described their concerns about, and recommendations for, several of the definitions that relate to event sequences. The commenter stated that there is some confusion with the terms "anticipated event sequence," "design-basis accidents (DBAs)," "licensing-basis events (LBEs)," "unlikely event sequences," and "very unlikely event sequences." The commenter warned that departure from the longstanding terms "design-basis events" (DBEs) and "beyond-design-basis events" (BDBEs) was unnecessary and would likely lead to misunderstanding and misuse of the new terms. The commenter suggested replacing the proposed definitions with the following language (NEI2-0031):

> *Licensing basis events (LBEs)* are unplanned events and include AOOs, DBAs, and BDBEs that are considered in the licensing of a production or utilization facility. LBEs may include one or more reactor modules.
>
> *Anticipated operational occurrences (AOOs)* are a grouping of similar event sequences that are unplanned but may occur one or more times during the life of a nuclear facility. AOOs established through quantitative methods are event sequences with a mean frequency of 1×10^{-2}/plant-year and greater. AOOs take into account the expected responses of all SSCs within the plant, regardless of safety classification.
>
> *Design-basis accidents (DBAs)* may be derived from the DBEs and are used to establish the design of safety-related SSCs. DBAs take into account the expected

> responses of only those safety-related SSCs relied upon to mitigate or prevent event sequences.

However, the commenter also suggested a different definition of LBEs. The commenter asserted that the word “considered” in the phrase “event sequences considered in the design and licensing” is unhelpfully vague for distinguishing between (1) LBEs that were initially evaluated but did not need to be included in the licensing basis; and (2) LBEs that were evaluated and retained for the licensing basis, which may be only a subset of potential LBEs. The commenter suggested replacing “considered in” with “relied upon to support” so that the definition of LBEs would read, in part, “event sequences relied upon to support the design and licensing” (NEI2-0035).

Another commenter relatedly expressed concerns that several definitions (i.e., LBE, DBA, anticipated event sequences, unlikely event sequences, and very unlikely event sequences) confuse the use of PRA and risk-informed decision-making (RIDM) by introducing and specifying new accident classifications or nomenclature which subdivide risk insights (RD-0010).

NRC Response: The NRC disagrees with the comments.

As explained in Section IV, Subpart A—General Provisions, of the final rule, the NRC acknowledges that 10 CFR Part 53 involves adopting new terms and definitions for similar concepts included in other NRC regulations and guidance documents. For example, 10 CFR Part 53 uses new terms for categorizing event sequences specifically to avoid conflicts with terms already used within 10 CFR Part 50 and 10 CFR Part 52 to represent different concepts and analysis methodologies. The NRC disagrees with replacing “considered” within the part of the definition of licensing-basis events stating: “Licensing-basis events means a collection of event sequences considered in the design and licensing of the commercial nuclear plant...” because, as stated, the licensing-basis events are not the sole determinates of the design and licensing of the commercial nuclear plant. The NRC also disagrees with making 10 CFR Part 53 more vague by not including specific definitions and encouraging each applicant to develop unique approaches and terminology.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.1.1.J: A commenter characterized the changes made to the definition of “site characteristics” from the preliminary proposed rule language as an improvement but nevertheless expressed concern about the revised definition’s inclusion of the licensing and permitting documents in which site characteristics appear. The commenter suggested further amending the definition to read as follows (NEI2-0032):

> *Site characteristics* means the meteorological, geological, seismological, topographical, hydrological, and other characteristics of the site and surrounding area that may have a bearing on the consequences of a radionuclide release from the nuclear plant as well as demographic features of a site.

NRC Response: The NRC disagrees with this comment.

The comment refers to a definition from the preliminary proposed rule language and not the published proposed rule. Nevertheless, the definition of “site characteristics” in 10 CFR Part 53 is intentionally the same as the definition in 10 CFR Part 52 to avoid confusion with different definitions for the same terminology in different NRC regulations.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.1.1.K: A commenter reasoned that to conform to the ADVANCE Act and address microreactor licensing issues (e.g., factory fueling and testing of a microreactor and transportation of a fueled microreactor), the NRC should define a utilization facility only after 10 CFR Part 70 measures to preclude criticality are removed, which would build on SECY-24-0008, “Micro-Reactor Licensing and Deployment Considerations: Fuel Loading and Operational Testing at a Factory,” issued January 2024 (ML23207A250) (NEI2-0034).

Accordingly, the commenter suggested removing the words “designed or” from the phrase “an apparatus, other than an atomic weapon, designed or used to sustain nuclear fission” in the definition of “commercial nuclear reactor” (NEI2-0190, NEI2-0034). The commenter also suggested removing the words “designed or” from the equivalent phrasing in the definition of “utilization facility” that references the definition of “commercial nuclear reactor” (NEI2-0034). By not defining fueled manufactured reactors as utilization facilities in 10 CFR Part 53, the commenter wrote, the NRC would remove redundancies with 10 CFR Part 70, 10 CFR Part 71, and 10 CFR Part 72 and facilitate the transportation of microreactors in line with the ADVANCE Act (NEI2-0190).

NRC Response: The NRC disagrees with the comments. See also the NRC’s response to Comment Bin 3.8.9.A.

The licenses to manufacture, construct, and operate manufactured reactors are issued under 10 CFR Part 53 consistent with section 103 of the AEA for utilization facilities. Although the requirements in 10 CFR Part 53 take advantage of the regulations for and history of handling special nuclear material by citing 10 CFR Part 70, a fueled manufactured reactor is best described as a reactor and the broader term of utilization facility. Moreover, contrary to the comment’s suggestion, 10 CFR Part 53 does not require the manufacturing license holder to obtain an additional reactor license to possess the manufactured reactor because the manufacturing license already authorizes possession of the reactor. However, as explained in the final rule, the NRC has historically defined operation to commence at fuel load.

Thus, under the NRC’s current policy, if the manufacturing licensee loaded fuel at the factory, the manufacturing licensee would need a separate combined license to authorize operation of the manufactured reactor, because the reactor would be considered to be in operation. However, in the final rule the Commission has redefined when a reactor is in operation: under this definition, a manufactured reactor is not in operation, even after fuel load, if mechanisms to prevent criticality are in place.

While the NRC considered the comment’s preferred approach of redefining utilization facility, the NRC determined that this would not address as many regulatory issues as redefining operation. Specifically, redefining “operation,” as opposed to “utilization facility” more efficiently facilitates completion of the inspections, tests, analyses, and acceptance criteria (ITAAC) process, as section 185(b) of the AEA requires the NRC to find that all acceptance criteria in the combined license’s ITAAC are met prior to reactor operation.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.1.1.L: A commenter asked the NRC to clarify the definition of “commercial operation” to align with the operational realities of microreactors and factory-fueled transportable reactors. Specifically, the commenter stated that for transportable microreactors, “commercial operation” should be defined as the generation of electricity, process heat, or other usable energy at the intended deployment site, not at the point of initial fueling (SCWG-0003).

NRC Response: The NRC disagrees with the comment.

10 CFR Part 53 does not use and therefore need not define the term “commercial operation,” which historically is used for purposes outside of the NRC’s purview.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.1.1.M: To provide clarity on the scope of activities covered under a manufacturing license (ML), the NRC should define the term “manufacturing,” and modify or add requirements in 10 CFR 53.620 a commenter said. The commenter suggested that the proposed definitions of “commercial nuclear reactor,” “manufactured reactor,” “manufacturing license,” and “utilization facility” do not make clear what activities can be performed prior to the receipt of an ML. Citing the proposed definition of “construction,” which outlines the activities that can be completed prior to the receipt of a construction permit (CP), combined license (COL), limited work authorization (LWA), or early site permit (ESP) authorizing construction, the commenter stated that it would be useful to include a similar definition of the term “manufacturing.” The commenter understood the proposed rule as granting the ML holder the authority to perform final assembly of what would constitute a commercial nuclear reactor under 10 CFR Part 53 or a nuclear reactor under 10 CFR Part 50. The components and sub-assemblies may have been procured, fabricated, assembled, inspected, and tested prior to receipt of the ML under an applicant’s previously approved quality assurance program and, according to the commenter, therefore would not be considered “manufacturing” for the purposes of activities controlled by an ML. The commenter suggested defining the term as follows:

> *Manufacturing* means the activities required to complete the final assembly of items or subassemblies issued to the bill of materials for a commercial nuclear reactor or nuclear reactor, including pre-operational inspection and pre-operational testing. Manufacturing does not include the procurement, fabrication, assembly, inspection, and testing of items and subassemblies prior to their issuance to the bill of materials for the final assembly of a commercial nuclear reactor or nuclear reactor.

The commenter reasoned that greater clarity would have implications not only for entities electing to begin procurement or fabrication of certain items that would become part of a manufactured reactor prior to receipt of an ML but also following the receipt of an ML from a licensing basis standpoint and for developers of SMRs seeking to begin component fabrication or procurement activities in advance of receiving permits or licenses for a future commercial nuclear plant (SHP-0006).

NRC Response: The NRC disagrees with the comment.

10 CFR 53.1279(b) addresses application content related to the processes that will be used to procure, fabricate, and assemble components that make up the manufactured reactor. The description should clearly define which activities are proposed to be within the scope of the ML and those, such as the making of a component to be procured from a separate company for installation in the manufactured reactor, that are not considered to be within the scope of the manufacturing license. As such, 10 CFR Part 53 can address the model described in the comment where the manufacturing facility is limited to final assembly but can also address models where the fabrication of components would be within the scope of the manufacturing license.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.1.1.N: A commenter objected to the proposed definition of “safety-related structures, systems, or components” on multiple grounds, asserting that it: (1) goes beyond what 10 CFR Part 50 and 10 CFR Part 52 consider safety-related, (2) conflates safety-related and important-to-safety functions, (3) has virtually no precedent in the history of U.S. nuclear regulation, (4) does not account for differences in safety-related and special treatment as to protecting the public from hazardous radiation, (5) is not logical, (6) ignores the risk-informed requirements of NEIMA, and (7) is likely illegal. For these reasons, the commenter suggested adopting the following language instead:

> *Safety-related* means those systems, structures, and components directly relied upon to function during and after limiting design basis events, with a frequency of no more than 10^{-5}, to protect public health by minimizing hazardous radiation danger to life by insuring:
>
> (1) Retention of nuclear material within boundaries; and
>
> (2) Capability to shut-down the reactor and maintain the nuclear core in a safe configuration; or
>
> (3) Capability to prevent or mitigate event public radiation exposure in excess of 25 rem as conservatively determined at the site (or public evacuation zone) boundary for an event duration lasting until a safe core configuration is achieved.

The commenter said this definition parallels the universally respected definition long in use for worldwide commercial nuclear power (HPT38-0001, HPT5-0001), except with the frequency lowered from 10^{-4} to 10^{-5} since a lower frequency should be acceptable for emerging reactor types, with those unable to meet the criteria subject to 10 CFR Part 50 and 10 CFR Part 52 as before (HPT38-0001).

NRC Response: The NRC disagrees with the comments.

10 CFR Part 53 is based on a performance-based methodology and an overall hierarchy that covers: (1) plant-level safety criteria; (2) safety functions needed to demonstrate compliance with the safety criteria; (3) design features, human actions, and programmatic controls needed to fulfill the safety functions; and (4) functional design criteria defined for each design feature relied on to demonstrate the safety criteria are met. This construct does not require or preclude particular design features or related functional design requirements such as those traditionally defined for the reactor coolant pressure boundary for light-water reactors and thereby fulfills

NEIMA's direction to provide a technology-inclusive licensing framework. The comment appears to suggest an approach more similar to 10 CFR Part 50 wherein the NRC defines more prescriptive design requirements and deterministic design rules. 10 CFR Part 50 and 10 CFR Part 52 remain available for those applicants wanting to use more deterministic approaches for design and analysis. The requirements in 10 CFR Part 53 include defining special treatments for both SR and NSRSS SSCs but also distinguish between the safety categories and define specific requirements (e.g., quality assurance) for SR SSCs.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.1.1.O: A commenter held that providing definitions for the types of reactors applicable under 10 CFR Part 53, including microreactors, would help applicants better prepare applications under 10 CFR Part 50, 10 CFR Part 52, and 10 CFR Part 53; support the proposed rule's goal of limiting exemptions requested by applicants in their licensing applications; and reduce implementation issues for applicants and evaluation issues for NRC staff reviewing applications. Therefore, the commenter suggested defining microreactors as follows:

> *Micro-reactor* means a type of power reactor licensed to produce energy up to 30 megawatts electric. A microreactor may be of a modular design, an advanced design, or both, and may be an nth of a kind design meant to be factory-fabricated.

The commenter explained that this definition is based on SECY-24-0008 and could limit exemptions as the licensing process for microreactors is developed (DP-0001).

NRC Response: The NRC disagrees with the comment.

10 CFR Part 53 is technology-inclusive and can support microreactors through the flexibility provided by the overall framework and ability to scale requirements based on risk assessments considering both frequency and consequences of potential accidents. That said, the issuance of 10 CFR Part 53 does not foreclose future rulemakings to address particular design and deployment models for microreactors, which could benefit from a definition as suggested in the comment. For example, the NRC is also responding to the ADVANCE Act and EOs issued in 2025 by developing an additional rulemaking to expedite licensing qualified microreactors and other potentially low-risk, low-consequence reactors. The NRC does not see a significant benefit at this time from defining microreactors within 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.1.1.P: To help address section 103 of NEIMA, a commenter suggested adding to the rule a definition of "technology-inclusive framework" as follows (BI1-0017):

> *Technology-inclusive framework* means a regulatory approach that applies uniformly to all reactor designs by emphasizing performance-based and risk-informed safety objectives rather than design-specific prescriptive requirements, enabling the evaluation of a diverse range of advanced reactor technologies.

NRC Response: The NRC disagrees with the comment.

The NRC believes that the context of developing 10 CFR Part 53, which is intended to be a "technology-inclusive framework," is adequately addressed in the final rule and that the definition of commercial nuclear reactor in 10 CFR 53.020 clearly indicates the rule is technology-inclusive. Accordingly, the NRC does not see a benefit to including a definition of technology-inclusive framework within the actual rule language in 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.1.1.Q: A commenter urged the NRC to define "adequate protection" more clearly, to align with established legal precedents, rather than maintain ambiguity that unnecessarily burdens applicants (NNY-0005).

NRC Response: The NRC disagrees with this comment.

As explained in Section IV, Subpart B—Technology-Inclusive Safety Requirements, of the final rule, the collective set of performance-based requirements would be sufficient, if met, for the NRC to make the findings required to grant an application for a utilization facility under section 182 of the AEA that the utilization of special nuclear material will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public. This construct would be similar to existing NRC regulations, which the Commission has said on many occasions do not specifically define "adequate protection." However, compliance with NRC regulations may be presumed to assure adequate protection at a minimum.

Accordingly, the NRC did not change the rule language in response to this comment.

3.1.2 Other comments on Subpart A

Comment Bin 3.1.2.A: A commenter asserted that the NRC staff historically has operated in a prescriptive fashion in which the level of regulatory effort does not correspond to the public radiation risk, with this lack of restraint causing applicants to incur steep licensing costs (e.g., the commenter asserted that NuScale had expended more than half a billion dollars on licensing for a passively fail-safe design). Cautioning that 10 CFR Part 53 is on the same path, the commenter urged the NRC to establish upper-level expectations for NRC activities by amending 10 CFR 53.015 to state that Subpart A applies to the NRC in addition to applicants and licensees and urged the NRC to revise 10 CFR 53.000 to include NEIMA (HPT6-0001).

NRC Response: The NRC disagrees with the comment.

The NRC's existing regulations in 10 CFR Part 50 and 10 CFR Part 52 were promulgated with appropriate consideration of the information available and were put in place to ensure that licensed facilities will not present an undue risk to the public health and safety, and are consistent with the common defense and security. The focus of 10 CFR Part 53 is likewise on the requirements needed to ensure that future commercial nuclear plants are designed, constructed, and operated such that the radiological hazards will not present an undue risk to the public health and safety, and are consistent with the common defense and security. Where appropriate, the regulations in 10 CFR Part 53 provide constraints on the NRC. An example includes 10 CFR 53.1590 that specifies needed assessments and findings prior to the NRC imposing changes to licensed facilities. Additionally, 10 CFR 53.000 reflects the NRC's statutory basis for licensing nuclear reactors, as such it appropriately omits NEIMA, which did not modify those authorities. Nonetheless, the NRC has included NEIMA in its recitation of authorities for this overall rulemaking.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.1.2.B: Describing NRC staff reviews of licensee application documents as not risk-informed and expressing concern that 10 CFR Part 53 directly conflicts with NEIMA and is unacceptably inefficient, a commenter suggested adding a new section 10 CFR 53.005 (Reviews) to subpart A as follows:

> NRC review activities must be commiserate [sic] with risk, as correlated to the applicant's design and probabilistic risk assessment.

The commenter argued that this addition establishes clear staff review requirements, is technology neutral while relying on probabilistic methods the applicant already must provide, does not require modification of guidance documents, and would avoid situations like an application being denied because of failure to comply with esoteric considerations involving the theory of statistics (which the commenter said has occurred). The commenter also suggested that the volume of the NRC's existing guidance documents inappropriately imposes excessive requirements on license applicants (HPT9-0001).

NRC Response: The NRC disagrees with the comment.

The focus of 10 CFR Part 53 is on the requirements needed to ensure that future commercial nuclear plants are designed, constructed, and operated such that the radiological hazards will not present an undue risk to the public health and safety, and are consistent with the common defense and security. The NRC does consider potential risks to public health and safety as it develops and implements plans for the review of applications, including assigning resources and establishing schedules. The review plans are shared with applicants and discussions between the NRC staff and applicants provide opportunities to ensure risk insights are appropriately considered. Generic milestone schedules of requested activities of the Commission were developed as directed by NEIMA and are posted on the NRC's public website. Thus, the NRC concludes that its regulatory activities are already sufficiently risk-informed, and the addition of the comment's suggested regulation is unnecessary. Nonetheless, the NRC will continue to explore avenues to further risk-inform its activities.

Finally, because the NRC's guidance documents only describe methodologies that the NRC will find acceptable for meeting its regulations, the guidance documents do not impose requirements on licensees (but they may yield efficiencies in the licensing process for applicants that choose to follow them). Many of the existing guidance documents would not apply to applicants under 10 CFR Part 53, but the NRC will continue to develop guidance documents for the most important areas of licensing under 10 CFR Part 53 following the finalization of this rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.1.2.C: A commenter warned that proposed 10 CFR 53.110, which provides that licensees and applicants need not provide design features or other measures to protect against sabotage of a facility by an enemy of the United States, appears to be inconsistent with 10 CFR Part 73, whose postulated events include a terrorist attack on a nuclear facility (HPT40-0002).

NRC Response: The NRC disagrees with the comment.

10 CFR 53.110 states that licensees and applicants are not required to provide design features or other measures for the specific purpose of protection against the effects of attacks and destructive acts by enemies of the United States directed against the facility or deployment of weapons incident to U.S. defense activities. These requirements are equivalent to those in 10 CFR 50.13. These regulations are not intended to cover all malicious acts that have and continue to be addressed under 10 CFR Part 73.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.1.2.D: To clarify that the rule includes various technologies, a commenter suggested the NRC may issue supplemental guidance to address technology-specific considerations, as long as that guidance does not impose prescriptive requirements inconsistent with the objectives of 10 CFR 53.210 (BI1-0017).

NRC Response: The NRC agrees with the comment.

The NRC agrees that it may be prudent for future guidance documents to address technology-specific considerations and will consider developing such guidance, as warranted. As with all NRC guidance, such guidance documents would not impose requirements but only provide methodologies the NRC finds acceptable for meeting the NRC's regulations.

Accordingly, the NRC did not change the rule language in response to this comment.

3.2. Subpart B: Technology-Inclusive Safety Requirements (§§ 53.210-53.270)

3.2.1. Safety criteria (§§ 53.210-53.220)

3.2.1.1. General comments on safety criteria and analysis of DBAs or LBEs other than DBAs

Comment Bin 3.2.1.1.A: A commenter wrote that 10 CFR 53.210 departs significantly from 10 CFR Part 50 because defining safety-related items as pressure boundaries preventing radiation release is "no longer in-play." The commenter wrote that both approaches, analyzing design-basis accidents under 10 CFR Part 50 and 10 CFR 53.210, share a key metric of 25 rem event dose over two hours; but the commenter observed there is no clear acceptance criteria for the frequency of events under 10 CFR Part 53. The commenter said this will cause confusion and burden applicants with unnecessary costs. The commenter added that they are unclear why the proposed rule complicates regulations by using DBAs and the LBE term of 10 CFR 53.240 as both end up safety related. The commenter wrote that the proposed rule does not include any definitive acceptance criteria and that a dose without identification of frequency cannot be used to establish risk, which contradicts NEIMA. The commenter wrote that the absence of acceptance criteria exposes the applicant to financial costs and is potentially arbitrary in nature. The commenter recommended a revised definition for safety related (see Section 3.1.1). The commenter wrote that a 25 rem dose and 10^{-4} frequency demonstrates low public risk and constitutes a suitable regulatory acceptance criteria. The commenter also wrote that meaningful risk must involve frequency or likelihood, and while various NRC guidance documents provide target event frequencies, guidance cannot be used to codify requirements (HPT5-0001, HPT5-0002).

NRC Response: The NRC disagrees with the comments.

10 CFR Part 53 is based on a performance-based methodology and an overall hierarchy that covers: (1) plant-level safety criteria; (2) safety functions needed to demonstrate compliance with the safety criteria; (3) design features, human actions, and programmatic controls needed to fulfill the safety functions; and (4) functional design criteria defined for each design feature relied on to demonstrate the safety criteria are met. As a result, this construct provides considerable design flexibility but does not preclude particular design features or related functional design requirements such as those traditionally defined for the reactor coolant pressure boundary for light-water reactors. Consequently, the flexible licensing approach in Part 53 provides the applicant with the option to utilize components like pressure boundaries or select an alternate approach that provides an equivalent level of safety. While this approach provides greater flexibility than the NRC's existing regulations, it also provides a sufficient acceptance criteria in 10 CFR 53.210.

Part 53 meets NEIMA's requirement to provide a risk-informed licensing approach by complementing the analysis of design-basis accidents with a risk assessment of other licensing-basis events. The frequency of event sequences making up licensing-basis events other than design-basis accidents is addressed through the requirement in 10 CFR 53.450(e) for applicants and licensees to define evaluation criteria for each event or specific categories of LBEs to determine the acceptability of the plant response to the challenges posed by internal and external hazards to provide an appropriate level of safety. The requirements related to design-basis accidents in 10 CFR 53.450(f) are defined in terms of a deterministic approach to address challenges to safety functions and therefore are not characterized in terms of event frequency. Additionally, rather than provide competing requirements for design-basis accidents, 10 CFR 53.210 and 10 CFR 53.240 describe the criteria for design-basis accidents and how applicants should analyze them, respectively. The requirements in 10 CFR Part 53 include defining special treatments for both SR and NSRSS SSCs but also distinguish between the safety categories and define specific requirements (e.g., quality assurance) for SR SSCs.

To the degree that an applicant prefers deterministic approaches such as those in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50 and the related analyses methodologies for postulated accidents, the applicant may still use 10 CFR Part 50 and 10 CFR Part 52. 10 CFR Part 53 provides an optional alternative using more risk-informed and performance-based approaches for the design, licensing, and operation of commercial nuclear plants.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.2.1.1.B: A commenter wrote that the use of 25 rem total effective dose equivalent (TEDE) in "Section 53.22, First Tier Safety Criteria" as an acceptance criterion for the evaluation of DBAs for advanced reactors is inappropriate and fails to adequately protect the public. The commenter wrote that current NRC policy assesses this criterion utilizing dose coefficients based on biokinetic and dosimetric data based on the "standard man model." The commenter wrote that this 25 rem reference value lacks support from the health physics community for public exposure during emergencies and significantly exceeds the International Commission on Radiation Protection's recommended reference levels. The commenter wrote that substantial evidence indicates that 25 rem TEDE can cause significant harm to vulnerable populations like expecting mothers and children and added that there is substantial evidence that a maximum level of 10 rem would provide an appropriate upper-level reference for the evaluation of DBAs. The commenter added that the Commission's regulations provide a value of 5 rem TEDE as an upper bound to provide adequate protection and asked how the same Commission could endorse a value of 25 rem TEDE.

The commenter asked how the NRC can explain the continued use of 25 rem TEDE for advanced reactors given:

- EPA Protective Action Guideline (PAG) Manual EPA-400/R-17/001, "Protective Action Guides and Planning Guidance for Radiological Incidents," issued January 2017, recommends PAGs of 1 to 5 rem TEDE projected over four days for sheltering-in-place or evacuation of the public and 5 rem projected child thyroid dose from exposure to radioactive iodine for supplementary administration of potassium iodide.
- International Commission on Radiological Protection Publication 103 recommends a dose range of 2-10 rem for the public during an accident.
- National Council on Radiation Protection & Measurements (NCRP) Publication 180 recommends that the effective dose to emergency workers should not exceed 10 rem.
- International Atomic Energy Agency (IAEA) Publication General Safety Guide-8 recommends 2-10 rem for emergency exposure situations, and that the IAEA Integrated Regulatory Review Service mission to the U.S. in October 2010 identified a concern with the NRC's DBA acceptance criteria.

The commenter provided additional extensive background on the 25 rem TEDE value JP-0001, JP-0002).

Another commenter wrote that risk involving public exposure to hazardous radiation is anchored at 10^{-4} and 25 rem as a result of the AEA, but lesser levels of potential radiation releases are subject to "murky considerations." The commenter wrote that this requires "time-consuming no-win exercises" and instead the NRC should prioritize reasonable design, construction, and operational measures. The commenter suggested using industry consensus codes and standards, and requiring applicants and licensees to identify methods employed to protect against potential radiation releases involving abnormal operational events. The commenter wrote that any such release would trigger a formal incident response (HPT44-0001). Another commenter suggested removing 25 rem from 10 CFR 53.210(a) and (b) and replacing it with 5 rem (TG26-0001).

NRC Response: The NRC disagrees with the comments.

As explained in the footnote to 10 CFR 53.210 and in Section IV, Subpart B—Technology-Inclusive Safety Requirements, of the final rule, 25 rem is included as a safety criterion for design-basis accidents to support the identification of design features and programmatic controls. The specific reference value was chosen as a design tool to maintain consistency with requirements in other NRC regulations and is not presented as or intended to be interpreted as a radiation standard for an acceptable dose resulting from design-basis accidents. Additionally, the reference value in 10 CFR 53.210 is one of many licensing criteria in 10 CFR Part 53, others include the evaluation of licensing-basis events and defense-in-depth under 10 CFR 53.220 and 10 CFR 53.450. Thus, the NRC's assurance of safety does not rest on a single element of its regulations; rather the entirety of the NRC's standards ensures an appropriate level of safety. For additional information on the basis for the NRC's design basis accident dose criteria used for assessing containment performance, exclusion areas and low population zones, and control room envelopes, see the agency's denial of the petition for rulemaking (PRM)-50-121, published in the *Federal Register* on July 28, 2025 (90 FR 35441).

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.2.1.1.C: A commenter wrote that the proposed nomenclature and subdivision of accident types by limits on mean frequencies is arbitrary and not truly risk-based, as low frequencies and scenarios are unverifiable outside of human experience. The commenter recommended eliminating traditional nomenclature and/or event frequency based calculations, avoiding "arbitrary" sub-division and largely historical nomenclature for event categories and covering the continuous risk-informed decision marking risk spectrum, removing traditional distinctions between deterministic and probabilistic analyses, and integrating the use of risk-informed decision-making and PRA analysis for the full spectrum of events (RD-0011).

NRC Response: The NRC disagrees with the comment.

The use of frequency-based LBE categories and the design-basis accident LBE category in 10 CFR Part 53 is informed by similar features in approaches such as the Licensing Modernization Project (LMP) methodology described in Nuclear Energy Institute (NEI) 18-04, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," dated August 2019. The LMP methodology was approved by the Commission in staff requirements memorandum (SRM)-SECY-19-0117, "Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform The Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors," issued December 2019 (ML18312A253), as a reasonable approach for establishing key parts of the licensing basis and content of applications for licenses, certifications, and approvals for non-LWRs. NEI 18-04 was subsequently endorsed by the NRC in RG 1.233. As such, the use of these LBE categories and nomenclature in 10 CFR Part 53 is informed by a well-established, technology-inclusive, risk-informed, and performance-based methodology and establishes the dynamic between the use of LBEs other than DBAs to inform the development of DBAs.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.2.1.1.D: A commenter wrote that the requirement in 10 CFR 53.210 uses language that is prescriptive rather than performance-based. Specifically, the commenter says that the phrase "design features and programmatic controls must be provided" prescribes features rather than defining the desired outcome. The commenter suggested revising 10 CFR 53.210, which requires that design-basis accidents be identified and analyzed in accordance with 10 CFR 53.240, to delete the phrase "design features and programmatic controls must be provided" (NEI2-0036).

Another commenter proposed revising 10 CFR 53.210 as follows (BI1-0017):

> (a) Safety criteria must be established to ensure the safe operation of all commercial nuclear reactor technologies, regardless of design. These criteria shall be based on performance outcomes that align with risk-informed principles.
>
> (b) The criteria must:
>
> (1) Address all potential radiological hazards without imposing design-specific technical solutions;
>
> (2) Allow licensees to propose innovative approaches to meet safety performance standards; and
>
> (3) Be scalable to the size, complexity, and risk profile of the technology.

NRC Response: The NRC disagrees with the comments.

The safety criteria in 10 CFR 53.210 refer to design features and programmatic controls as a matter of reflecting the hierarchical nature of the regulatory framework under 10 CFR Part 53. This is consistent with the established regulatory construct that the applicant is responsible for providing the design features and programmatic controls to satisfy the safety criteria.

The NRC disagrees with the proposed revisions to 10 CFR 53.210. The safety criteria in 10 CFR 53.210 are technology-inclusive and do not impose design-specific technical solutions for addressing all potential radiological hazards. 10 CFR Part 53 already allows for substantial flexibility for an applicant to choose a variety of approaches to developing a safety analysis, and the use performance-based, high-level safety criteria would unduly impose additional uncertainty on licensing processes.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.2.1.1.E: A commenter wrote that 10 CFR 53.220(a) references 10 CFR 53.240 bringing in 10 CFR 52.240(c) which explicitly requires analysis of DBAs and analysis of LBEs to meet the criteria of 10 CFR 53.210. Additionally, 10 CFR 53.240(a) references 10 CFR 53.450 broadly which could imply 10 CFR 53.220 is meant to cover safety criteria for aircraft impact assessments and fire protection. The commenter suggested revising the text to add "classified as NSRSS" after "Design features and programmatic controls" to clarify that design features and programmatic controls to meet 10 CFR 53.220 are not required to be safety related. The commenter also suggested removing references in 10 CFR 53.220 and 10 CFR 53.240 so that safety criteria for LBEs other than DBAs do not reference requirements for DBAs, and to provide clarity on whether 10 CFR 53.220 was intended to cover criteria from 10 CFR 53.450(e) or 10 CFR 53.450 broadly. To do this, the commenter suggested removing "in accordance with 53.240 and 53.450(e), and provide measures for defense in depth in accordance with 53.250;" from 10 CFR 53.220(a) (NEI2-0037).

Another commenter recommended removing "other than DBAs" throughout 10 CFR 53.220 to avoid confusion. The commenter also recommended removing comprehensive risk metrics language from the section to improve regulatory certainty and reduce confusion. The commenter suggested rewriting 10 CFR 53.220 as follows (SCWG-0011):

> Design features and programmatic controls for NSRSS SSCs must be provided for each commercial nuclear plant to assure adequate protection of public health and safety. This is achieved through an integrated safety assessment, which must consider the necessary capabilities and reliability of design features and programmatic controls in accordance with 53.450(e), provide measures for defense in depth in accordance with 53.250.

NRC Response: The NRC disagrees with the comments.

The requirements under 10 CFR 53.220 specifically refer to LBEs other than DBAs when citing 10 CFR 53.240. As such, meeting the safety criteria under 10 CFR 53.220 in accordance with 10 CFR 53.240 logically implies the requirements under 10 CFR 53.240 specifically related to LBEs other than DBAs would need to be met. For example, the requirement under 10 CFR 53.240(c)(1) that requires the analysis of LBEs to include analysis of one or more DBAs under 10 CFR 53.450(f) is not applicable for meeting the safety criteria under 10 CFR 53.220 because it does not relate to LBEs other than DBAs. As discussed in the proposed and final rules, the safety criteria under 10 CFR 53.220 for LBEs other than DBAs would establish the connections between SSC design, human actions, and programmatic controls and a broader set of potential internal and external hazards. These safety criteria would also address defense-in-depth matters such as a balanced consideration of prevention and mitigation. While an SSC may be designated as safety-related per the definition of safety-related SSCs under 10 CFR 53.020, the safety-related SSCs can also be used to inform other aspects of the licensing basis such as LBEs other than DBAs.

The NRC disagrees with the suggestion to replace the comprehensive risk metric with a reference to “assure adequate protection of public health and safety.” When it approved the proposed rule, the Commission emphasized that the comprehensive metric was intended to be one element of the agency’s review that collectively provided a reasonable assurance of adequate protection of public health and safety. Given the other components of this review, the staff does not see a benefit to equating the criteria in 10 CFR 53.220 with the adequate protection standard.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.2.1.1.F: A commenter wrote that RG 1.233 and RG 1.253, “Guidance for a Technology-Inclusive Content-of-Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,” issued March 2024 (ML23269A222), make a distinction between safety criteria and associated design criteria to meet DBA requirements, safety criteria, and associated design criteria to meet the non-DBA LBE requirements. The commenter wrote that this helps applicants understand and apply the appropriate level of rigor to different classifications of components. The commenter wrote that DID and cumulative risk metrics should be considered in the broader context of the safety case, and suggested the following language in 10 CFR 53.220 to align it with RG 1.233 and the SRM to assess cumulative risk in the broader context of an integrated safety assessment (NEI3-0011):

> Design features and programmatic controls for NSRSS SSCs must be provided for each commercial nuclear plant to assure adequate protection of the public health and safety. This is achieved through an integrated safety assessment which must consider the necessary capabilities and reliability of design features and programmatic controls to

address LBEs in accordance with 53.450(e), provide measures for defense in depth in accordance with 53.250; and evaluate residual risk.

NRC Response: The NRC agrees, in part, with the comment.

As explained in Section II.A of the final rule FRN, the 10 CFR Part 53 regulatory framework is built upon concepts such as those included in RG 1.233 and 1.253, and thus much of the discussion within the comment generally aligns with 10 CFR Part 53 because the rule indicates that components relied on to address DBAs must be classified as SR but components relied on to address non-DBA LBEs would be classified as NSRSS (although some components classified as SR may also be used to address non-DBA LBEs as well as DBAs). The various sections in the subparts of 10 CFR Part 53 provide an integrated approach, including the consideration of cumulative or comprehensive risk metrics. The comment is related to other comments on the use of comprehensive risk metrics and risk evaluation techniques other than probabilistic risk assessments.

The NRC disagrees with the proposal to replace the comprehensive risk metric with a reference to “assure adequate protection of public health and safety,” as discussed in the NRC’s response to Comment Bin 3.2.1.1.E. The NRC disagrees with the specific proposal to replace references to comprehensive risk metrics and associated risk performance objectives in 10 CFR 53.220 through referencing an integrated safety assessment that assures adequate protection. As noted in the NRC’s response to other comments, such as Comment Bin 3.2.1.2.J, the comprehensive risk metric was intended to be one of many elements that collectively provide that assurance and that no single regulatory requirement governs whether a plant is “safe enough.” The NRC revised the language in some sections, such as 10 CFR 53.450, in direct response to some comments that also partially address this comment, such as Comment Bins 3.3.2.2.A and 3.3.2.2.E.

However, the NRC did not change the rule language in 10 CFR 53.220 in response to this comment.

Comment Bin 3.2.1.1.G: A commenter wrote that “safety-related” has always been the highest functional element for protection of the public from hazardous radiation. The commenter wrote that the proposed rule equalizes all programs in terms of nuclear safety significance which places unnecessary burdens on licensees. The commenter wrote that a clear distinction should be made between licensee efforts involving safety-related and “lesser” nuclear safety efforts. The commenter recommended that “program[s]” be used for safety-related efforts, and “measures” be used for “lesser” nuclear safety efforts. The commenter provided recommended tables of programs and measures (HPT39-0001, HPT39-0002).

NRC Response: The NRC disagrees with the comments.

While 10 CFR Part 53 does require applicants to establish a number of programs needed for safety, it includes the grading of requirements to address variations in the risk significance of design features and programmatic controls. As explained in the proposed and final rules, applicants and licensees have flexibility in deciding which design features or programmatic controls to categorize as safety-related and to rely on for meeting the safety criteria for design-basis accidents in 10 CFR 53.210.

Once selected, the safety-related design features or programmatic controls are subject to specific requirements such as the application of quality assurance requirements under Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50. The role of design features or programmatic controls satisfying the safety requirements in 10 CFR Part 53.220 for licensing-basis events other than design-basis accidents are captured through the requirements for special treatments under 10 CFR 53.460 and requirements for operations in Subpart F to 10 CFR Part 53.

The NRC disagrees with the recommendation that the term "program[s]" be used exclusively for safety-related efforts, and the term "measures" be used for "lesser" nuclear safety efforts because each of these terms is already used in 10 CFR Part 53 and redefining them in this way in the final rule would provide no apparent benefit given that the programmatic requirements are already graded according to risk significance, as described above.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.2.1.1.H: A commenter provided a quote from a National Academy of Engineering report, "Laying the Foundation for New and Advanced Nuclear Reactors in the United States, Consensus Study Report" which argues that there will always be new accident scenarios and combinations of events to challenge expectations and assumptions about advanced reactor systems, and creative thinking will be required to identify unique situations and scenarios (TG18-0001).

NRC Response: The NRC agrees with the comment.

10 CFR Part 53 includes requirements for applicants and licensees to systematically evaluate the design and operation of commercial nuclear plants to identify and, where appropriate, provide design features and programmatic controls to prevent or mitigate a wide range of event sequences. The comment did not suggest changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

3.2.1.2. <u>RFC: Comprehensive risk metrics and associated risk performance objectives (§ 53.220), including comments on QHOs, other comprehensive risk metrics, codification of novel approaches</u>

Comment Bin 3.2.1.2.A: A commenter wrote that risk metrics in the proposed rule are subject to interpretation and seemingly have no formal or underlying basis. The commenter wrote that metrics defined in the proposed rule are not consistent with "LBE and DBA etc. subdivisions given in PR10CFR nor reflect PRA and deterministic limitations and uncertainties."

The commenter wrote that in the proposed rule accident classification also requires analysis type classification, and if operational margins change by 25 percent then rereview is required. However, there is no information on whether this threshold contains uncertainties in the existing, new or calculated margins for whatever criteria are applicable, and in whatever physical or risk-informed decision-making reasoning contributes to the newly found, disclosed, or discovered uncertainty in the margin. The commenter added that having a firm threshold may provide an incentive to never claim or build-in margins in design and planned operation of significantly less than 25 percent or any other such specified threshold so that any changes or improvements will not invoke additional review and final safety analysis report (FSAR) revision. The commenter wrote that it would be preferable to allow risk-informed decision-making justification using mechanistic and probabilistic analyses to provide incentives to improve or establish margins and to quantify and reduce uncertainty (RD-0012).

NRC Response: The NRC agrees, in part, with the comment.

The requirements in 10 CFR Part 53 provide a framework for the identification and analysis of licensing-basis events; the identification of appropriate special treatments for structures, systems, and components; the development of programmatic controls; the consideration of site characteristics; the identification and implementation of appropriate staffing; and a variety of other measures and processes for the design, operation, and licensing of commercial nuclear plants. While providing a structure for ensuring some degree of predictability and consistency, the framework also provides flexibility for applicants and licensees to propose different risk metrics and associated risk performance objectives, demarcation criteria for the categories of licensing-basis events, and evaluation criteria for event sequences or categories of licensing-basis events. This approach is consistent with the current state of practice and offers appropriate flexibility for PRAs or other systematic risk evaluations to be developed and assessed based on the application they are used to support, which includes consideration of how the results and insights are relied upon, together with factors such as safety margin, simplicity of design, and treatment of uncertainty.

The NRC disagrees with those parts of the comment related to risk metrics because as explained above the rule is intended to provide flexibility to applicants. The final rule FRN addresses some risk metrics that the NRC would find acceptable, and the NRC intends to provide further information on specific methodologies to meet this standard through guidance. Accordingly, the NRC did not change the rule language in response to this part of the comment.

Regarding 10 CFR 53.1550, the NRC agrees that including a specific margin reduction as a threshold for facility changes requiring NRC approval may introduce implementation issues that would be better addressed through addressing the matter in guidance. Accordingly, the NRC revised the rule language for the criterion in 10 CFR 53.1550(a)(2)(vii) in response to this part of the comment. See also the response to Comment Bin 3.9.1.F for revisions made in the final rule for 10 CFR 53.1550.

Comment Bin 3.2.1.2.B: A commenter proposed deleting all of 10 CFR 53.220, writing that the definition and use of LBE invites event spaces involving “massive numbers of combinations and permutations” with no frequency values or linkage to public radiation doses. The commenter added that these criteria are open ended, difficult to meet, and open to interpretation from the NRC staff. The commenter wrote that the Commission specifically asked the NRC staff to remove QHOs from earlier versions of the 10 CFR Part 53 rule language, and the requirement is a “back-door” attempt around this. The commenter added that if a nuclear plant’s safety-related release barriers prevent the release of any significant amounts of radiation, then the whole issue is “moot.” The commenter also added that these requirements are contrary to several pieces of legislation and other laws including NEIMA and the Supreme Court decision in *Michigan v. EPA* (HPT7-0001, HPT7-0002). Another commenter asserted that the NRC needs to have an “actual number set” of acceptable risk to be used in calculations (TG17-0009).

NRC Response: The NRC disagrees with the comments.

Subpart B to 10 CFR Part 53, including 10 CFR 53.220, provides the safety requirements and specific criteria needed for a performance-based, technology-inclusive regulatory framework directed by NEIMA. The proposed and final rules mention the quantitative health objectives (QHOs) from the NRC's policy statement, "Safety Goals for Nuclear Power Plant Operation'' (Safety Goals Policy Statement), dated August 4, 1986 (51 FR 28044), as one acceptable approach for meeting the requirements for comprehensive risk metric(s) and related risk performance objectives but also states that applicants and licensees are free to propose other approaches. The QHOs and their related risk metrics are surrogate measures derived from the Commission's quantitative objectives for the qualitative safety goals described in the Commission's Safety Goals Policy Statement. The qualitative safety goals are based on the principle that nuclear risks should not be a significant addition to other societal risks.

The requirements for licensing-basis events in 10 CFR 53.240 and 10 CFR 53.450 require a systematic approach to address a wide range of potential event sequences to gain risk insights and identify appropriate design features and programmatic controls to prevent or mitigate potential damage states. The proposed and final rules provide examples and refer to available guidance such as RG 1.233 for event categories and associated evaluation criteria, but the rule language provides flexibility for applicants and licensees to propose other approaches. Finally, *Michigan v. EPA* established the principle that rational decision-making requires consideration of cost where agencies have discretion to consider that cost; here the NRC completed a regulatory analysis which includes consideration of both costs and benefits.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.2.1.2:C: A commenter wrote that QHOs should be eliminated for technologies that can demonstrate, by analysis, a less than 1 rem dose consequence for postulated accidents at the site boundary, as such a threshold already demonstrates there are very low consequences to public health and safety from plant operations (KAP-0003).

NRC Response: The NRC disagrees with the comment.

10 CFR Part 53 does not require the use of the QHOs from the NRC's safety goal policy statement. The proposed and final rule FRNs mention the QHOs as one acceptable approach for meeting the requirements for comprehensive risk metric(s) and related risk performance objectives but also state that applicants and licensees are free to propose other approaches. Nonetheless, the NRC recognizes that some plants could present a low risk profile while also meeting the requirements in 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.2.1.2.D: A commenter wrote that QHOs should be included in the rule, saying that they rank human health above any efficiency gains from not including them. The commenter referenced two studies on links between radiation exposure and cancer (JH-0001).

NRC Response: The NRC disagrees with the comment.

While the proposed and final rules mention the QHOs as one acceptable approach for meeting the requirements for comprehensive risk metric(s) and related risk performance objectives, they also state that applicants and licensees are free to propose other approaches that will also provide an appropriate level of safety.

In terms of the health effects related to various radiation doses, 10 CFR Part 53 generally refers to the regulations in 10 CFR Part 20 to address normal operations and worker doses and requires applicants and licensees to propose risk performance objectives and evaluation criteria for each event or specific categories of LBEs to address the radiological consequences from unplanned events. Issues pertaining to the Three Mile Island restart and general issues relating to the relation between dose and health effects are outside the scope of this rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.2.1.2.E: A commenter wrote that determining what is most probable requires data, analysis, and probabilistic methods, while addressing technology neutral aspects of concepts requires a general framework and a risk evaluation structure. The commenter wrote that the “key question” of whether any reactor is safer or has lower risk than another, or how comparative safety, risk, and performance is evaluated, is not discussed in the rule.

The commenter added that the formation and harmonization of agreement and licensing processes with international regulators is not considered in the rule, and the rule should adopt risk-informed decision-making practices from other international licensing approaches. The commenter wrote that language in 10 CFR 53.610 which states that any international differences “would ultimately need to be found acceptable by the NRC” is “almost dictatorial” in nature. The commenter wrote that even when the NRC exchanges information or has agreements with other nuclear regulators, there is no guarantee of licensing reciprocity, and these types of arrangements should be a part of risk-informed decision-making. The commenter provided a general model for thinking about risk-informed decision-making (RD-0014).

NRC Response: The NRC disagrees with the comment.

Consistent with long-standing Commission policy, the requirements in 10 CFR Part 53 are not intended to establish reactor safety by comparison, rather the requirements would independently establish the safety or a reactor application by providing a framework for the identification and analysis of licensing-basis events; the identification of appropriate special treatments for structures, systems, and components; the development of programmatic controls; the consideration of site characteristics; the identification and implementation of appropriate staffing; and a variety of other measures and processes for the design, operation, and licensing of commercial nuclear plants. While providing a structure for ensuring some degree of predictability and consistency, the framework also provides flexibility for applicants and licensees to propose different risk metrics and associated risk performance objectives, demarcation criteria for the categories of licensing-basis events, and evaluation criteria for event sequences or categories of licensing-basis events. This approach is consistent with the current state of practice and offers appropriate flexibility for PRAs or other systematic risk evaluations to be developed and assessed based on the application they are used to support, which includes consideration of how the results and insights are relied upon, together with factors such as safety margin, simplicity of design, and treatment of uncertainty. The collective set of performance-based requirements in 10 CFR Part 53 would be sufficient, if met, for the NRC to make the findings required to grant an application for a utilization facility under section 182 of the AEA that the utilization of special nuclear material (SNM) will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public.

This construct would be similar to existing NRC regulations, which the Commission has said on many occasions do not specifically define ‘‘adequate protection.’’ However, compliance with NRC regulations may be presumed to assure adequate protection at a minimum.

Regarding international construction experience, 10 CFR 53.610(a)(4) states that licensees must have "procedures to evaluate the applicability of other national and international construction experience to the planned and ongoing construction activities and to ensure the applicable experience will be provided to those constructing the plant." The requirement relates to the applicability of construction experience in terms of technologies, techniques, or other potential lessons learned and not the NRC's acceptance of the regulations imposed by other regulatory bodies. As a general matter, the regulations in 10 CFR Part 53 do allow for the use of generally accepted consensus codes and standards that could include those developed in other countries or by international organizations provided they have been endorsed or otherwise found acceptable by the NRC.

The NRC also acknowledges the general model for considering risk provided in this comment.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.2.1.2.F: A commenter wrote that the NRC should clarify the use and role of comprehensive risk metrics in 10 CFR Part 53 to enable a variety of different quantitative and qualitative metrics and evaluation metrics. The commenter wrote that this would enable applicants to meet the intent of comprehensive risk metrics without creating additional regulatory uncertainty or regulatory inefficiency (NIA2-0004).

Similarly, another commenter wrote that risk metrics are vaguely defined except for allowable releases, so risk metrics are intertwined with safety criteria for QHOs. The commenter added that it is not clear how or on what basis individual early fatality risk (IEFR) and individual latent cancer fatality risk (ILCFR) numbers of 5×10^{-7} per year and 2×10^{-6} per year are derived. The commenter wrote that the goal must be zero release as the linear hypothesis does not have a threshold of radiation exposure. The commenter wrote that there is no apparent consistency between these various metrics, QHOs and arbitrary DBA event divisions, analysis requirements or classifications with allowable frequencies, and dose limits.

Regarding the NRC's request for comment the commenter suggested using the results of PRA analyses for the complete spectrum or set of events to define core damage frequency (CDF) and large early release frequency (LERF), and to define the degree of redundancy and diversity required for both active and passive safety systems even for negligible releases (RD-0034).

Another commenter wrote that they were concerned about the lack of specificity in the proposed rule's requirements for the development of comprehensive risk metrics. The commenter wrote that the requirement is subjective in nature and would complicate the NRC's goal of ensuring that the safety of new reactors will be comparable to the existing fleet (UCS-0006).

NRC Response: The NRC disagrees with the comments.

The history of the development and implementation of the NRC's safety goals, including the QHOs, are well documented. The proposed and final rules mention the QHOs as one acceptable approach for meeting the requirements for comprehensive risk metric(s) and related risk performance objectives but also state that applicants and licensees are free to propose other approaches. The use of surrogate measures such as CDF and LERF are specifically mentioned in the proposed and final rules as one possible approach that might be pursued by applicants and licensees under 10 CFR Part 53. However, the NRC recognizes that CDF and LERF may not be applicable metrics for all technologies because it may not be possible to meaningfully define “core damage” for certain reactor types (e.g., molten salt reactors).

However, 10 CFR Part 53 does not require the use of the QHOs or even the NRC’s higher level qualitative goals from the safety goal policy statement to meet the requirements for using comprehensive risk metrics and related risk performance objectives. As explained in the proposed and final rules, applicants and licensees are provided with flexibility to propose their own comprehensive risk metrics and risk performance objectives. As discussed in the proposed and final rule, the NRC recognizes that guidance development to support 10 CFR Part 53 and advanced reactors will continue as the industry and NRC learn lessons from licensing reviews and operating experience and the NRC appreciates comments’ suggestions to that end. Thus, the NRC concludes that the comprehensive risk metric rule is sufficiently clear to ensure a level of safety that is comparable to the existing fleet.

The categorization of licensing-basis events considering event frequencies is a well-established part of most frameworks for the design and licensing of nuclear plants. While 10 CFR Part 53 does identify particular event categories to be used, the rule provides flexibility in both the criteria used to distinguish between categories of licensing-basis events other than design-basis accidents as well as the evaluation criteria for those event sequences. As explained in the proposed and final rules, 10 CFR Part 53 also defines a role for a largely deterministic design-basis accident category, consistent with the existing requirements in 10 CFR Parts 50 and 52.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.2.1.2.G: A commenter wrote that defense-in-depth and cumulative risk metrics should be considered in the broader context of the safety case and, in line with the SRM [SRM-SECY-23-0021], which stated that “the NRC's approval of the metric or set of metrics is not, by itself, an indicator of adequate protection.” The commenter suggested revising 10 CFR 53.220 as follows in order to align it with RG 1.233 and the SRM to assess cumulative risk in the broader context of an integrated safety assessment (NEI2-0243, NEI3-0011):

> Design features and programmatic controls for NSRSS SSCs must be provided for each commercial nuclear plant to assure adequate protection of the public health and safety. This is achieved through an integrated safety assessment which must consider the necessary capabilities and reliability of design features and programmatic controls to address LBEs in accordance with 53.450(e), provide measures for defense in depth in accordance with 53.250; and evaluate residual risk.

The commenter explained that comprehensive risk metrics should be a piece of an integrated safety assessment, which would be consistent with NEIMA and NEI 18-04 (NEI2-0243). Another commenter expressed support for this proposed revision (NEX-0019).

Two more commenters expressed support for this proposed rewording of 10 CFR 53.220. These two commenters added that it is incongruous to conflate estimated frequencies from a

PRA with the observational criteria established through a performance-based approach. The commenters wrote that the Commission in SRM for SECY-23-0021, “Staff Requirements – SECY-23-0021 – Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31),” issued March 2024 (ML24064A039), had previously disapproved the inclusion of QHOs in 10 CFR Part 53 and said that the origins of “risk performance objectives” appear unclear and unrelated to the Commission’s direction. The commenters suggested that applicants should be required to perform a "risk evaluation” as part of an "integrated safety assessment" under 10 CFR 53.220 (ROSE-0003, RAD-0002).

Another commenter wrote that they agreed with proposals to view a comprehensive risk metric as one piece of a holistic, integrated safety analysis, and added that this would be consistent with the decision-making framework in RG 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” issued January 2018 (ML17317A256) (ROSE-0006).

NRC Response: The NRC agrees, in part, with the comments.

The comments suggest an approach and rule language that generally align with 10 CFR Part 53. However, as explained in the proposed and final rules, specific language from the AEA is not incorporated into the safety objectives or safety criteria in 10 CFR Part 53. This is because, consistent with historical practice and as noted in response to other comments such as Comment Bin 3.2.1.2.J, the NRC is not defining ‘‘adequate protection’’ through the individual safety requirements in 10 CFR Part 53, and no single regulatory requirement governs whether a plant is “safe enough.” Rather, 10 CFR Part 53 enables the NRC to make its required findings under the AEA by providing sufficient performance standards, safety criteria, and related requirements on how applicants must demonstrate compliance with subpart B and other subparts.

The safety criteria and other requirements in 10 CFR Part 53 therefore need to have sufficient specificity to be a usable performance measure and to be considered as elements of a broader risk-informed decision-making process. The requirements throughout 10 CFR Part 53 that support demonstrating compliance with 10 CFR 53.220 would be similar to current regulations that both contribute to assuring adequate protection of public health and safety and are desirable to promote the common defense and security or to protect health or to minimize danger to life or property under section 161 of the AEA.

Regarding the NRC’s partial agreement with allowing the use of systematic risk evaluations within 10 CFR 53.450, see the response to Comment Bin 3.3.2.2.E (response to comments on 10 CFR 53.450(a)). The NRC revised the rule language in 10 CFR 53.450(a) and made conforming changes throughout in response to this and similar comments.

Accordingly, the NRC did not otherwise change the rule language in response to these comments.

Comment Bin 3.2.1.2.H: Two commenters suggested including language that comprehensive risk metrics “ensure risk is controlled with sufficient margin to risk performance objectives.” Both commenters wrote that getting an accurate approximation or risk level is less important than ensuring that risk is controlled under acceptable levels (NEI2-0017, USNIC2-0019).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees with the premise of these comments but disagrees with the specific proposed changes to the rule language. The margins between the calculated risks using a comprehensive risk metric and the associated risk performance objective can be used to help determine the degree of rigor going into the analyses and the design features and programmatic controls needed to meet the safety requirements in 10 CFR Part 53, including the defense-in-depth requirements in 10 CFR 53.250. As explained in the proposed and final rules, the use of screening tools and bounding or simplified methods for any mode or hazard may be sufficient provided the use of those tools and methods is justified by an acceptable technical basis. Therefore, the NRC disagrees that changes to the rule language are needed to acknowledge the underlying premise related to the use and benefits of analytical margins.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.2.1.2.I: Two commenters provided an overview of the NRC's history of risk management policy development (LMNT-0002, BI1-0014). Regarding the proposed rule and the NRC's request for comment, one commenter wrote that QHOs are suitable for assessment of comprehensive risk but added that the NRC should allow applicants to propose their own standards. The commenter added that the NRC has previously stated that the methodology for comprehensive plant risk assessment endorsed in RG 1.233 is acceptable for a 10 CFR Part 53 application as well. The commenter wrote that, regarding formal NRC approval for hypothetical alternatives, the need has not yet been demonstrated; however, if needed, it could be handled through plant-specific application or, on a generic basis, through a topical report.

Additionally, the commenter wrote that the proposed rule defines a new term "risk performance metric" but the coupling of "risk" and "performance" is problematic as this phrase is not used in the NRC Safety Goals Policy Statement. The commenter wrote that performance implies something that is measurable, but quantitative risk is a calculated number, not a measurement. The commenter suggested using a phrase such as "risk objective" instead (LMNT-0002).

The other commenter wrote that it is unrealistic to require applicants to propose new, comprehensive risk metrics within a single licensing application. The commenter wrote that historical evidence shows that developing risk metrics involve extensive research, multiple layers of approval, and significant stakeholder engagement over many years. This underscores that a streamlined or adaptive approach is needed for advanced nuclear applicants to meet safety requirements efficiently. The commenter wrote that provisions in the proposed rule requiring applicants to conduct a PRA and define their own comprehensive risk metrics introduce significant regulatory uncertainty, and it is "counterintuitive and incongruent" for the proposed rule to state that a comprehensive metric of overall risk, that considers the effects of all regulatory requirements in the licensing framework and constitutes an appropriate level of safety, represents something other than adequate protection.

The commenter added that without clear guidance on what constitutes an acceptable risk metric, applicants face an unpredictable and burdensome process. The commenter added that while comprehensive metrics are required, they are not stand-alone indicators of safety; rather, they are intended to be one component of a broader risk-informed regulatory framework. The commenter wrote that the NRC historically has undertaken lengthy processes to define and validate risk metrics, therefore requiring applicants to propose and gain approval for new risk metrics within a single application is unrealistic. The commenter wrote that, given this, 10 CFR Part 53 should include predefined metrics or adaptable frameworks that enable innovative reactor designs to meet safety compliance benchmarks without imposing an unrealistic burden on applicants (BI1-0014).

NRC Response: The NRC disagrees with the comments.

10 CFR Part 53 provides flexibility for applicants to propose comprehensive risk metrics and associated risk performance objectives developed for specific technologies or analytical approaches. The NRC is aware that past efforts by the agency, reactor designers, and other organizations to develop such risk-informed decision-making frameworks have been resource intensive and time consuming. As explained in the proposed and final rules, existing safety goals, including the QHOs, and guidance such as RG 1.233 are available as a way to meet the requirements in 10 CFR 53.220 for comprehensive risk metrics and associated risk performance objectives. The terminology for “risk performance objective” was selected to align with historical references such as SRM-SECY-98-144, “Staff Requirements – SECY-98-144 – White Paper on Risk-Informed and Performance-Based Regulation,” issued February 1999 (ML003753593), that explain that parameters or metrics may involve either measurable or calculable outcomes to be compared to objective criteria to assess performance. Lastly, the NRC plans to issue RG 1.263, “Comprehensive Risk Metrics and Associated Risk Performance Objectives for Commercial Nuclear Plants,” to provide additional guidance on the developing and submitting proposals related to comprehensive risk metrics and associated risk performance objectives to the NRC for review and approval.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.2.1.2.J: Two commenters wrote that the comprehensive risk metric should not be codified in the rule language but should instead be endorsed in guidance which would allow flexibility essential for the differences between new reactor designs (NEI2-0179, USNIC2-0028). One commenter added that some traditional LWR applicants may choose to keep CDF and LERF risk surrogates, others may choose to use the risk metrics from LMP and endorsed in RG 1.233, others may choose a technology-inclusive risk surrogate, and microreactors may choose consequence-based limits for a bounding event or set of events as suggested in DG-1414, “Alternative Evaluation for Risk Insights (AERI) Framework” (ML22146A041). The commenter continued that as industry develops technology-inclusive risk metrics, they will consider whether, and under which conditions, a second metric is needed. The commenter added that several microreactors expect to have no credible accidents that could result in an offsite dose greater than 100 rem, which was used as the lower threshold dose for early fatality in NRC technical report (NUREG)-1860, “Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing,” issued December 2007 (ML080440170). The commenter added that in terms of a minimal set of dose criteria that could align with the QHOs, one potential approach would be a dose crediting SR SSCs multiplied by the 1-year annual frequency, summed with a maximum credible accident dose multiplied 1^{-4}. The commenter wrote that the treatment of event sequences from hazards, non-core sources, and lower modes is also an important consideration. The commenter added that the PRA standards provide screening criteria for many of these which remain valid for screening hazards, sources, and modes from consideration for a comprehensive risk metric, but the non-LWR PRA standard also provides the ability to use supplemental evaluations in lieu of PRA. The commenter also observed that, while not a fatal flaw, the proposed 10 CFR Part 53 imposed significant and unnecessary burdens (NEI2-0179, NEI2-0006).

NRC Response: The NRC agrees, in part, with the comments.

To the degree that the comments describe multiple possible ways to use risk insights, comprehensive risk metrics, and associated risk performance objectives, the NRC agrees that the rule should not preclude any of these approaches to the extent a given approach involves the use of probabilistic risk assessment, other systematic risk evaluations, or combination thereof together with other generally accepted approaches for systematically evaluating engineered systems (see the response to Comment Bin 3.2.2.F).

To the extent that the comments suggest that the rule is unable to accommodate a spectrum of approaches or that the comprehensive risk measure should be contained in guidance, the NRC disagrees. 10 CFR 50.220 provides sufficient flexibility in 10 CFR Part 53 for applicants to propose such alternatives for NRC review and approval.

However, the Commission has emphasized in approving the proposed rule that, while this measure is an important element in establishing reasonable assurance of adequate protection, no single regulatory requirement governs whether a plant is “safe enough.” Therefore, the NRC disagrees that moving it entirely to a guidance document would be appropriate as it would remove a foundational element of the regulatory framework and unnecessarily reduce regulatory certainty. The NRC is not, however, making any judgments at this time on the specific proposals in the comment. See the NRC’s response to Comment Bin 3.12.C and the related response regarding regulatory burden imposed by the 10 CFR Part 53 proposed rule.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.2.1.2.K: Regarding the NRC’s request for comment on the use of comprehensive risk metrics, a commenter wrote that “applicant-defined” comprehensive risk metrics and associated risk performance objectives create regulatory uncertainty, and it is a challenge for applicants to create and define their comprehensive risk metrics without proper guidance. The commenter added that existing metrics took significant time to develop and required multiple layers of approval. The commenter also argued that comprehensive risk metrics were only introduced to 10 CFR Part 53 as a result of direction from the Commission in the SRM, and there was no public engagement regarding this outside of an NRC workshop that the NRC staff indicated was not related to 10 CFR Part 53. The commenter highlighted several challenges with the concept of comprehensive risk metrics in the proposed rule (BI1-0005):

- The commenter wrote that the proposed rule language mixes regulatory terminology, writing that several terms including “adequate protection”, “appropriate level of safety”, “acceptable risk”, “safe enough”, “comprehensive risk”, and “overall risk”, are used interchangeably. The commenter added that comprehensive risk metrics are defined in the proposed rule as the “total, overall risk from the facility” and associated risk performance objectives are indicative values of the comprehensive risk metrics; and that requirements are analogous to those in 10 CFR Part 50 and 10 CFR Part 52, where no single regulatory requirement governs whether a plant is “safe enough.” However, the proposed rule states that the QHOs would be acceptable as a risk performance objective. The commenter wrote that the 10 CFR Part 50 and 10 CFR Part 52 licensing frameworks used an amalgamation of deterministic requirements and compare the outcomes to risk goals, but 10 CFR Part 53 is significantly different where risk is a core principle and as drafted requires a comprehensive metric of “overall” risk.

- The commenter wrote that there are functional barriers to developing comprehensive risk metrics including historical timelines, layers of approval necessary, and shifting application of existing NRC risk metrics. The commenter wrote that it is unrealistic to expect an applicant to effectively or efficiently define a new novel risk metric or set of metrics and receive NRC approval on a much shorter timeline as part of an application; and, given these challenges, applicants will default to existing metrics, particularly the QHOs even though the Commission moved to remove them from the proposed rule language.

- The commenter highlighted what they said were policy and legal defects in the proposed rule. Specifically, the commenter wrote that the proposed rule does not specify a metric for adequate protection and does not make clear what is "safe enough." This makes the approach arbitrary and capricious and would hold similarly situated applicants to different standards. The commenter added that the proposed rule is inconsistent with Congressional intent, citing the 1990 CAA Amendments, NEIMA, and the ADVANCE Act. The commenter wrote that as a result 10 CFR Part 53 is not a risk-based rule as risk value is not the sole basis for decisions.

The commenter wrote that an integrated safety approach requires that a comprehensive safety metric should capture the cumulative effects of all regulatory requirements, rather than serving as an isolated indicator of risk. Accordingly, the rule should reflect that a comprehensive safety performance objective is sufficient to demonstrate that a plant is "safe enough" (BI1-0005).

The commenter added that if comprehensive risk metrics are retained in the final rule, then further revision to the definition is required. Additionally, the commenter wrote that comprehensive risk metrics and associated risk performance objectives must be consistent with Congressional direction on radiological risk standards in section 112 of the CAA; and, if metrics are applicant-defined, the NRC must give clear direction in the preamble and separate guidance documentation that proposed metrics and objectives should be consistent with the level of risk established by Congress that define "acceptable risk" and "ample margin of safety to protect public health" (BI1-0005).

The commenter also wrote that, in order to better align language between the preamble and rule text, the NRC needs to define what "appropriate level of safety" means in the preamble. The commenter argued that SRM-SECY-23-0021, "Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)," issued March 2024 (ML24064A039), directed the staff to not apply a PRA consensus standard as a strict checklist, but the preambles stated that these standards are retained because they have sufficient flexibility (BI1-0035).

Another commenter recommended that comprehensive risk metrics should be retained in the rule as they are one of several key requirements that characterize the safety of a reactor in a performance-based regulatory framework. Additionally, the commenter recommended that comprehensive risk metrics proposed by applicants and approved by the NRC staff have the option of being codified through NRC staff development of regulatory guidance, NRC staff endorsement of applicant reports, or NRC staff approval of topical reports that document the risk metrics. The commenter wrote that in their own engagement with stakeholders they found confusion over the use of the term "risk metric" to describe a performance-based regulatory requirement, and concerns that "risk metric" would limit applicant proposals of metrics and demonstration of compliance with metrics to numerical evaluations of risk and would exclude qualitative evaluations of safety that could enable the NRC to help reach the same finding of "reasonable assurance of adequate protection" (NIA2-0010).

Another commenter wrote that the NRC needs to clarify proposed requirements for applicant-defined comprehensive risk metrics and associated risk performance objectives in to avoid creating regulatory uncertainty. The commenter said that the preamble for the final rule and the rule language should be clear and consistent in relation to the definition and use of the term "risk" in the context of safety, and NRC expectations of the appropriate levels of risk. The commenter added that the proposed rule is not clear or consistent in relation to expectations of levels of risk, using multiple terms, including "appropriate" levels of risk, "overall" risk, and "acceptable" risk.

The commenter argued that the proposed rule introduces new requirements for applicant evaluation of plant risks that differ from the existing regulatory requirements in 10 CFR Part 50 and 10 CFR Part 52 that do not utilize a comprehensive metric of overall risk. The commenter wrote that it is important that the discussion and application of comprehensive risk metrics in final rule reflect the position that it is one tool to help characterize plant safety and that the NRC Safety Goals, including the QHOs, are not intended to serve as the sole basis of licensing decisions but can enable NRC to quantify levels of "acceptable risk" and the regulatory basis for "safe enough." The commenter wrote that, as written, comprehensive risk metrics in the proposed rule could become interpreted as a risk-based requirement instead of a performance-based requirement (SCWG-0010).

To address concerns regarding comprehensive risk metrics, all three commenters offered the following recommendations (NIA2-0010, BI1-0005, SCWG-0010):

- Revise the terminology from a "comprehensive risk metric" to a "comprehensive safety metric" to emphasize that the purpose of the metric is to evaluate overall safety of the facility.

- Define a comprehensive safety metric as the figure of merit that will be assessed during licensing and "comprehensive safety assessment" as the methodology or set of methodologies used to evaluate and demonstrate compliance with the figure of merit.

- Clarify in the preamble the intended relationship between existing NRC risk objectives, comprehensive safety metric, and comprehensive safety assessment to establish a clear framework for assessing overall safety while ensuring that comprehensive safety metrics are not the sole basis for regulatory decision-making.

- Emphasize that the overall goal of comprehensive safety metric is to help ensure the outcome of "adequate protection of public health and safety" when evaluating existing or proposed metrics.

- Enable applicant definition and use of comprehensive safety metric to align with accepted industry practices for safety and risk evaluations completed during design and allow applicants to select metrics (e.g., QHOs, CDF, LERF) and evaluation methodologies (e.g., PRA, AERI) that meet the overall intent of the comprehensive safety metric.

- Remove explicit references to QHOs in the rule text to prevent QHOs from becoming a de facto regulatory requirement. QHOs should remain an acceptable option for applicants who choose to use them as their comprehensive safety metric.

- Revise rule text to focus on applicant completion of an “integrated safety assessment” rather than mandating specific evaluation methodologies (e.g., PRA) be used when demonstrating the overall safety of a facility.

NRC Response: The NRC agrees, in part, with the comments.

To the degree that these comments are generally describing risk-informed decision-making processes and stating that there are multiple possible ways to use risk insights, comprehensive risk metrics, and associated risk performance objectives, the NRC agrees and has provided flexibility in 10 CFR Part 53 for applicants to propose such alternatives for NRC review and approval. The NRC acknowledges the concern that the language in the comprehensive risk metric standard may reduce regulatory certainty because of the greater flexibility it provides applicants. However, as explained in the proposed and final rules, while 10 CFR Part 53 does not define specific risk measures or associated risk performance objectives, the QHOs and their related surrogates of IEFR and ILCFR are cited within the proposed and final rules as one acceptable approach.

As noted in the comments, the NRC has discussed the comprehensive risk metric generically at a previous public meeting, and at a meeting on Part 53 during the comment period. The NRC intends to continue to interface with stakeholders and develop additional guidance on other acceptable approaches to meeting the comprehensive risk metric requirements. Therefore, the NRC disagrees that referring to the QHOs and their related surrogates in the final rule will result in them becoming de facto regulatory requirements and disagrees that applicants will need to default to the QHOs and their related surrogates because of the challenges of developing and using alternatives. As explained in the NRC’s responses to Comment Bins 1.3.B and 3.2.1.2.G, the NRC also does not agree that the CAA alters the NRC’s regulatory authority to set appropriate safety standards, that a risk-informed licensing framework requires the NRC to establish a definition of adequate protection, or that reliance on an ill-defined “integrated safety assessment” is appropriate.

The NRC also acknowledges that 10 CFR Part 53 uses many similar but different terms to describe its safety requirements. However, these terms are generally intended to capture different meanings; therefore, the differing terminology is intentional. Based on context, language in the final rule, and guidance documents, the different meaning in terms should be apparent. For example, while “adequate protection” refers to the minimum level of safety NRC regulation must provide in the AEA, “appropriate level of safety” refers to the standard that the applicant’s proposed comprehensive risk metric must meet, which as discussed elsewhere, is one component of the agency’s overall “adequate protection” finding.

The NRC disagrees with the suggestion to use the phrase “comprehensive safety metric(s).” The alternate wording does not provide any meaningful advantage over the existing text and could blur the distinction between risk-informed and deterministic frameworks.

Accordingly, the NRC did not change the rule language in response to these comments. However, the NRC revised the rule language for 10 CFR 53.450(a) in response to Comment Bin 3.3.2.2.E to support the potential for systematic risk evaluation techniques other than PRA.

3.2.2. Defense in depth (§ 53.250), including RFC on inherent safety characteristics

Comment Bin 3.2.2.A: A commenter suggested deleting 10 CFR 53.250 from the rule, stating that 10 CFR Part 50 and 10 CFR Part 52 do not contain such requirements and instead achieve the desired outcome by applying a defense-in-depth philosophy.

The commenter characterized 10 CFR 53.250 as prescriptive rather than performance-based or risk-informed, giving as an example the phrase “Measures must be taken” in paragraph (a), which they said prescribes the feature rather than defining the desired outcome. The commenter also questioned why 10 CFR 53.250 is written to be applicable to NSRSS and S[R] SSCs when the single failure would be more effectively applied to SR SSCs relied upon for DBAs. The commenter argued that 10 CFR 53.250 is inconsistent with the basis for the Commission’s direction in SRM-SECY-19-0036, “Staff Requirements – SECY-19-0036 – Application of the Single Failure Criterion to Nuscale Power LLC's Inadvertent Actuation Block Valves,” issued July 2019 (ML19183A408), not to apply deterministic criteria when they are unnecessary based on risk insights.

Ultimately, the commenter suggested that if the NRC does not delete 10 CFR 53.250, then paragraphs (a) and (c) should be revised as follows (NEI2-0041):

> (a) Defense in depth must be provided to compensate for uncertainties in the analysis of the safety criteria such that there is reasonable assurance that the safety criteria in this subpart are met over the life of the plant.
>
> . . .
>
> (c) Defense in depth measures may include increased safety margin and redundant layers of protection.

Another commenter wrote that a simple PRA can provide useful insights to generally assess defense-in-depth, however the proposed rule suggests the NRC staff would be involved at “more than a macro level” which is a “semi-terrifying prospect” for applicants and licensees (HPT42-0004).

Another commenter requested that the NRC should work with stakeholders to establish acceptable means to comply with 10 CFR 53.250 defense-in-depth requirements for non-LMP applicants (NEI2-0006).

NRC Response: The NRC agrees, in part, with the comments.

The NRC disagrees with the suggestion to delete 10 CFR 53.250 from the rule. The requirement under 10 CFR 53.250(c) is different from the single failure criterion described in Appendix A to 10 CFR Part 50 in that the 10 CFR 53.250(c) requirement does not allow the safety analysis to exclusively rely on a single engineered design feature, human action, or programmatic control to address the range of LBEs other than DBAs (i.e., ranging from very unlikely event sequences to anticipated event sequences). In contrast, the single failure criterion under Appendix A to 10 CFR Part 50 relates, in part, to the failure of a component to perform its intended safety functions, regardless of whether that component was exclusively relied on to address the range of LBEs. This means the requirement under 10 CFR 53.250(c) does not strictly disallow single failures, as defined in Appendix A to 10 CFR Part 50, because a component could experience such a single failure and, if it is not otherwise relied on to address the range of LBEs other than DBAs, its failure alone does not preclude being able to meet

10 CFR 53.250(c). In that regard, 10 CFR 53.250 would allow for greater flexibility such that other measures could be taken to ensure appropriate defense in depth without needing to accommodate single failures, as defined in Appendix A to 10 CFR Part 50. However, the NRC identified that the rule language in 10 CFR 53.250(c) in the proposed rule did not include the qualifier “exclusively,” consistent with the discussion in Section IV of the FRN for the proposed rule. Accordingly, the NRC revised the rule language in 10 CFR 53.250(c) to include “exclusively,” as discussed in this response.

As discussed in the proposed and final rules, defense in depth is addressed in 10 CFR Part 50 and 10 CFR Part 52 through layered, prescriptive technical requirements for LWRs. However, under 10 CFR Part 53, applicants have flexibility related to how they could propose demonstrating compliance with the high-level safety criteria. As such, without specific requirements to explicitly address defense in depth, 10 CFR Part 53 could otherwise allow for substantial deviation from the NRC’s longstanding philosophy of providing defense in depth to address uncertainties about the design, operation, and performance of commercial nuclear plants (e.g., proposed measures that only address preventing versus mitigating an event sequence and vice versa). As such, the requirement under 10 CFR 53.250(a) is expressed in terms of “measures” because those are the aspects of managing the risks posed by a commercial nuclear plant that would be evaluated by the NRC to determine whether a design has appropriate defense in depth.

The NRC agrees that it would be beneficial to work with stakeholders to establish acceptable means to comply with 10 CFR 53.250 defense-in-depth requirements for non-LMP applicants when non-LMP approaches are developed. This comment suggests no changes to the proposed rule.

Accordingly, the NRC revised the rule language in 10 CFR 53.250(c) only to align with the intent of the discussion in Section IV of the FRN for the final rule, as discussed above.

Comment Bin 3.2.2.B: Two commenters supported the clarification in the preamble regarding “engineered design feature” and crediting inherent characteristics within the design analysis and added that they supported additional clarification and guidance in RG 1.233 (NEI2-0180, USNIC2-0029). One of the commenters argued, the rule could be clearer about how, beyond the methodology endorsed in RG 1.233, this concept can be acceptable to the NRC (e.g., clear criteria that build on the information in SECY-18-0096, “Functional Containment Performance Criteria for Non-Light-Water-Reactors,” issued September 2018 (ML18115A157), for a more conservative approach to design criteria for radionuclide retention). The commenter also advocated allowing the use of the traditional approach to defense-in-depth, which they indicated would require the use of the single failure criterion and would have implications across 10 CFR Part 53, stating that it remains a valid method for achieving adequate protection of public health and safety and should remain an option under 10 CFR Part 53 (NEI2-0180).

Another commenter wrote that the proposed rule only vaguely defines the uncertainties that a licensee’s defense-in-depth analysis must consider (NYS2-0007).

NRC Response: The NRC agrees, in part, with the comments.

As explained in the proposed and final rules, the term ‘‘engineered design feature’’ within 10 CFR 53.250(c) does not preclude the possible crediting of inherent characteristics within the design and analysis for commercial nuclear reactors. Uncertainties related to inherent characteristics of design features are addressed by the other provisions in 10 CFR 53.250 as well as the design requirements of 10 CFR 53.440(a) that require each design feature, including any credited inherent characteristics, to be demonstrated by analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof. Although the NRC is preparing guidance related to the content of applications for 10 CFR Part 53, the rule provides a great deal of flexibility in terms of the variety of designs and related safety approaches, which limits how prescriptive the guidance can be.

The NRC disagrees with the suggestions to revise 10 CFR Part 53 to include an optional approach that defines specific design requirements and design rules, such as the single-failure criterion. 10 CFR Part 53 was developed as an alternative to the traditional, deterministic regulations in 10 CFR Part 50. The NRC recognizes that there may be cases where a reactor designer wishes to apply to the NRC under 10 CFR Part 53 while also incorporating certain design rules into a proposed reactor design to meet the requirements established by other regulators or international standards. The requirements in 10 CFR Part 53 do not preclude such an approach but meeting the requirements of multiple regulatory frameworks could result in additional design features, functional design criteria, or programmatic controls when compared to those needed to meet a single regulatory framework.

With regards to defense in depth, 10 CFR 53.250(b) strikes a balance between permitting flexibility and offering regulatory certainty by addressing uncertainties at a high enough level so as not to be too prescriptive, but by also acknowledging well-known types of uncertainty that may potentially be impactful in risk-informed decision-making related to the design and operation of commercial nuclear plants.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.2.2.C: A commenter wrote that the rule should clearly state that the applicant is responsible for identifying and justifying their defense-in-depth approach; nuclear safety functions and their associated design criteria; risk based methodology used to establish the importance of their various defense-in-depth measures; programs used to enhance their defense-in-depth measures, including identifying and justifying their measures that demonstrate that their on-going programs operate effectively; and identifying the key codes and standards employed with their defense-in-depth measures (HPT3-0001).

NRC Response: The NRC agrees, in part, with the comment.

For a given licensing process, an applicant would be required to submit information to the NRC consistent with the requirements in 10 CFR Part 53, Subpart H, related to that licensing process. The requirements in 10 CFR Part 53 accommodate the considerations described in the comment in that the information submitted by an applicant must necessarily be sufficient to demonstrate that the related technical requirements under 10 CFR Part 53, including 10 CFR 53.250, “Defense in depth,” are met such that the NRC can make the required regulatory determinations related to the subject licensing process. So, while the NRC agrees in concept with many of the sentiments described in the comment, the NRC disagrees that additional changes are needed in 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.2.2.D: A commenter wrote that previous legislation on nuclear energy over the previous five decades have embedded the defense-in-depth approach for radiation protection, and nuclear safety functions and implementing design criteria are foundational elements of this defense-in-depth approach. The commenter added that generally industry codes and standards are implementing vehicles, and another key defense-in-depth element lies with the use of various programs in conjunction with industry codes and standards. The commenter wrote that, as legislation evolved over time, recognition emerged that protective measures involve varying levels of importance and that risk-based evaluations can provide a method to help establish importance (HPT3-0002).

NRC Response: The NRC agrees with the comment.

The NRC agrees that various legislative actions and rulemakings have led to requirements intended to protect public health and safety, including the defense-in-depth approach. The comment did not suggest changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.2.2.E: A commenter wrote that to enhance defense-in-depth, the NRC should concentrate on a subset of accident scenarios that might cause a rapid loss of containment integrity. The commenter continued that this subset of unidentified, potentially serious accidents can be narrowed by eliminating those prompt release scenarios whose source terms are too small to cause an early or latent fatality. Additionally, scenarios which have well heated and buoyant plumes and/or happen when there are considerable ongoing wind shifts during the plume release could be excluded from further analyses. The remaining unidentified accident scenarios that might lead to a rapid loss of containment integrity, a large source term and a ground level release are very different from the accident sequences in the present spectrum of accidents that the NRC now reviews. The commenter wrote that advancing defense-in-depth in a modern NRC would require focusing resources on looking for a special subset of sequences that have specific characteristics. The commenter wrote that the NRC should establish a special group of experts to review past plant operating incidents to see if they offer clues on potential rapid containment failure scenarios and other accidents outside of the usual spectrum of accidents the NRC examines (MU1-0004).

NRC Response: The NRC disagrees with the comment.

As explained in the proposed and final rules, 10 CFR Part 53 requires the evaluation of a wide range of event sequences for comparison to evaluation criteria defined for each licensing-basis event (LBE) or category of LBEs. Such evaluation criteria for specific LBEs or categories of LBEs would be defined in terms of limits on the release of radionuclides or maintaining the integrity of one or more barriers used to limit the release of radionuclides and reflect a graded approach of allowing lesser potential consequences from more frequent events. Although the approach described in the comment may be appropriate for some event sequences or as a means to define a bounding offsite consequence, the NRC disagrees that the approach is a suitable replacement for the broader systematic evaluation of a range of event sequences required under 10 CFR Part 53.

To the extent that the comment suggests establishing a group of experts to investigate such event sequences, the comment is outside the scope of this rulemaking. Although, the NRC notes that the Advisory Committee on Reactor Safeguards (ACRS) will review new reactor applications and provide additional safety insights to the staff, which can include highlighting overlooked event sequences.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.2.2.F: A commenter stated that while the proposed rule's discussion of defense in depth focusing on DBEs other than DBAs, which the NRC interprets as meaning LBEs other than DBAs, aligns with LMP, a bounding risk assessment also can inform a defense-in-depth assessment. The commenter gave an example where systems credited in the DBA perform a mitigation function and systems that fail to create the initial conditions of the DBA perform a prevention function. The commenter suggested that the NRC remove the "other than DBAs" language from the discussion of defense in depth (NEI2-0018).

NRC Response: The NRC agrees, in part, with the comment.

As explained in the proposed and final rules, screening tools and bounding or simplified methods may be used for any mode or hazard, provided that the applicant provides an acceptable technical basis. As such, the NRC agrees a bounding risk assessment used together with PRA, other systematic risk evaluations (SREs), or combination thereof can inform an evaluation of defense-in-depth adequacy. However, the exclusive use of bounding risk assessments or a traditionally developed, deterministic safety analyses would not be sufficient for meeting other analysis requirements under 10 CFR 53.450(e), such as paragraph (4), as it relates to identifying event sequences deemed significant for controlling risks. This is because the analysis used to identify event sequences deemed significant for controlling risk necessarily rely on greater degrees of realism to allow a decisionmaker to better distinguish between the relative importance of different risk contributors and better prioritize different safety aspects of a design. In contrast, artificially pessimistic assumptions associated with bounding risk assessments or a traditionally developed, deterministic safety analyses can significantly misrepresent (i.e., mask) the relative risk importance of a related aspect of a design.

As explained in the proposed and final rules, while the dedicated success paths associated with DBAs contribute to the overall defense in depth for each commercial nuclear plant under 10 CFR Part 53, DBAs are conservative in their nature and, depending on the design under consideration, the overall defense in depth for that design may need to be further complemented with other, more realistic scenario evaluations.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.2.2.G: A commenter wrote that they supported including specific defense-in-depth requirements including the "single-failure-like provision" in 10 CFR 53.250(c). The commenter wrote that this provision should also apply to DBAs as they are more likely events that have a higher degree of assurance than the lower probability beyond-design-basis events. The commenter also stated that crediting of "inherent" characteristics of SSCs should not be allowed as the sole means of prevention or mitigation unless those characteristics can be demonstrated through testing to be at least as reliable as engineered active or passive safety features (UCS-0007).

NRC Response: The NRC agrees in part with the comment.

The NRC agrees that it is appropriate to maintain the requirement in 10 CFR 53.250(c) for the safety analyses to not rely upon a single engineered design feature, human action, or programmatic control, no matter how robust, to address the range of LBEs other than DBAs. The NRC disagrees with the part of the comment suggesting that a single-failure-like provision be added to the analysis of DBAs. As explained in the proposed and final rules, the role of DBAs within 10 CFR Part 53 is more narrowly focused on selecting SR SSCs and determining functional design criteria for those SSCs to ensure the commercial nuclear plant meets the safety criteria in 10 CFR 53.210. The overall control of risks posed by commercial nuclear plants under 10 CFR Part 53 is addressed by the analyses of and measures taken for both DBAs and other LBEs, including very unlikely event sequences. This contrasts with the traditional deterministic approach in 10 CFR Part 50 wherein the analyses of DBAs are used to provide bounding assessments, incorporate standard design rules such as assumptions related to single failures, and to define conservative performance requirements for SR SSCs.

The NRC agrees with limiting crediting of inherent characteristics as the comment states. The proposed and final rules explain that the term ''engineered design feature'' within 10 CFR 53.250(c) does not preclude the possible crediting of inherent characteristics within the design and analysis for commercial nuclear reactors. However, this statement is also in the context of the preceding requirements in 10 CFR 53.250(a) and (b) to provide defense in depth to address uncertainties related to the state of knowledge and modeling capabilities, the ability of barriers to limit the release of radioactive materials from the facility during LBEs other than DBAs, the reliability and performance of plant SSCs and personnel, and the effectiveness of programmatic controls. Uncertainties related to inherent characteristics of design features are addressed by these provisions as well as the design requirements of 10 CFR 53.440(a) that requires each design feature, including any credited inherent characteristics, to be demonstrated by analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.2.2.H: Two commenters wrote that the proposed rule's defense-in-depth requirement is deterministic instead of performance-based as 10 CFR 53.250(c) requires that no single barrier be used to address licensing-basis events other than design-basis accidents, even if there is reasonable assurance that the uncertainty in 10 CFR 53.250(a) and (b) has been addressed (BI1-0006, SCWG-0012).

Another commenter wrote that the rule text in 10 CFR 53.250 is a remnant of the single failure criterion and not consistent with 10 CFR 53.220 if the risk metrics already include, do not require, or do not allow a single failure (RD-0018).

Two commenters recommended removing 10 CFR 53.250(b) and (c) writing that the approach in 10 CFR 53.250(a) is risk-informed and appropriately compensates for uncertainties (BI1-0006, SCWG-0012).

Another commenter recommended rewriting the requirements to assess single points of failure using multiple tool and analyses and to provide sufficient diversity and redundancy in the design (RD-0018).

A commenter wrote that the approach in the proposed rule creates challenges for anticipated event sequences that are not expected to result in the release of radioactive materials, even if the event does occur, as the definition of licensing-basis events includes these anticipated event sequences. The commenter added that the preamble should explicitly acknowledge that inherent safety features can play a role in meeting defense-in-depth objectives without dictating their use or precluding other approaches (BI1-0006).

A commenter recommended that the role of inherent safety features in defense in depth be emphasized in guidance rather than rule language, highlighting specifically that (SCWG-0012):

- The principle that no single barrier should be relied upon for non-design basis licensing events should be addressed in guidance rather than codified in rule.
- The NRC should clarify in the preamble that inherent safety features can be relied upon for defense-in-depth, ensuring that applicants can use them effectively without rigid prescriptive requirements.
- The existing regulatory framework, including RG 1.174, provides sufficient guidance on DID without additional process-level requirements.

NRC Response: The NRC disagrees with the comments.

Regarding the comments suggesting deletion of 10 CFR 53.250(b), identifying some specific uncertainties to be addressed through defense in depth measures contributes to regulatory certainty. The NRC also disagrees with the suggested deletion of 10 CFR 53.250(c) and the prohibition against the safety analysis relying upon a single engineered design feature, human action, or programmatic control, no matter how robust, to address the range of LBEs other than DBAs. The comment which references defense in depth for anticipated event sequences misinterprets the requirement, as explained below.

As described in the final rule, the requirement under 10 CFR 53.250(c) is different from the single failure criterion described in Appendix A to 10 CFR Part 50 in that 10 CFR 53.250 allows for greater flexibility such that other measures could be taken to ensure appropriate defense in depth without needing to accommodate single failures, as defined in Appendix A to 10 CFR Part 50.

The underlying concept of 10 CFR 53.250(c) is similar to that described in various standards and guidance issued by the International Atomic Energy Agency, the LMP methodology, and NRC references such as NUREG/KM-0009, “Historical Review and Observations of Defense-in-Depth,” issued April 2016 (ML16104A071).

References within the comment to the existing regulatory framework fail to acknowledge that defense in depth is addressed within 10 CFR Part 50 by prescribing specific principal design criteria, including specific layers or barriers to limit the release of radionuclides, specific design rules such as application of the single failure criterion to each layer, and the identification of specific events to be analyzed. As explained in the proposed and final rules, 10 CFR Part 53 reflects an integrated decision-making process similar to that described in RG 1.174, but RG 1.174 is not directly applicable since it is used to evaluate changes within the generally prescriptive and deterministic 10 CFR Part 50 framework. Regarding that part of the comment mentioning inherent characteristics, the proposed and final rules explain ‘‘engineered design feature’’ would not preclude the possible crediting of inherent characteristics within the design and analysis for commercial nuclear reactors. Limitations on the crediting of inherent characteristics are explained in the response to Comment Bin 3.2.2.G.

Accordingly, the NRC did not change the rule language in response to these comments.

3.2.3. Radiation protection programs (e.g., §§ 53.260-53.270, meeting the requirements of 10 CFR Part 20)

Comment Bin 3.2.3.A: Multiple commenters suggested deleting the requirements in 10 CFR 53.270 for keeping dose as low as reasonably achievable (ALARA), writing that 10 CFR 53.260 and 10 CFR 53.270 are unnecessary as they are redundant with the dose standards in 10 CFR Part 20 and ALARA is already achieved by operational considerations through 10 CFR Part 20, which they said applies to all 10 CFR Part 53 licensees even if 10 CFR Part 53 does not explicitly state this (NEI2-0042, NEI2-0043, USNIC2-0022, NEI2-0006). One of the commenters wrote that 10 CFR 53.430 elevates ALARA requirements to specific design requirements and new functional design criteria, increasing regulatory burden compared to 10 CFR Part 50 and 10 CFR Part 52 (USNIC2-0022).

NRC Response: The NRC agrees, in part, with the comments.

As explained in the proposed and final rules, the NRC has historically seen and continues to see benefits to including requirements for radiation protection during normal operations for commercial nuclear plants, even though this includes references to 10 CFR Part 20. The requirements in 10 CFR 53.425 and 10 CFR 53.430 for design features and functional design criteria to support radiation protection activities have parallels in other regulations such as 10 CFR 50.34(a) and (b)(3), which require in part that the means be provided for meeting the requirements of 10 CFR Part 20; 10 CFR 50.34a, “Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors”, General Design Criterion 60, 61, 63, and 64 in Appendix A to 10 CFR Part 50, which provide radiation protection related design criteria; and Appendix I, “Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion "As Low as is Reasonably Achievable" for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents,” to 10 CFR Part 50.

Accordingly, the NRC did not change the rule language in response to these comments.

However, the NRC agrees that referring to 10 CFR Part 20 is sufficient to address radiation protection standards. Accordingly, the NRC revised the final rule to remove specific references within Part 53 to ALARA and only included direct references to 10 CFR Part 20.

3.2.4. Other comments on Subpart B (§§ 53.230-53.270)

Comment Bin 3.2.4.A: Two commenters wrote that it is unclear what purpose is served by defining primary and alternative safety functions other than to justify including the comprehensive risk metrics in 10 CFR 53.220 (NEI2-0039, USNIC2-0021). One of the commenters questioned what purpose is served by defining primary and alternative safety functions, other than to justify including the comprehensive risk metrics in 10 CFR 53.220, and asked whether the NRC intends that some safety functions (primary) are only needed to meet the “reasonable assurance of adequate protection of public health and safety” standard while other safety functions (additional) are needed to meet the “to protect health or to minimize danger to life or property” standard. The commenter reasoned that safety functions should relate to DBAs and requirements for SR SSCs because any other functions the plant needs to provide may be safety-significant but would not be safety-related.

The commenter read the statement that safety functions must be maintained for LBEs as implying that there is an equivalence in the design standards for SR SSCs that are needed for DBAs to meet 10 CFR 53.210 and those for NSRSS and non-safety-significant SSCs that are relied upon for AOOs and BDBEs. The commenter warned that such an equivalence could lead to unintended consequences in that it would elevate the NSRSS and non-safety-significant SSCs to need similar confidence in performance as SR SSCs, thus increasing regulatory burden without increasing safety. Noting that many codes and standards rely on the term “safety function” as traditionally understood to mean safety-related functions, the commenter expressed concern that expanding it to NSRSS would cause confusion and overprescription of requirements.

Because examples in regulation may be interpreted as minimum requirements, the commenter stated, the language used in the rule should make clear that safety functions are design specific.

The commenter suggested that the NRC could address their concerns and improve the clarity of 10 CFR 53.230 by removing paragraph (a), redesignating paragraphs (b) and (c) as (a) and (b), and revising them to read as follows (NEI2-0039):

> (a) The safety functions necessary to meet 53.210 must be identified for each commercial nuclear plant. Controlling reactivity, heat generation, heat removal, and chemical interactions are examples of possible safety functions depending on the specific technology and design.
>
> (b) The SR SSCs must be capable of performing their intended safety functions. NSRSS SSCs may be relied upon to accomplish the safety functions for other LBEs, or more restrictive alternative criteria adopted under § 53.470.

Another commenter wrote that the term “primary safety function” is a broad new construct which will be subject to ill-defined and moving regulatory requirements. The commenter wrote that both the AEA and NEIMA require safety functions involving graduated levels of risk with appropriately tethered design criteria requirements which would not be met by the primary safety criteria term introduced in the rule. The commenter recommended replacing 10 CFR 53.230 with the following text (HPT10-0001, HPT10-0002):

> Nuclear Safety Functions are: (1) those graduated, risk-informed features that directly protect the public from hazardous radiation releases (25 Rem of section 53.210) that may occur as a result of limiting Design Basis Events and Design Basis Accident; and (2) those lesser graduated, risk-informed features that support defense-in-depth protection of the public. The Nuclear Safety Functions shall be used in conjunction with development of Nuclear Safety Design Criteria and the accompanying nuclear safety categorization of systems, structures, and components. The applicant is to identify and justify the use of their Nuclear Safety Functions.

A commenter wrote that they agreed with another commenter’s proposal to relocate rule text to guidance in order to reduce the level of prescription in the requirements. Specifically, the commenter approved of rewriting 10 CFR 53.230 as follows (RAD-0013):

(a) The primary safety function is limiting the release of radioactive materials from the facility over the life of the plant.

(b) Safety functions needed to support the retention of radioactive materials--such as controlling reactivity, heat generation, heat removal, and chemical interactions--must be identified for each commercial nuclear plant.

NRC Response: The NRC disagrees with the comments.

As explained in the proposed and final rules, 10 CFR 53.230 requires safety functions needed to ensure that the safety criteria under 10 CFR 53.210 and 10 CFR 53.220 can be met if an assumed LBE were to occur at a commercial nuclear plant. Limiting the release of radioactive materials from the facility is identified as the primary safety function to support a technology-inclusive framework since the risks posed by the effects of ionizing radiation are the common hazard from any commercial nuclear plant. The identification of limiting the release of radioactive materials as the primary safety function also supports use of estimated doses to hypothetical individuals resulting from licensing-basis events as the primary performance metric throughout 10 CFR Part 53. The additional or subsidiary safety functions needed to limit the release of radionuclides may include, without limitation, controlling processes related to reactivity, heat generation, heat removal, and chemical interactions. 10 CFR Part 53 provides flexibility to applicants and licensees in identifying, implementing, and maintaining the safety functions supporting retention of radionuclides for commercial nuclear plants of varying sizes and technologies.

The risk-informed and performance-based framework in 10 CFR Part 53 uses an overall hierarchy that covers: (1) plant-level safety criteria; (2) safety functions needed to demonstrate compliance with the safety criteria; (3) design features, human actions, and programmatic controls needed to fulfill the safety functions; and (4) functional design criteria defined for each design feature relied on to demonstrate the safety criteria are met. This hierarchy is reflected throughout 10 CFR Part 53 and is most obvious in the structure and requirements within Subpart B, which addresses the plant-level safety criteria and safety functions, and Subpart C, which addresses design features and functional design criteria. The sections of 10 CFR Part 53 for design features and functional design requirements allow a grading of requirements based on risk insights, safety categorization, and special treatments that will differ between safety-related and non-safety-related but safety-significant structures systems and components. 10 CFR 53.240(c) requires that the safety functions be fulfilled by the design features, human actions, and programmatic controls specified throughout 10 CFR Part 53, including provisions in Subpart F, "Requirements for Operation," to maintain the capabilities to fulfill the identified safety functions during plant operations.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.2.4.B: A commenter recommended that the NRC replace the use of "LBEs other than DBAs" with "LBEs" throughout 10 CFR Part 53, asserting that the phrase "LBEs other than DBAs" could create confusion. The commenter argued that replacing the phrase would not change the intent of the regulation, and supporting guidance can provide clarity in the LBEs requiring assessment.

Specifically, the commenter wrote that for 10 CFR 53.220 and 10 CFR 53.250, RG 1.233 holistically accounts for both DBAs and non-DBA LBEs. For 10 CFR 53.220(b), the commenter wrote that the design-basis external hazard level (DBEHL) concept ensures that risk of a set consequence remains below a certain frequency. The commenter also recommended that 10 CFR Part 53 use the NEI 21-07, “Technology Inclusive Guidance for Non-Light Water Reactors, Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology” issued February 2022, design-basis hazard levels (DBHLs) concept instead of DBEHLs or clarify when requirements apply to either. For 10 CFR 53.240, the commenter wrote that DBAs and other LBEs, informed by general design criteria (GDC) can establish the safety criteria in 10 CFR 53.420. For 10 CFR 53.450(e)(1), the commenter wrote “other generally accepted approaches for systematically evaluating engineered systems” should allow for traditional DBA approaches to systematic evaluations (NEI2-0013).

The commenter also suggested that removing “other than DBAs” would enable applicants to take more flexible analytical approaches, beyond an analysis meeting consensus standards for a PRA, which would comport with the SRM-SECY-23-0021 and section 208 of the ADVANCE Act (NEI2-0251, NEI2-0013).

The commenter also asserted that this approach would help facilitate transitions from 10 CFR Part 50 and 10 CFR Part 52 to 10 CFR Part 53, such as the transition from a CP to an operating license (OL) or design certification and provide public confidence in the equivalence of all parts in addressing public health and safety (NEI2-0013).

NRC Response: The NRC agrees, in part, with the comments.

The NRC disagrees with the majority of these comments related to the organization and terminology for LBEs. The NRC selected the terminology to distinguish between those LBEs in the categories of anticipated, unlikely, and very unlikely event sequences analyzed under 10 CFR 53.450(e) that are considered in assessing the risk performance objectives under 10 CFR 53.220(b) and design-basis accidents analyzed under 10 CFR 53.450(f). These LBE categories are similar to the related construct from NEI 18-04, as endorsed by RG 1.233, which describes the DBA category and three, frequency-based categories as being types of LBEs. Three event categories are also used in recent NRC activities under 10 CFR Part 50 and 10 CFR Part 52 and in the framework developed by IAEA. The requirements under 10 CFR Part 53 refer to “DBA” and “LBE other than DBA” consistent with the different purposes those types of LBEs serve in meeting safety criteria under 10 CFR 53.210 and 10 CFR 53.220, respectively. Thus, the NRC concludes that the clarity provided by the phrase “other than DBA” outweighs the risk of confusion. Additionally, changes to the rule language in 10 CFR 53.450 in response Comment Bin 3.3.2.2.E allow a broader spectrum of types of systematic risk evaluations, which offers applicants flexibility to potentially use more traditional approaches in combination with risk-informed approaches when developing safety analyses under 10 CFR Part 53.

Regarding the need to address both internal hazards such as room flooding from fluid system malfunctions and external hazards such as flooding from extreme precipitation, the NRC agrees that both need to be addressed within the design and analyses for commercial nuclear plants. 10 CFR Part 53 specifically addresses the protection of safety-related SSCs from external hazards up to design-basis external hazard levels in 10 CFR 53.415 to reflect the relationships between the design and analysis requirements in Subpart C and the siting requirements in Subpart D. The consideration of ranges of internal and external hazards is otherwise addressed within the LBEs by the requirement in 10 CFR 53.240 for the systematic evaluation of appropriate risk-informed combinations of malfunctions of plant SSCs, human errors, facility hazards, and the effects of external hazards. The NRC made a clarifying change to 10 CFR 53.240(b) in response to Comment Bin 3.2.4.D. Regarding the potential use of the GDC from Appendix A to 10 CFR Part 50 to inform the development of functional design criteria under 10 CFR 53.420, see the NRC's response to Comment Bin 3.1.1.A. Regarding the assertion on transitions from 10 CFR Part 50 and Part 52 to 10 CFR Part 53, see the NRC's response to Comment Bin 3.8.1.A.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.2.4.C: A commenter wrote that 10 CFR 53.240 requires applicants to identify their own licensing-basis events on a case-by-case basis which is ambiguous and will negatively impact the public's ability to understand the current licensing basis or participate in the 10 CFR 2.206 process (NYS2-0007).

NRC Response: The NRC disagrees with the comment.

As explained in the proposed and final rules, 10 CFR Part 53 is a risk-informed, performance-based, and technology-inclusive regulatory framework for commercial nuclear plants. The framework provides a general methodology for the identification of licensing-basis events that includes a systematic assessment of reactor designs and analysis of various combinations of malfunctions of plant SSCs, human errors, facility hazards, and the effects of external hazards, which enables the rule to meet the requirements in NEIMA to establish a technology-inclusive licensing framework.

Additional information on one way that licensees may meet these general standards is provided in RG 1.254, ''Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants," issued concurrently with the final rulemaking. Moreover, the NRC anticipates providing additional guidance on meeting 10 CFR Part 53 following the rule's publication. The NRC acknowledges that 10 CFR Part 53 provides high level standards that could be met by applicants employing a wide-range of technology; nonetheless, for all plants licensed under 10 CFR Part 53, the licensing process will yield a set of requirements and specifications in the plant's individual license that will clearly state the facility's licensing basis and thereby also allow meaningful participation in the 10 CFR 2.206 process.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.2.4.D: A commenter asserted that because 10 CFR 53.240 duplicates requirements elsewhere in the rule, it could lead to unintended consequences and increased regulatory complexity and burden without an increase in safety. The commenter added it is important to ensure that only "relevant" or "appropriate" combinations of hazards are considered. The commenter suggested multiple revisions to the section as follows (NEI2-0040, NEI2-0013, NEI3-0013):

- In paragraph (a), delete "and analyzed under § 53.450 to demonstrate that the safety requirements in this subpart have been satisfied."

- In paragraph (b), change the language from "address combinations of" to read "address appropriate combinations of" or "address relevant combinations of."

- In paragraph (c), remove paragraph (1) (“Include analysis of one or more DBAs under § 53.450(f)”).

The commenter also wrote that the existing language in 10 CFR 53.240(c)(2) is ambiguous and recommended replacing “Confirm the adequacy of design features and programmatic controls” with “Evaluate the adequacy of design features and programmatic controls” (NEI3-0014).

NRC Response: The NRC agrees, in part, with the comments.

The NRC disagrees with deleting the reference to 10 CFR 53.450 in 10 CFR 53.240(a) because it makes a distinction between what analyses are required for LBEs versus measures and design features addressed by other analyses.

The NRC agrees that clarification was warranted for the language used in 10 CFR 53.240(b) and revised the final rule to state that LBEs must collectively address “appropriate risk-informed” combinations of malfunctions of plant SSCs, human errors, facility hazards, and the effects of external hazards.

The NRC disagrees with deleting 10 CFR 53.240(c)(1) because doing so would remove the requirement to include DBAs in a licensing basis, which is a fundamental construct of the 10 CFR Part 53 regulatory framework.

The NRC disagrees with the recommended change to 10 CFR 53.240(c)(2) because requiring that the evaluation only be performed may not result in determining whether design features and programmatic controls are adequate to satisfy the safety criteria in 10 CFR 53.210 and 10 CFR 53.220.

Accordingly, the NRC did not change the rule language in response to these comments, except for the suggested change to 10 CFR 53.240(b).

Comment Bin 3.2.4.E: A commenter recommended revising 10 CFR 53.230 to improve the structure and organization of the rule language. With regard to 10 CFR 53.230(a), the commenter wrote that this paragraph identifies limiting release of radioactive materials as the primary safety function over the life of the plant. The commenter wrote that, interpreted according to the terms of ANSI/American Nuclear Society (ANS)-30.3, the requirement would apply at the plant level so that all design features and programmatic controls support the requirement. The commenter wrote that from the perspective of structured performance objectives in a performance-based approach, the safety objective of limiting release of radioactive materials would occur at the highest level, then decomposed to show relationships and dependencies of other supporting functions, and the performance standard associated with the primary safety function should apply consistently for requirements specified for all phases. The commenter recommends revising 10 CFR 53.230(a) as follows:

> (a) The primary safety function is limiting the release of radioactive materials from the facility over the life of the plant.

The commenter also wrote that the rule language in 10 CFR 53.230(b) is confusing as it implies that the functionalities associated with controlling reactivity, heat generation, heat removal, and chemical interactions are significant only during those events identified as LBEs. This would be erroneous because these functionalities are important considerations during all phases of the plant life cycle. The commenter recommends revising 10 CFR 53.230(b) as follows:

> (b) Safety functions needed to support the retention of radioactive materials - such as controlling reactivity, heat generation, heat removal, and chemical interactions - must be identified for each commercial nuclear plant.

The commenter wrote that these changes to both paragraphs would apply systems-engineering best practices and would make the requirements better aligned with performance-based principles (ROSE-0005).

NRC Response: The NRC disagrees with the comment.

As explained in the proposed and final rules, 10 CFR 53.230 requires safety functions needed to ensure that the safety criteria under 10 CFR 53.210 and 53.220 can be met if an assumed LBE were to occur at a commercial nuclear plant. The structure of 10 CFR Part 53 distinguishes between the safety functions associated with preventing or mitigating unplanned events and the design features and programmatic controls to limit doses to the public and workers that result from normal operations.

Accordingly, the NRC did not change the rule language in response to this comment.

3.3. Subpart C: Design and Analysis Requirements (§§ 53.400-53.480)

3.3.1 Design features and functional design criteria (§§ 53.400-53.430)

Comment Bin 3.3.1.A: For alignment with the licensing framework under 10 CFR Part 50 and 10 CFR Part 52, a commenter recommended the NRC revise 10 CFR 53.425 to make the requirements apply on a per-reactor and/or per-license basis rather than on a per-site basis, which could impose overly restrictive constraints from a design perspective for effluents during normal operations, especially when multiple reactors are planned for a single site (NEI2-0044).

NRC Response: The NRC disagrees with the comment.

As a technology-inclusive regulatory framework, 10 CFR Part 53 was developed for the evaluation of unplanned and routine releases of radiological material to be performed on a sitewide basis recognizing that some designs may have multiple reactors operating at a single site and some designs could have many more reactors on site than currently operating facilities. In addition, some reactor technologies will have significant inventories of radioactive material in storage and process systems that may differ from single reactors and associated waste systems in the current operating reactor fleet. Thus, in 10 CFR Part 53, the NRC is establishing release limits and performance goals on a site basis to more accurately address the risks posed by all of the potential sources of radiological effluents associated with a commercial nuclear plant.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.3.1.B: Stating that the functional design requirements in 10 CFR 53.410, 10 CFR 53.420, 10 CFR 53.425, and 10 CFR 53.430 are nearly identical, a commenter expressed concern that such repetition and duplication would reduce regulatory clarity and predictability and increase regulatory complexity and burden without an increase in safety. The commenter suggested revising 10 CFR 53.410 by:

- shortening the section heading to “Functional design criteria” to align with the hierarchical flow of “design features” and “functional design criteria”;
- adding cross-references to 10 CFR 53.220, 10 CFR 53.260, and 10 CFR 53.270 at the end of paragraph (a); and
- deleting paragraph (b) as the requirements are appropriately addressed in Subpart F, “Requirements for Operation.”

The commenter stated that if the NRC revises 10 CFR 53.410 as suggested, then it should remove 10 CFR 53.420, 10 CFR 53.425, and 10 CFR 53.430 because the revision incorporates those requirements. If the NRC does not implement the above approach, the commenter recommended revising 10 CFR 53.420, 10 CFR 53.425, and 10 CFR 53.430 to limit the requirement that functional design criteria must be defined for each design feature to only those design features classified as NSRSS (NEI2-0045).

NRC Response: The NRC agrees, in part, with the comment.

Although some of the language in 10 CFR 53.410, 10 CFR 53.420, 10 CFR 53.425, and 10 CFR 53.430 is very similar, these sections are unique in that they are intended to distinguish between treatments of SR and NSRSS SSCs and with respect to normal operations, the control of identified functional design criteria though the design lifecycle, and special treatments. This organization is consistent with other similar portions of 10 CFR Part 53 in Subparts B and C. However, the NRC agrees these requirements may benefit from additional specificity to further make these distinctions. Accordingly, the NRC revised the rule language in response to this part of the comment to add specificity in 10 CFR 53.410 and 10 CFR 53.420 on the applicable safety categories of SSCs.

The NRC disagrees with the other suggested changes related to the observed repetition as it does not see an advantage to such a reorganization of requirements. Accordingly, the NRC did not change the rule language in response to this part of the comment.

Comment Bin 3.3.1.C: A commenter stated that, should the NRC not remove 10 CFR 53.425, the NRC should remove from 10 CFR 53.425(c) the footnote that indirectly establishes a design objective of 10 mrem[/year] for keeping doses to the public ALARA, as there is currently no guidance available on how this design objective can be achieved, and instead develop and provide guidance that documents what could be considered a reasonable design objective, including flexible methods or criteria for meeting it (NEI2-0046).

NRC Response: The NRC agrees with the comment.

The NRC and its predecessor the Atomic Energy Commission recognized the benefits of including a design objective to allay fears that ALARA would be interpreted as a need to continually strive for lower and lower goals for radiation exposures to the public or plant workers. In the original version of Appendix I to 10 CFR Part 50 (40 FR 19442, May 5, 1975), the Commission stated that “[d]esign objectives and limiting conditions for operation conforming to the guidelines of [Appendix I] shall be deemed a conclusive showing of compliance with the “as low as practicable” requirement of 10 CFR 50.34a and 10 CFR 50.36a. The NRC continues to believe that including a requirement to define a design objective in 10 CFR 53.425 is beneficial, but that such a requirement is sufficient without including numerical guidelines for the design objective and that the detail in the footnote in the proposed rule is not required.

Accordingly, the NRC revised 10 CFR 53.425(c) to remove the footnote, which had provided an acceptable design objective of an annual dose to members of the public of less than 10 mrem. Additionally, the NRC revised the final rule to remove specific references within Part 53 to ALARA because referring directly to 10 CFR Part 20 is sufficient to address radiation protection standards.

Comment Bin 3.3.1.D: A commenter recommended the NRC revise 10 CFR 53.420(a) to apply only to design features classified as NSRSS, stating this revision would help applicants understand and apply the appropriate level of rigor to different classifications of components (NEI3-0012).

NRC Response: The NRC agrees in part with the comment.

The NRC agrees that adding specificity improves the requirement. The NRC disagrees that applying functional design criteria only to design features classified as NSRSS is appropriate since functional design criteria for SR SSCs may be accounted for in LBEs other than DBAs in addition to functional design criteria for NSRSS SSCs.

Accordingly, the NRC revised the rule language in response to this comment to address both SR and NSRSS in 10 CFR 53.420(a).

Comment Bin 3.3.1.E: A commenter stated that 10 CFR 53.415 could be interpreted to require all SR SSCs to be able to withstand and be capable of performing their safety functions for the DBHL of all hazards, which would be inappropriate for the performance-based nature of Part 53 and may impose onerous design requirements on SR SSCs and complex analyses to demonstrate that the requirement is met. The commenter added that while the primary role of DBAs under the proposed rule is the identification of SR SSCs that are necessary to ensure plant safety, the role and importance of the SR SSCs may differ depending on the accident scenario. The commenter stated that 10 CFR 53.415 should require that SR SSCs be protected against or be designed to withstand all DBHLs, but the requirement to be capable of performing their safety functions should only be required for those DBHLs where performance of the SR SSC may be necessary. The commenter also provided recommended rule text changes for 10 CFR 53.415. The commenter added that this would align the requirements of SR SSCs with the approach of special treatments for NSRSS SSCs (IDNL-0004).

NRC Response: The NRC disagrees with the comment.

The construct of 10 CFR Part 53 includes evaluating a range of event sequences as LBEs other than DBAs. These event sequences can be organized into licensing-basis events and distinguish between contributors to initiating events related to various natural or constructed hazards. This flexibility provides opportunities to refine special treatments for some SSCs. However, in addition to the realistic evaluations and flexibilities associated with LBEs other than

DBAs, 10 CFR Part 53 requires the analysis of DBAs using a more deterministic approach and requires the identification of safety-related SSCs.

As explained in the proposed and final rules, SR SSCs provide that a defined success path exists for DBAs and 10 CFR 53.415 states that those SR SSCs remain capable of performing the safety functions stated in 10 CFR 53.230 for which they are credited up to the design-basis external hazard levels as determined under 10 CFR 53.510. This requirement maintains the traditional protection of SR SSCs and generally allows the DBAs to be analyzed separately from the evaluations of design basis external hazard levels. The comment provides possible examples where the protection of specific SR SSCs from specific external hazards may not be warranted. The NRC believes these special circumstances can be addressed using the language in 10 CFR 53.415, which states that protections from external hazards should preclude "losing the capability to perform the safety functions identified under §53.230."

Accordingly, the NRC did not change the rule language in response to this comment.

3.3.2. Other comments on Subpart C provisions (§§ 53.440-53.480, including design and analysis requirements, safety categorization, and special treatment)

3.3.2.1. Comments on § 53.440

Comment Bin 3.3.2.1.A: Many commenters expressed concern about the scope and substance of 10 CFR 53.440(b), which proposed a requirement to use generally accepted consensus codes and standards that have been endorsed or otherwise found acceptable by the NRC for SR SSCs and NSRSS SSCs (HPT8-0001, HPT8-0002, HPT32-0001, HPT32-0003. NEI2-0049, HPT42-0006, ANS-0002, RAD-0001, BI1-0012, ROSE-0016, ROSE-0002, NEI3-0019, NEI2-0009, DOM-0006, USNIC2-0013).

A few commenters added that the proposed requirement could increase regulatory burden and create barriers to efficient licensing and oversight without an apparent safety benefit (RAD-0001, ROSE-0016, ROSE-0002, DOM-0006).

One commenter stated this approach has no historical precedence and NEIMA established that consensus is acceptable for licensing purposes (HPT8-0001, HPT32-0001, HPT42-0006). The commenter also questioned the legality of the NRC's endorsement of industry codes and standards through guidance documents and suggested that requiring such endorsement conflicts with NEIMA's directive to use such codes and standards. The commenter further stated that there is no apparent mechanism for obtaining NRC endorsement other than during the application process (HPT8-0002). The commenter also stated that the process of endorsing codes and standards is extraordinarily time consuming and would lessen the public's safety because reactor designs, inspections, and operations would be forced to employ outdated standards/codes (HPT32-0001).

The commenter proposed removing this requirement from 10 CFR 53.440, and instead replacing it with a requirement for the applicant to identify the codes and standards involving the principal design criteria (as used in 10 CFR Part 50) associated with nuclear safety functions, noting that NRC review and enforcement efforts would need to recognize that the Nuclear Safety-Related items carry more importance that lesser functional items (HPT8-0002, HPT42-0006).

The commenter also recommended that the NRC identify codes/standards with which the NRC has participated in consensus code/standard development activities and that specific sub-sections of 10 CFR Part 53 identify that the applicant is expected to identify the key codes/standards, as well as the intended application involving the sub-section. If the NRC requires more specific information than that, the commenter recommended that the inquiries should be employed as part of the NRC licensing review efforts and appropriately consider the level of risk, and that 10 CFR Part 53 should state that review efforts must be proportionate to the level of risk (HPT32-0003).

Another commenter recommended that the NRC should at a minimum limit the scope of paragraph 10 CFR 53.440(b) to SR SSCs and clarify what the scope of “design” is. The commenter stated that including NSRSS SSCs here is problematic, because for many of them there are no NRC-endorsed codes and standards other than safety-related codes and standards, which would create a barrier to the use of NSRSS SSCs that is contrary to the goal of a more flexible and efficient licensing process. The commenter suggested changing the qualification for design features from those that are “required by § 53.400” to those that are “safety related” (NEI2-0049).

Two commenters recommended changing the qualification for codes and standards from those that “have been endorsed or otherwise found acceptable by the U.S. Nuclear Regulatory Commission (NRC)” to those that “are sufficient to meet the design criteria defined under 53.410, 53.420, 53.425, and 53.430” (BI1-0012, NEI2-0049). One commenter wrote that under this change: the NRC would still be able to endorse codes and standards to define what is acceptable in meeting 10 CFR 53.440(b) but without unnecessarily slowing down the licensing process. The commenter also recommended adding language to the preamble to describe the scope of the requirements in 10 CFR 53.440(b) (NEI2-0049).

The commenter also suggested that if the scope of the section continues to include NSRSS SSCs, then the NRC should endorse these codes and standards as appropriate for NSRSS SSCs: International Organization for Standardization (ISO)-9001, NEI 22-04, American Society of Mechanical Engineers (ASME) Section VIII, ASME B31.1 and B31.3, American Society of Civil Engineers (ASCE) 7, American Institute of Steel Construction (AISC) 360, and American Concrete Institute (ACI) 318, plus any additional unendorsed codes and standards that may have been used or proposed for use for U.S. reactors. The commenter noted that this list is incomplete, and effort would be needed to identify a comprehensive set of codes and standards that applicants intend to use for NSRSS SSCs under LMP (NEI2-0009, NEI3-0019).

One commenter stated that NEIMA demands the NRC to collaborate with standards-setting organizations to identify specific technical areas and incorporate the respective consensus-based codes and standards into the regulatory framework, and the proposed rule should be modified to ensure that codes and standards for safety components are applied at least as stringently as they are in the current licensing frameworks, particularly for 10 CFR Part 50 and 10 CFR Part 52. The commenter also suggested that 10 CFR 53.440(c) be revised to only apply to SR SSCs, and that the NRC should ensure that components are classified using performance-based approaches (BI1-0012).

Commenters urged the NRC to conform with directives for “Federal agencies to adopt voluntary consensus standards wherever possible” and “to meet respective agency requirements in an efficient and cost-effective manner for the agency and its stakeholders,” noting that consensus standards provide the basis for currently operating plants, and some were not reviewed and endorse by the NRC, and safety improvements for advanced reactors are often reflected in approved consensus standards before the NRC gets involved (RAD-0001, ROSE-0016, ROSE-0002).

Another commenter stated that commercial codes and standards have been applied at large complex chemical facilities that are considering co-location of nuclear facilities at their industrial facilities, and that the NRC should allow such codes that have a long history of allowing safe commercial operations to be used in meeting nuclear requirements. The commenter added that the requirement to use NRC-endorsed codes and standards is not performance-based and presents an implementation challenge and noted that useful dialog to address this issue was provided in the February 11, 2025 NRC public meeting "Application of Commercial Codes and Standards by Advanced Reactor Vendors and Applicants." The commenter asked the NRC to justify why existing codes/standards not endorsed by the NRC are insufficient for use (USNIC2-0013).

Another commenter stated that the phrasing “generally accepted consensus codes and standards” is different than that in section 12(d)(1) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104-113) and Office of Management and Budget (OMB) Circular A-119, which refer to and establish preference for "volunteer consensus standards," and asked the NRC to revise this language for clarity or justify the departure. The commenter also stated the apparent requirement for prior endorsement of codes and standards could discourage the use of new, revised, or previously unapproved codes and standards, and asked the NRC to either provide additional justification for this requirement, if this interpretation is correct, or revise the rule text for clarity (ANS-0002).

Another commenter added there are no codes and standards currently endorsed for NSRSS SSCs, which could make applicants feel like they are required to apply codes and standards for SR SSCs to NSRSS SSCs, and the current requirement would provide no reason for applicants to choose 10 CFR Part 53 over 10 CFR Part 50 or 10 CFR Part 52. The commenter suggested limiting the scope of 10 CFR 53.440(b) to SR SSCs, as is the case for other sections (e.g., 10 CFR 53.415), and stated that if the scope of the section continues to include NSRSS SSCs, then the NRC should endorse ASCE 7, AISC 360, and ACI 318 for NSRSS SSCs (NEI2-0005, NEI2-0182).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees that NRC review and endorsement of the numerous consensus codes and standards that may be used for SSC not classified as safety-related would potentially create a substantial obstacle to efficient licensing and could impede flexibilities that are otherwise intended to be afforded by the regulatory framework under 10 CFR Part 53. The NRC therefore revised 10 CFR 53.440(b) in the final rule to be applicable to only SR SSCs. Related changes were made to the definition of special treatment in 10 CFR 53.020 (see the NRC’s response to Comment Bin 3.1.1.G) and the related discussion in the final rule FRN to further clarify that special treatment are those measures taken beyond the procurement, installation, and maintenance of commercial grade products. The design and fabrication of commercial grade products may include the use of selected consensus codes and standards. The consensus codes and standards for commercial grade products used for NSRSS SSCs would be cited in applications to support the identification of special treatments that may go beyond what would otherwise be required by those selected commercial codes and standards. The NRC also acknowledges that the consideration of consensus codes and standards for NSRSS SSCs is also being discussed in the context of applications developed using the LMP methodology and broader NRC efforts to improve the efficiency of its regulatory programs.

While acknowledging the above revision to limit the need for NRC approval of consensus codes and standards to those used for SR SSCs, the NRC disagrees that the NRC review and endorsement of consensus codes and standards is a new concept introduced by 10 CFR Part 53. The regulations in 10 CFR Part 50 incorporate by reference selected consensus codes and standards and numerous other consensus codes and standards endorsed by the NRC are referenced in RGs issued by the NRC. The NRC explained the use of consensus standards consistent with the provisions of the NTTAA and the role of related NRC reviews in the document "Analysis of Public Comments on Draft Interim Staff Guidance [ISG] Division of Advanced Reactors and Non-Power Production or Utilization Facilities [DANU]-ISG-2022-01; Advanced Reactor Content of Application Project 'Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications-Roadmap'" (ML23277A148).

The NRC acknowledges the suggestion to revise the rule language from "generally accepted consensus codes and standards" to "volunteer consensus standards" but has not incorporated the change. The phrase "generally accepted consensus codes and standards" has been maintained in recognition that codes and standards referenced in applications and possibly submitted to the NRC for endorsement may come from organizations other than recognized standards development organizations. The NRC did, however, remove the definition of "consensus code or standard" from 10 CFR 53.020 (see response to Comment Bin 3.1.1.C) to remove some conflicting language within the regulations.

Finally, the NRC observes that guidance documents, such as those that endorse industry codes and standards, are a well-established part of the regulatory process. Requiring use of codes and standards that the NRC has endorsed or found acceptable does not conflict with NEIMA's direction to use such codes and standards. NRC review of consensus codes and standards can be requested independently from and on an individual basis outside of an application review via mechanisms like the Topical Report review process.

Accordingly, the NRC revised the rule language in response to this comment. Specifically, the NRC revised the requirement in 10 CFR 53.440(b) to specifically apply to SSCs classified as SR and also removed the definition of "consensus code and standard."

Comment Bin 3.3.2.1.B: A few commenters expressed concern about language in 10 CFR Part 53 that suggests requirements traditionally limited to SR SSCs or a subset of "important to safety" SSCs under 10 CFR Part 50 and 10 CFR Part 52 are being placed on all NSRSS SSCs under 10 CFR Part 53 (NEI2-0005, NEI2-0182, NEX-0012, USNIC2-0004).

A commenter stated this includes requirements in 10 CFR 53.440(e) and 10 CFR 53.875(b) related to fire protection, 10 CFR 53.440(c) and (d) related to environmental qualifications, 10 CFR 53.440(b) related to codes and standards, and 10 CFR 53.480 related to equipment qualifications (NEI2-0005, NEI2-0182).

A commenter suggested that, should the NRC not adopt their suggestion to delete most of the requirements from the section, the NRC should limit the scope of 10 CFR 53.440(e) to SR SSCs, consistent with the guidance in RG 1.189, Rev. 4, "Fire Protection for Nuclear Power Plants," issued May 2021 (ML21048A441) for safe shutdown equipment, specifically by deleting the words "and NSRSS" throughout. The commenter reasoned that while requirements for NSRSS SSCs may flow from the risk assessment and design process, paragraph 10 CFR 53.440(e) should not be a blanket requirement for all NSRSS SSCs (NEI2-0050).

A commenter suggested reducing requirements for non-safety-related with special treatment (NSR-ST) SSCs when such classification is due solely to ensuring defense in depth adequacy (ENW-0002).

NRC Response: The NRC agrees, in part, with the comments.

Regarding 10 CFR 53.440(b), see the NRC's response to Comment Bin 3.3.2.1.A, which describes changes made to this paragraph in the final rule.

Regarding those parts of the comment related to 10 CFR 53.440(c), see the NRC's response to Comment Bin 3.3.2.1.E, which describes changes made to this paragraph in the final rule.

Regarding those parts of the comment related to 10 CFR 53.440(d), see the NRC's response to Comment Bin 3.6.3.4.A, which addresses the related topic of integrity assessment programs.

Regarding those parts of the comment related to 10 CFR 53.440(e), the NRC agrees, in part, and revised the language in this paragraph to add the qualifier "where appropriate" for the scope of NSRSS SSCs required to be designed and located to minimize the probability and effect of fires and explosions. This change addresses the concerns included in the comment that some NSRSS SSCs may not need to incorporate fire protection measures.

The NRC acknowledges that part of the comment suggesting reduced requirements for SSCs designated as NSRSS due to their role in providing defense in depth but believes that this flexibility is already afforded by 10 CFR 53.460 in both safety categorization and assigning special treatments to such SSCs.

Accordingly, the NRC revised the rule language in paragraphs 10 CFR 53.440(b) through 10 CFR Part 53.440(e) in response to these comments.

Comment Bin 3.3.2.1.C: A few commenters stated that the aircraft impact requirements in 10 CFR 53.440(j) should be removed (HPT16-0001, HPT16-0002, HPT16-0004, NEI2-0016, NEI2-0021, KAP-0004). Two commenters stated that the aircraft impact requirement in 10 CFR 53.440(j) conflicts with 10 CFR 53.110, which establishes that the facility is not required to provide design features or other measures to protect against a malicious act (HPT16-0001, HPT16-0004, NEI2-0021). One commenter also said 10 CFR 53.440(j) and 10 CFR 50.150 are unnecessary given 10 CFR 50.13 and 10 CFR 53.110 and should be removed (NEI2-0016).

One commenter stated the requirement is also in conflict with the U.S. Constitution, which requires the federal government to mitigate such risk, and the risk-informed requirements of NEIMA. The commenter stated that both 10 CFR 53.440(j)(1) and 10 CFR 53.450(g)(2) would be illegal. The commenter recommended revising 10 CFR 53.440(j), including by referencing a commercial regional commuter sized aircraft instead of a large commercial aircraft, which the commenter believes may pose a higher level of accident risk because such aircraft are relatively common with somewhat less robust security measures (HPT16-0001, HPT16-0002, HPT16-0004).

Two commenters stated that following September 11, 2001, there have been significant increases in security, so large commercial aircraft impact design requirements are not necessary, due to the lowered risk (KAP-0004, HPT16-0002).

NRC Response: The NRC agrees, in part, with the comments.

The NRC has reconsidered the need for the requirement in proposed 10 CFR 53.440(j) that facilities be designed to limit the release of radionuclides from reactor systems, waste stores, or other significant inventories of radioactive materials assuming the impact of a large, commercial aircraft and agrees with the comment to delete it from the final rule. The NRC does not agree with the suggestion to revise 10 CFR 53.440(j) by referencing a commercial regional commuter sized aircraft instead of a large commercial aircraft for the reasons discussed below.

The NRC also does not agree that the proposed requirements in 10 CFR 53.440(j) conflicted with the proposed requirements in 10 CFR 53.110. The provisions of 10 CFR 53.110, “Attacks and destructive acts,” exempt licensees or applicants under 10 CFR Part 53 from providing design features to protect against attacks or destructive acts directed at the facility by United States adversaries. The requirement in 10 CFR 53.110 is equivalent to that provided in 10 CFR 50.13 for licensees and applicants under 10 CFR Part 50 and 10 CFR Part 52.

When the Commission promulgated the final rule, “Consideration of Aircraft Impacts for New Nuclear Power Reactors,” (74 FR 28112; June 12, 2009), it addressed the relationship of the rule to the requirements in 10 CFR 50.13 and proceeded with codification of requirements to address the impact of a large, commercial aircraft. In doing so, the NRC noted that “the impact of a large aircraft on the nuclear power plant is regarded as a beyond-design-basis event” and it was “the NRC’s view that effective mitigation of the effects of events causing large fires and explosions (including the impact of a large, commercial aircraft) can be provided through operational actions,” which were covered by other requirements. In light of this view, the Commission stated that “the mitigation of the effects of aircraft impacts through design should be regarded as a safety enhancement which is not necessary for adequate protection.”

In the Regulatory Analysis that accompanied the aircraft impact rule, the NRC quantified the costs of the rule, but did not quantify the benefits of the rule, stating that the “benefits of the final rule can be evaluated only on a qualitative basis.” The NRC concluded that the key benefit of the rule was “improvement in knowledge.” The Commission acknowledged that “it is difficult to quantify the safety enhancement gained through implementation of the aircraft impact rule,” but stated that “the NRC nevertheless believes that the cost of performing the assessment and incorporating the results into the design…is justified in view of the increased safety provided by implementation of the aircraft impact rule.”

It has been over 15 years since promulgation of the aircraft impact rule in 2009. The NRC agrees that events like the terrorist attacks of 9/11 are now much less likely due to significant increases in security at commercial aviation facilities as well as hardened access to aircraft cockpits. It is not clear that the Commission’s previous belief that the cost of implementation of the aircraft impact rule was justified by the increase in safety provided by the rule would hold true for future reactors licensed under 10 CFR Part 53. As stated previously, the NRC concluded that the key benefit of the rule was “improvement in knowledge” achieved by performing the aircraft impact assessment.

The NRC notes that licenses issued under 10 CFR Part 50 and 10 CFR Part 52 were largely based on deterministic analyses of the safety of the facility based on the General Design Criteria. The technical requirements in 10 CFR Part 50 were supplemented over the years to address specific beyond-design-basis events, such as the loss of large areas of the plant due to fires and explosions, as mentioned above. In contrast, under 10 CFR Part 53, applicants will be required to perform a comprehensive assessment of their reactor design to identify potential failures, susceptibility to internal and external hazards, and other contributing factors that could pose a risk to public health and safety. The spectrum of events and hazards considered will include those that have traditionally been considered design-basis events and those that have been considered beyond-design-basis events. Although 10 CFR Part 53 does not include prescriptive requirements to assess a licensing-basis event comprising an *intentional* act that could cause large fires or explosions, it does require applicants to assess a full spectrum of unplanned events, to include anticipated events, unlikely events, and very unlikely events. The NRC believes that the systematic evaluations of internal hazards, external hazards, and security threats under 10 CFR Part 53 and 10 CFR Part 73 sufficiently address the potential loss of large areas of the plant due to explosions or fire currently addressed under 10 CFR 50.155(b)(2).

Therefore, the 10 CFR Part 53 applicant will have considered how to mitigate the broader potential plant impacts that may result from an event such as the impact of a large aircraft. As a result, applicants and licensees under 10 CFR Part 53 will have substantially more information about the design of their facilities than applicants and licensees did before promulgation of the aircraft impact rule. Accordingly, the “improvement in knowledge” to be gained by requiring a separate assessment of the impact of a large commercial aircraft under 10 CFR Part 53 is expected to be significantly less than the improvements in knowledge for 10 CFR Part 50 or 52 applicants the Commission estimated when it promulgated the aircraft impact rule. Because the potential impact of beyond-design-basis events are considered in other ways under 10 CFR Part 53, the NRC concludes that the cost of performing the aircraft impact assessment and incorporating the results into the design of a commercial nuclear plant licensed under 10 CFR Part 53 would not be justified.

Accordingly, the NRC has revised the rule language in response to these comments to remove the requirements that were contained in proposed 10 CFR 53.440(j).

Comment Bin 3.3.2.1.D: A commenter provided input on the requirements in 10 CFR 53.440 and 10 CFR 53.450 and how guidance can be used to meet these requirements. The commenter also noted whether or not the method of meeting the requirements depends on the type of technology-inclusive, risk-informed, performance-based analysis method used (NEI3-0018, NEI3-0020, NEI3-0021, NEI3-0022, NEI3-0023, NEI3-0024, NEI3-0025, NEI3-0026, NEI3-0027, NEI3-0028, NEI3-0029, NEI3-0030, NEI3-0031, NEI3-0032, NEI3-0033).

NRC Response: The NRC agrees with the comments.

As explained in the proposed and final rules, guidance documents are being prepared or are expected to be prepared or updated in the future to address various requirements in 10 CFR Part 53, including those in 10 CFR 53.440 and 10 CFR 53.450.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.3.2.1.E: A commenter said that the “design requirements” in 10 CFR 53.440 are duplicate requirements and that duplication of requirements reduces clarity and predictability and increases regulatory complexity and burden without an increase in safety.

The commenter stated that 10 CFR 53.440(c), which requires that SSCs must be qualified for their service conditions over the design life of the SSC, contributes to eliminating the need for an Integrity Assessment Program in 10 CFR 53.870. The commenter also stated that

10 CFR 53.440(d), which requires the evaluation of possible degradation mechanisms over the plant lifetime, could be reassigned to provide further clarification for the need to qualify materials under 10 CFR 53.440(c).

The commenter wrote that the requirements in 10 CFR 53.440(c) and (d) increase the traditional scope of qualification beyond SR SSCs to also include NSRSS SSCs and proposed that qualification should only be a requirement for SR SSCs and an option for NSRSS SSCs. The commenter suggested that the NRC combine paragraphs (c) and (d) to read as follows (NEI2-0048):

> The materials used for safety related SSCs must be qualified for their service conditions over the plant lifetime. Qualification must consider possible degradation mechanisms related to service time, fatigue, chemical interactions, operating temperatures, effects of irradiation, and other environmental factors that may affect their performance."

The commenter also suggested that NRC (NEI2-0048):

- delete paragraph (e) related to fire protection due to its redundance with paragraph (a).
- delete paragraph (f) related to safety and security due to it duplicating 10 CFR 73.58.
- delete paragraphs (g) and (h) due to their duplicating elements of 10 CFR 53.210, 10 CFR 53.220, and 10 CFR 53.240.
- remove paragraph (i) related to fuel and radionuclides outside the reactor as the commenter states it is covered implicitly in 10 CFR Part 53, Subpart B, and is explicitly required for analysis under 10 CFR 53.450(b)(4) and (5).
- remove paragraph (j) as it postulates an aircraft impact that results from an attack or destructive action. The commenter states that per 10 CFR 53.110, licensees are not required to provide for design features to protect against such attacks.
- delete paragraph (k) but ensure chemical hazards are addressed in the EP plan consistent with language in 10 CFR 70.22.
- delete paragraphs (l) due to it duplicating requirements in 10 CFR 20.1406.
- delete paragraph (m) due to some elements being duplicative of 10 CFR 70.24. The commenter suggested some elements would be better suited for Subpart F.
- delete paragraph (n). The comment suggested the human factors elements are duplicative of Subpart F, including individual elements of a human factors program within regulation may prevent applicants from maintaining the "state-of-the art" as required, and that program elements should be relocated to guidance.

Two commenters stated that the requirements in 10 CFR 53.440(k) addressing chemical hazards are unwarranted and go beyond existing regulatory requirements and exceed chemical safety requirements in 10 CFR Part 70. The commenters noted that consistent with 10 CFR 70.22(i)(1)(ii), chemical hazards should be addressed in the emergency plan responding to radiological hazards and should not be included as a design requirement (NEI2-0048, USNIC2-0023).

NRC Response: The NRC agrees, in part, with the comments.

The NRC revised the rule language in response to comments on 10 CFR 53.440(c). Specifically, the NRC revised the rule language for 10 CFR 53.440(c) to address concerns expressed that "qualify" has a historical meaning that might imply that requirements for safety-related SSCs necessarily also apply to NSRSS SSCs. The NRC revised the paragraph to include qualifications as appropriate to address the special treatments identified under 10 CFR 53.460.

Regarding 10 CFR 53.440(d), see the response to Comment Bin 3.6.3.4.A, which addresses the related topic of integrity assessment programs.

The NRC disagrees with the suggestion to combine 10 CFR 53.440(c) and (d) because, while related, the requirements for qualification of equipment to meet the special treatments established for an SSC can be a separate activity from the identification of degradation mechanisms and the monitoring of those degradation mechanisms during operations. See the NRC's response to Comment Bins 3.3.2.1.A, 3.3.2.1.B, 3.3.2.1.C, and 3.3.2.1.D for other items in 10 CFR 53.440 that are mentioned in the comment. Accordingly, the NRC did not change the rule language in response to these comments.

Regarding 10 CFR 53.440(e), see the response to Comment Bin 3.3.2.1.B.

Regarding 10 CFR 53.440(f), the NRC disagrees that 10 CFR 73.58 duplicates the security by design concept in 10 CFR 53.440(f). The safety/security interface requirements in 10 CFR 73.58 address changes to plant configurations, facility conditions, or security for operating licensees, and do not apply to an initial design. Accordingly, the NRC did not change the rule language in 10 CFR 53.440(f) in response to this comment. However, the NRC did delete the related stand-alone requirement in 10 CFR 53.1239(a)(14) to address this topic in FSARs with the expectation that meeting the requirement in 10 CFR 53.440(f) is better addressed in documents related to various security plans. Furthermore, the NRC added clarifying language to the final rule FRN regarding the security by design concept in 10 CFR 53.440(f).

Regarding 10 CFR 53.440(g) and (h), the NRC disagrees with the comments. As explained in the proposed and final rules, these design requirements are included to ensure commercial nuclear reactors under 10 CFR Part 53 have the capability to achieve and maintain subcriticality and long-term cooling. The requirements are included to address the potential that some reactor designs may be able to achieve a stable end state for the purpose of event analyses but might need further actions to completely shut down and service the facility. Accordingly, the NRC did not change the rule language in response to this comment.

Regarding those parts of the comment related to 10 CFR 53.440(i), the NRC disagrees. As explained in the proposed and final rules, the design, analysis, and development of programmatic controls under Part 53 considers the number of reactor units and other significant inventories of radioactive materials contributing to the risks to public health and safety. While implied in other sections of 10 CFR Part 53 and addressed in the analysis requirements of 10 CFR 53.450, the NRC has maintained 10 CFR 53.440(i) in the final rule to emphasize the importance of this distinction from the traditional design requirements in 10 CFR Part 50 and 10 CFR Part 52. Accordingly, the NRC did not change the rule language in response to this comment.

Regarding 10 CFR 53.440(j), see the response to Comment Bin 3.3.2.1.C, which describes the deletion of this paragraph in the final rule.

Regarding 10 CFR 53.440(k), the NRC agrees, in part, with the comments. The NRC disagrees that it should delete paragraph (k) and instead ensure chemical hazards are addressed in the EP plan. Because of the diversity of technologies that may be proposed to be licensed under 10 CFR Part 53, the NRC does not presume to know how chemical hazards associated with releases of licensed material from a commercial nuclear plant would compare to the same type of hazard associated with facilities licensed under 10 CFR Part 70. Additionally, addressing such hazards only through a proposed Emergency Preparedness plan would not achieve the goal of establishing a balance between mitigation and prevention of potential chemical hazards. Nevertheless, the NRC agrees that greater flexibility in how an applicant or licensee meets this requirement is warranted, which may include the use of programmatic controls. Accordingly, the NRC has revised the rule language in response to this comment. Specifically, the revisions indicate that 10 CFR 53.440(k) can be met through the use of design features, programmatic controls, or combinations thereof.

Regarding 10 CFR 53.440(l), it is the NRC's view that retaining certain references to other parts and sections within 10 CFR is useful and the NRC has maintained these references in the final rule. In this case, maintaining the reference to 10 CFR 20.1406 allows a comprehensive list of design requirements to be conveyed in one location, which the NRC views as helpful to future applicants under 10 CFR Part 53. Accordingly, the NRC did not change the rule language in response to this comment.

Regarding the comment on 10 CFR 53.440(m), the NRC disagrees. As explained in the proposed and final rules, 10 CFR 53.440(m) provides an alternative to meeting the requirements of 10 CFR 70.24 similar to the provisions included in 10 CFR 50.68. Accordingly, the NRC did not change the rule language in response to this comment.

Regarding the comment on 10 CFR 53.440(n), the NRC disagrees. As explained in the proposed and final rules, 10 CFR 53.440(n) requires that the design of commercial nuclear plants reflect state-of-the-art human factors principles for safe and reliable performance in all settings that human activities are expected for performing or supporting the continued availability of plant safety or emergency response functions. Since this requirement is addressing the human-system interface, the NRC accepts that there is some degree of duplication within the sections in 10 CFR 53.730 that are addressing similar topics but from the perspective of the role of personnel in ensuring safe operations. Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.3.2.1.F: A commenter stated that since 10 CFR 53.440 defines required design features in terms of "generally accepted consensus codes and standards," the provision is ambiguous and would negatively impact state and public stakeholders and their ability to understand the current licensing basis or participate in the 10 CFR 2.206 process. The commenter added that it will be difficult for the NRC to enforce such a provision, and suggested the NRC include in the rule a more clear and structured process to allow for the involvement of State regulators and stakeholders in the entire licensing process (NYS2-0007).

NRC Response: The NRC disagrees with the comment.

10 CFR 53.440(b) is being revised in response to other comments (see the NRC's response to Comment Bin 3.3.2.1.A) to limit the applicability of the requirement for using generally accepted consensus codes and standards approved by the NRC to safety-related SSCs. The discussion is also being revised to explain that special treatment is defined in Subpart A of 10 CFR Part 53

and generally refers to measures (e.g., quality assurance, testing, monitoring) taken beyond normal commercial practices related to the procurement and installation of commercial-grade products to provide confidence that the SSC will comply with the applicable functional design criteria. Such normal commercial practices include the use of consensus codes and standards, as identified in an application to support the identification of special treatments which includes special treatments that may go beyond the use of commercial codes and standards. The consensus codes and standards used for both SR and NSRSS SSCs are expected to be identified in safety analysis reports (SARs) provided with applications and so would provide a comparable level of information as has been made available to state and public stakeholders under 10 CFR Part 50 and 10 CFR Part 52.

Regarding the part of the comment on public participation in the licensing process — the licensing provisions in 10 CFR Part 53, availability of information, opportunities to participate in licensing proceedings and rulemakings, opportunities to participate in environmental reviews, opportunities to request NRC actions, and other interactions with states and public stakeholders incorporated in 10 CFR Part 53 are structured to provide the same opportunities for public participation as the equivalent provisions included in 10 CFR Part 50 and 10 CFR Part 52.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.3.2.1.G: A commenter stated that the NRC should not operate with a zero risk tolerance and suggested that a specific value of acceptable risk of event occurrence needs to be established for NRC use when analyzing advanced reactor designs, which would reduce costs for both the NRC and industry (TG28-0001).

NRC Response: The NRC agrees, in part, with the comment.

The NRC does not regulate to achieve a goal of zero risk to public health and safety from the operation of commercial nuclear plants and has not incorporated such a concept into 10 CFR Part 53. As explained in the proposed and final rules related to 10 CFR 53.220, applicants are required to identify comprehensive risk metrics and associated risk performance objectives that are acceptable to the NRC and provide an appropriate level of safety.

Further, the final rule text provides some specific examples of risk metrics the NRC would find acceptable, and the NRC intends to issue further guidance that will provide additional examples of acceptable risk metrics. The NRC anticipates that use of these guidance documents will reduce costs for both applicants and the NRC.

Accordingly, the NRC did not change the rule language in response to this comment.

3.3.2.2. Comments on § 53.450

Comment Bin 3.3.2.2.A: A commenter stated that the proposed 10 CFR 53.240 intends to introduce PRA to "identify and assess LBEs," but explained that that PRA event trees and scenarios have several deficiencies. Specifically, the commenter wrote that PRA event trees and scenarios: are not mathematically or physically complete in including all possible scenarios and events; cannot today conduct accurate dynamic analyses and represent passive design features; must appeal to using deterministic analyses; and should be utilized with judgement in risk-informed decision-making to a greater extent. The commenter also noted that current PRA methods are essentially pre-selected static event trees, whereas present deterministic methods are inherently dynamic, and stated that the two approaches are often stated to be complementary, but in the proposed rule the types of analyses used also depend on the types of accident based on frequency criteria. The commenter added that it is preferable to have a fully integrated and physically consistent coupled and dynamic RIDM methodology for the full spectrum of significant events relevant to the chosen design. The commenter urged the NRC to explicitly state the limits of PRA applicability and completeness and note that the PRA cannot be independently verified, so it cannot be validated by direct comparisons against data or cover all possible scenarios. The commenter concluded that judgment must be used in RIDM based on data and known uncertainties in data, methods, and completeness (RD-0016).

NRC Response: The NRC agrees, in part, with the comment.

The references to a PRA or other systematic risk evaluation within 10 CFR Part 53 include the broader set of analyses discussed in the comment (e.g., simulations of plant response) and not simply the elements of the PRA referred to in the comment, such as static event trees. Additionally, 10 CFR Part 53 does not rely entirely on the PRA or systematic risk evaluation to demonstrate safety; 10 CFR Part 53 also requires applicants to perform a deterministic analysis of design-basis accidents to further inform the plant's licensing basis. Moreover, engineering judgment will continue to be an important part of the design and analyses processes addressed in 10 CFR Part 53. For example, references such as ASME/ANS RA-S-1.4-2020, "Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants," highlight the importance of risk-informed decision-making, expert judgment, and peer review.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.3.2.2.B: A commenter recommended the NRC incorporate digital twin technology as a critical component of the 10 CFR Part 53 framework, noting this would align with the rule's goals of enhancing safety, optimizing performance, and fostering innovation, and described the benefits of such technology, including enhanced safety, operational efficiency, innovation and flexibility, and valuable insights for data-driven decision-making. To integrate this technology into 10 CFR Part 53, the commenter suggested amending 10 CFR 53.450 to require that the PRA must leverage digital twin technology to continuously update risk assessments based on real-time data and simulations, ensuring adaptive and proactive risk management strategies. The commenter also suggested additional language to be incorporated into 10 CFR 53.1239 related to digital twin technology (MR-0008).

NRC Response: The NRC disagrees with the comment.

This rule was developed as a risk-informed, performance-based, and technology-inclusive regulatory framework for commercial nuclear plants in response to NEIMA. To prescribe a specific means of monitoring and optimizing reactor operations would be counter to the performance-based nature of the rule. Notwithstanding the potential benefits of digital twin technology, the NRC disagrees that it should be required within the regulations.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.3.2.2.C: A commenter discussed language in Section IV, "Part 53 Framework," of the FRN of the proposed rule that states that "These analyses would need to use realistic approaches and address uncertainties associated with states of knowledge, modeling, and performance of SSCs," noting that previously uncertainty did not need to be addressed and adequate results were still achieved. The commenter questioned whether addressing uncertainty is necessary and asked how much it would cost and how much value it would provide, noting it may be a better use of resources to spend more on a stronger design, or if the design appears adequate, not spend at all (TG5-0001).

NRC Response: The NRC disagrees with the comment.

Uncertainties related to the state of knowledge, or the performance of plant systems are accounted for in both the largely deterministic framework of 10 CFR Part 50 and the more risk-informed framework of 10 CFR Part 53. The means of addressing uncertainties under the 10 CFR Part 50 framework is primarily through the need to verify and validate analytical models and by conservatisms included in the regulations to provide design margins and defense in depth. The 10 CFR Part 53 framework provides more flexibility in addressing uncertainties but, in the absence of prescriptive requirements, includes a more general requirement to identify and address uncertainties.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.3.2.2.D: A commenter stated that while the NRC stated it intends for the new rulemaking to offer a transparent and efficient process for the licensing of advanced nuclear reactors, the proposed 10 CFR Part 53 only requires applicants to provide a summary of the PRA and risk insights to support safety findings. The commenter stated that proprietary information is unlikely to be provided to host states, municipalities, or other interested parties, so the public will be precluded from reasonably evaluating the accuracy and thoroughness of the applicant's analysis of potential accidents or mitigating systems and noted this may undermine public confidence in the safety of new designs coupled with limited opportunity for public input. The commenter urged the NRC to provide the public with a detailed review of PRAs and risk insights to facilitate public confidence regarding the safety of advanced reactor designs and other matters important to public safety, such as emergency planning, physical security, and fire protection (NYS2-0006).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees with the comment in terms of the importance of transparency in the licensing process and the need to provide information on the risks posed by commercial nuclear plants to the public. The NRC requires applicants to submit sufficient information on the record to support the NRC's licensing review; this information will generally address the risks posed by the licensed activity. If necessary, the NRC also has mechanisms and the obligation to protect sensitive information submitted as part of the application, which includes a process for the public to access protected information when needed to support an adjudicatory challenge to the application. The level of information reviewed by the NRC related to the PRA, other systematic risk evaluations, and related risk insights will be more detailed under 10 CFR Part 53 than has traditionally been the case under 10 CFR Part 52 since the risk evaluations are integral to much of the licensing basis information under 10 CFR Part 53.

However, as explained in the proposed and final rules, 10 CFR Part 53 is designed to avoid problems experienced with the submittal of voluminous PRA information initially required under 10 CFR Part 52 that proved to be impractical and was subsequently addressed with the 2007 revision of 10 CFR Part 52 (72 FR 49352; August 28, 2007). In that regard, the NRC agrees that 10 CFR Part 53 requires the content of applications to include a description of the PRA, other systematic risk evaluations, or combination thereof. Based on the application information and any other pertinent information the NRC deems necessary to reach conclusions about the safety of the facility, the NRC will continue to document its safety decisions and will be guided by what is necessary to explain any findings of reasonable assurance of adequate protection of public health and safety and the common defense and security. The information needed to support the NRC's determination will continue to be docketed either as part of the initial application or a supplement or in a response to a request for additional information; therefore, the public will continue to have adequate information to assess the application. Publicly available information will also include details on emergency planning, fire protection, and physical security. RG 1.253 provides information on the format and content of SARs for applications developed using the LMP methodology and the NRC expects applications under 10 CFR Part 53 will be similar in terms of structure and level of detail.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.3.2.2.E: Many commenters discussed PRA requirements in the proposed rule, generally voicing opposition to requiring PRAs for 10 CFR Part 53 applicants (TG22-0002, TG22-0004, NEI2-0019, NEI2-0003, NEI2-0051, HPT42-0001, HPT42-0002, HPT42-0003, HPT42-0005, SCWG-0013, KAP-0002, NIA2-0003, NIA2-0009, NGO-0003, USNIC2-0030, RAD-0013, NEI3-0003, NEI3-0004, NEI3-0006, NEI3-0007, DOM-0004, NEX-0018, NEX-0009, USNIC2-0005, USNIC2-0025, USNIC2-0016, HPT13-0001, HPT13-0002).

A commenter stated that the requirement to perform a PRA is unnecessarily inflexible and especially not appropriate for technologies with simple safety case strategies (KAP-0002). Another commenter stated that the burden associated with the proposed requirements is out of proportion with the benefit to nuclear safety, and that PRAs are a useful tool, but not if deployed in a heavily prescriptive manner while overlooking the inherent shortcomings of statistical analysis (HPT42-0001, HPT42-0002, HPT42-0005).

The commenter added that in the context of protection of the public from hazardous radiation, limiting events are the key, noting that these events should be based on "danger to life," and not "unreasonable risk to the public health and safety." The commenter also stated that components of the PRA, including the likelihood of events and assumptions regarding individual component failures, are imprecise and lead to uncertainty in PRA results, reinforcing the idea that the PRA is useful, but not as a key part of regulation (HPT42-0002).

Another commenter stated that the level of detail in the PRA requirements reduces flexibility, without any increase in clarity or predictability, and increases regulatory complexity and burden, because it likely increases the amount of information from the PRA that must be included in the licensing basis, without any increase in safety (NEI2-0051). Another commenter agreed with the previous commenter (NEX-0009).

Many commenters requested that the NRC generally allow for the use of a risk evaluation instead of requiring a PRA (SCWG-0013, NIA2-0003, NIA2-0009, NGO-0003, USNIC2-0030, NEI3-0006, NEI3-0007, NEI3-0009, DOM-0004, NEX-0018, USNIC2-0025, USNIC2-0016, NEI2-0019, NEI2-0003, NEI2-0051). A commenter specifically recommended allowing the use of alternative risk evaluations to PRA in all current and proposed licensing frameworks. The commenter requested that the NRC make conforming changes throughout 10 CFR Part 53 to describe how risk evaluations are used to support licensing and require applicants to submit analyses and documentation that support their specific safety case (NIA2-0009). Another commenter stated that the following sections should specifically be updated to reference a risk evaluation rather than a PRA: 10 CFR 53.450(b), 10 CFR 53.450(c), 10 CFR 53.450(e), 10 CFR 53.1239(a)(18), 10 CFR 53.1416(e)(1), 10 CFR 53.1416(f)(1), 10 CFR 53.1416(g)(1), 10 CFR 53.1545(a)(3), and 10 CFR 53.800 (NEI3-0009).

Several commenters stated that allowing risk evaluations instead of a PRA is necessary to meet the requirements of the ADVANCE Act (NIA2-0003, SCWG-0013, NIA2-0009, NGO-0003, NEI3-0003, NEI3-0004, NEI3-0006, NEI3-0007, USNIC2-0025, NEI2-0251, NEI2-0003), with a few commenters also stating this would be consistent with the Commission's direction in SRM-SECY-23-0021, "Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)," issued March 2024 (ML24064A039) (NIA2-0003, NGO-0003, NEI3-0003, NEI3-0006, NEI2-0251). A few commenters also stated this change is necessary for the rule to be technology-inclusive and meet the requirements of NEIMA (NIA2-0009, SCWG-0013, NEI3-0006, NEI3-0007). A commenter also argued this change would be consistent with Commissioner Caputo's markup of the proposed rule (NEI2-0003).

Regarding the required scope of a PRA, a few commenters specifically explained that an "all hazards" PRA is not needed by all applicants and should not be required (NIA2-0003, NIA2-0009, NGO-0003, NEI2-0003, NEI2-0051).

One commenter expressed concern about language in the preamble ("Existing processes for defining the scope and capability of a PRA supporting an application offer flexibility in determining the degree to which the PRA needs to be developed…") that they said contradicts the requirement in 10 CFR 53.450(a) for the PRA to assess susceptibility to internal and external hazards. The commenter wrote that the regulation should reflect the following language from the same paragraph of the preamble: "An NRC determination of the acceptability of a PRA includes… the use of screening tools and bounding or simplified methods for any mode or hazard." The commenter urged the NRC to remove the language in 10 CFR 53.450(a) requiring internal and external hazards to be addressed by the PRA (NEI2-0022). Another commenter agreed with the previous commenter (NEX-0020).

Alternatively, one commenter recommended that, at a minimum, wherever 10 CFR 53.450(a) refers to PRA, the NRC should change it to "PRA in combination with other generally accepted approaches for systematically evaluating engineered systems" for consistency with the phrasing in 10 CFR 53.450(e) (NEI2-0003, NEI2-0051, NEI3-0003). The commenter noted that doing so would address susceptibility to internal and external hazards and would align with RG 1.253, 10 CFR 53.450(e) and SRM-SECY-23-0021 (NEI3-0003).

One commenter stated that there is not sufficient operating experience to expect PRAs for reactors under 10 CFR Part 53 to provide valuable results (TG22-0004).

A commenter stated that 10 CFR Part 53 must accommodate multiple licensing approaches, including the use of RG 1.233 (LMP), a "less than full LMP" implementation, a maximum hypothetical accident (MHA) approach, and an "MHA-like" safety case, and urged the NRC to establish in the rule how the rule language and guidance are flexible enough to enable the use of additional approaches (USNIC2-0005).

Another commenter also stated that the current proposed requirement for a PRA would preclude the bounding approach described by the commenter as well as the traditional DBA approach that was used by most of the current operating fleet (NEI3-0007). The commenter suggested revising 10 CFR 53.450 to include requirements related to flexibility for bounding analyses in 10 CFR 53.450 (NEI2-0051).

Two commenters cited recent experience with the Kairos-Hermes construction permit application that was approved without using a strict PRA approach, indicating that alternative approaches can be successfully used (SCWG-0013, NIA2-0009).

A commenter suggested that 10 CFR 53.450(a) be revised to reference primary and secondary safety functions and require applicants to identify the key consensus codes and standards employed (HPT13-0001, HPT13-0002).

NRC Response: The NRC agrees, in part, with the comments.

Regarding the suggestion that 10 CFR Part 53 allow for risk evaluations other than PRA, the NRC agrees, in part. The requirements in 10 CFR 53.450(a) are being revised to allow other SREs to be used as a supplement or possibly an alternative to an “all hazards” PRA. Conforming changes have been made to other portions of the rule language that invoke the use of PRA. Additionally, the NRC has revised the rule language in 10 CFR 53.450(a) to require that a PRA, other SREs, or combination thereof be used together with other generally accepted approaches for systematically evaluating engineered systems. Understanding that other SREs are still under development, the NRC has also revised the rule language in 10 CFR 53.450(b) to include a requirement ensuring that PRA, other SREs, or combination thereof are used to inform the establishment and updating of appropriate controls on plant operations, including availability controls. Finally, the NRC has revised the discussion from the proposed rule to the final rule to emphasize that the term “*Event Sequence*” is used generically in 10 CFR Part 53 and does not imply the use of a specific type of systematic risk evaluation.

One statement observed that there is not sufficient operating experience to expect PRAs for reactors under 10 CFR Part 53, a lack of understanding of what possible malfunctions can occur, how often they may occur, and what would be the consequences should they occur, which would rightly present a fundamental challenge to licensing a commercial nuclear plant under any regulatory framework. The NRC acknowledges that uncertainties exist and need to be addressed through design and analyses. The use of PRAs and other systematic risk evaluations has been incorporated into various consensus codes and standards and regulatory frameworks for decades. The 10 CFR Part 50 framework remains available for those applicants that prefer more deterministic or prescriptive requirements such preestablished design rules and licensing-basis events. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC disagrees with the suggestion that 10 CFR 53.450 be revised to allow the use of bounding analyses or a MHA approach. 10 CFR Part 53 provides flexibility for establishing the comprehensive risk metrics and associated risk performance objectives and the evaluation criteria for licensing-basis events other than design-basis accidents. The actual analyses to demonstrate the risk performance objectives and evaluation criteria can use conservative or bounding-type analyses for particular parameters of interest such as estimated offsite doses. However, a notion that the design and licensing of a commercial nuclear plant, including the identification of special treatments for SR and NSRSS SSCs, functional allocations for staffing, and development of programs could be developed based on the analyses of a single event does not comport to any systematic engineering approach. Accordingly, the NRC did not change the rule language in response to these comments.

The NRC disagrees with the suggestion that 10 CFR Part 53 be revised to encompass any design or licensing approach. 10 CFR Part 53 has been developed as an integrated framework with relatively high-level safety requirements that are shown to be met through design and analyses, siting, construction and manufacturing, and requirements during operation and decommissioning for configuration control, staffing and programs. 10 CFR Part 50 has also evolved to provide an overall framework based on combinations of prescriptive design requirements, deterministic analyses, and consideration of risk insights. However, the NRC does not believe that it is practical to support both approaches within a single set of regulations and notes that 10 CFR Part 50 remains available for those applicants that prefer a more prescriptive, deterministic framework. Accordingly, the NRC did not change the rule language in response to these comments.

The NRC disagrees with the suggestion to revise 10 CFR 53.450(a) to reference primary and secondary safety functions and identify key consensus codes and standards employed because 10 CFR 53.450(a) already references 10 CFR 53.230 in relation to safety functions and the use of consensus codes and standards is addressed in other requirements under Subpart C. Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.3.2.2.F: A commenter suggested revising 10 CFR 53.450(b), to remove the requirement that a PRA and other evaluations need to consider all plant operating states, because assessment of lower modes of operation should be acceptable based on traditional methods (NEI2-0022). Another commenter suggested removing 10 CFR 53.450(b)(4) and (5), on the basis that there is no lawful requirement to analyze events beyond limiting DBEs (HPT13-0001, HPT13-0002).

Stating that a PRA should not be required to identify DBAs, particularly for LWRs with decades of regulatory precedent for DBA definition, a commenter expressed concern that the discussion of DBAs in 10 CFR 53.450 is too restrictive. The commenter thus suggested that the rule should allow for definition of DBAs based on past precedent for LWRs (where sufficient operating experience exists) and bounding or conservative assessments (with accepted methods endorsed in guidance) (NEI2-0015). Another commenter stated that the classification of SSCs does not require high levels of precision, and a PRA should not be employed for this purpose (HPT42-0003).

NRC Response: The NRC disagrees with the comments.

The NRC disagrees with revising 10 CFR 53.450(b)(4) to eliminate the need to identify and assess all plant operating states because plant operating states other than full-power operation can be as important to analyze as full-power operating states. Experience with such analyses for large-light-water reactors has demonstrated that the assessed risk associated with other than full-power plant operating states may be greater than for full-power plant operating states.

The NRC also disagrees that requirements to analyze events beyond DBEs are unlawful. The NRC’s jurisdiction is not limited to design-basis events; the NRC’s existing regulations contain requirements to analyze and mitigate events that are beyond the design basis of a facility to ensure that operating reactors provide an appropriate level of safety. Likewise, 10 CFR Part 53 contains similar requirements to systematically evaluate a spectrum of licensing-basis events to appropriately inform the plant's licensing basis. The NRC disagrees that the required uses of the analyses in 10 CFR 53.450(a) should not include informing the selection of LBEs, as per 10 CFR 53.450(b)(1). The regulatory construct under 10 CFR Part 53 is based on the concept of using systematic analyses to help provide confidence that the identification and evaluation of LBEs, including DBAs, for the operation of a commercial nuclear plant are appropriate and adequate. This construct is foundational to allowing an applicant the flexibility to identify necessary design features and establish their functional design criteria to demonstrate how the high-level safety criteria in 10 CFR 53.210 and 53.220 are met. This is in contrast to the more prescriptive construct in the regulatory frameworks of 10 CFR Part 50 and 10 CFR Part 52 that require meeting specific design rules and criteria.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.3.2.2.G: In 10 CFR 53.450(c), to be consistent with the Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing rulemaking, a commenter urged the NRC to have the requirement to upgrade analyses be triggered when a new standard is endorsed or a refueling outage, whichever is later, rather than on what the commenter considered an arbitrary (not performance-based) deadline of every 5 years (NEI2-0052). Another commenter recommended that the proposed requirements should be modified to require PRAs to be revisited periodically or as major events warrant (HPT42-0005).

A commenter suggested revising 10 CFR 53.450(c) to remove the requirement for NRC endorsement of codes and standards and require PRAs are reviewed, not maintained, and updated as necessary to reflect the plant's nuclear safety configuration (HPT13-0001, HPT13-0002).

NRC Response: The NRC disagrees with the comments.

The NRC disagrees with the comments suggesting the requirement in 10 CFR 53.450(c) be triggered only when a new PRA standard is endorsed or a refueling outage or only on an as-needed basis. The PRA, other SREs, or combination thereof used to establish the licensing basis need to be updated on a periodic frequency. Doing so at a minimum in five-year intervals appropriately accounts for potential changes in facility design, external hazards, and plant-specific or generic operating experience and ensures the configuration and operation of the as-operated, as-built facility continues to be appropriately represented in the analyses required under 10 CFR 53.450.

The NRC disagrees with revising 10 CFR 53.450(c) to remove the portion related to NRC-endorsed standards; ensuring adequate updates is critical given the central role the PRA, other SRE, or combination thereof play in the 10 CFR Part 53 licensing framework. However, as described in the response to Comment Bin 3.3.2.1.A, related changes to the rule language have been affected in 10 CFR 53.440(b).

The NRC also disagrees with replacing the requirement to maintain PRAs, other SREs, or combination thereof, with requirements to review and update those analyses as necessary to reflect a plant's nuclear safety configuration because doing so could exclude addressing maintenance of those analyses that do not involve changes to a plant's configuration, such as updating analysis parameters with operating experience.

Accordingly, the NRC did not change the rule language in 10 CFR 53.450(c) in response to these comments.

Comment Bin 3.3.2.2.H: A commenter urged the NRC to clarify how the NRC will maintain oversight of applicants' quality control for their PRA models and inputs, as well as consistency across different plants and applicants, noting that the NRC is pursuing a new approach with little operational history and that while PRA can be a valuable tool, it has inherent uncertainties (NYS2-0004).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that maintaining oversight of the applicant's quality control for the PRA, other SRE, or combination thereof will be essential. However, the NRC disagrees that additional clarity is needed because 10 CFR 53.450(c) already requires the maintenance and upgrade of analyses required in 10 CFR 53.450 and the requirements in 10 CFR Part 53, Subpart I, address maintaining and revising licensing-basis information. The NRC will perform oversight functions similar to that for currently operating reactors to ensure licensing-basis information for a given facility remains in compliance with performance-based regulatory requirements, including the use of PRA models and inputs.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.3.2.2.I: A commenter stated that the qualification of codes and standards, including PRA, for existing designs still remain incomplete, so it would be impossible to meet the requirement in 10 CFR 53.450(d) for a first of a kind or prototype reactor, as there is insufficient data for qualification for the range of conditions for which they are to be used. The commenter recommended the NRC define more precisely the licensing and approval process to be used to handle new concepts and designs with limited data or qualification capability, both with and without a prototype (RD-0021).

Another commenter suggested revising 10 CFR 53.450(d) to require applicants to identify the key consensus codes and standards employed (HPT13-0001, HPT13-0002).

Other commenters stated that the language in 10 CFR 53.450(d) could bar software used for PRA that cannot be qualified in the traditional sense of RG 1.203 compliance, and urged the NRC revise the requirement so that it refers to "physics-based" analyses, to maintain the PRA acceptability and qualification of codes used as part of current industry practice (e.g., CAFTA, SAPHIRE, FTREX, and PRAQUANT) (NEI2-0053, NEI3-0010).

NRC Response: The NRC agrees, in part, with the comments.

Regarding the statement that it is not possible to qualify analytical codes due to a lack of data, the NRC disagrees insofar as an analytical code that cannot be validated to cover the range of conditions for which it is to be used should not be presented to support the licensing of a commercial nuclear plant. However, uncertainties associated with the state of knowledge and modeling capabilities, the ability of barriers to limit the release of radioactive materials from the facility during LBEs other than DBAs, the reliability and performance of plant SSCs and personnel, and the effectiveness of programmatic controls can be addressed through adding measures for defense in depth. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC agrees, in part, with the concept of requiring applicants to identify key consensus codes and standards. However, as described in the NRC's response to Comment Bin 3.3.2.1.A, related changes to the rule language have been implemented in 10 CFR 53.440(b) that address this concept and, accordingly, the NRC did not change the rule language in 10 CFR 53.450(d) in response to these comments.

The NRC agrees with the suggestion that 10 CFR 53.450(d) be applicable to "physics-based" behavior in analyses of licensing-basis events. Accordingly, the NRC has revised the rule language to include equivalent wording in response to these comments.

Comment Bin 3.3.2.2.J: Regarding 10 CFR 53.450(e), a commenter recommended that the NRC change "LBEs other than DBAs" to just "LBEs" to allow the use of bounding risk assessment to inform a defense in depth assessment (NEI2-0023). Another commenter suggested revising 10 CFR 53.450(e) to apply to limiting DBEs and revise the specific analysis requirements (HPT13-0002).

NRC Response: The NRC disagrees with the comments.

Regarding changing "LBEs other than DBAs" to just "LBEs," see the NRC's response to Comment Bin 3.2.4.B.

The NRC disagrees that 10 CFR 53.450(e) should apply to limiting DBEs because the NRC does not see an advantage for introducing such a construct and doing so could unnecessarily complicate the existing analysis requirements in 10 CFR 53.450(e).

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.3.2.2.K: A commenter discussed language in the preamble related to 10 CFR 53.450(f) which references "frequencies as low as one in ten thousand years," and, assuming that the preamble is indicating that this would be accepted as a screening value for analysis purposes and anything lower can be "screened out," expressed support for this approach because a screening value is necessary to reduce analytical effort and the selected value is appropriate (TG2-0001).

A commenter stated that the use of the "deterministic" and "conservative" terminology in 10 CFR 53.450(f)(2) and (3) leads to confusion about the use of PRA to determine LBEs and DBAs, which themselves are and invoke "deterministic methods" (RD-0024).

Another commenter suggested deleting 10 CFR 53.450(f), because the commenter argues there is no need to distinguish between LBEs and DBAs, and deleting 10 CFR 53.450(f)(3), which the commenter states is of doubtful legality (HPT13-0001, HPT13-0002).

NRC Response: The NRC disagrees with the comments.

The proposed and final rules discuss the event sequence frequency of as low as one in ten thousand as being an example of part a frequency range for unlikely event sequences and associated with those event sequences from which the design-basis accidents would be derived and subsequently analyzed using deterministic methods. The discussion also provides an example of frequencies for very unlikely event sequences that uses a value of 5 in 10 million years.

As explained in the proposed and final rules, the 10 CFR Part 53 framework distinguishes between LBEs other than DBAs and DBAs because 10 CFR Part 53 includes a role for both risk assessment techniques (e.g., PRA or other systematic risk evaluations) and a deterministic element through design-basis accidents and the related analysis under 10 CFR 53.450(f). The use of this terminology in 10 CFR Part 53 is consistent with the common use of the terminology within the nuclear community.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.3.2.2.L: A commenter suggested revising 10 CFR 53.450(g) to condition the requirements related to fire protection and aircraft impacts on the applicability of these types of events to the nuclear facility (e.g., some designs, such as microreactors, should not need to consider aircraft impacts because the consequences do not pose an undue risk to the public) (NEI2-0051).

Another commenter suggested revising 10 CFR 53.450(g) to use the word “demonstrate” instead of “assess” and removing the aircraft impact requirement in 10 CFR 53.450(g)(2) (HPT13-0001, HPT13-0002).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees with the suggestion to revise 10 CFR 53.450(g) related to aircraft impacts. As addressed in the response to Comment Bin 3.3.2.1.C, the NRC has removed requirements related to aircraft impact assessments from 10 CFR Part 53. The NRC has removed the associated analysis requirements from 10 CFR 53.450(g).

The NRC disagrees with the suggestion to revise 10 CFR 53.450(g) related to fire protection and notes that 10 CFR 53.450(g) provides flexibility by allowing the assessment of fire protection measures through either inclusion of fires in the analysis of LBEs or by separate analyses.

The NRC disagrees with using the term “demonstrate” instead of “assess” in 10 CFR 53.450(g) because it does not otherwise see an advantage given both terms are used in those requirements.

Accordingly, the NRC did not change the rule language in response to these comments.

3.2.3.3. <u>Comments on § 53.460 – § 53.480</u>

Comment Bin 3.3.2.3.A: Two commenters expressed concern that NSRSS SSCs could receive an equivalent regulatory burden as SR SSCs because the rule does not define the differences in special treatments between these types of SSCs. The commenters cautioned that the lack of definition reduces regulatory predictability (NEI2-0054, USNIC2-0026).

One commenter suggested deleting 10 CFR 53.460(b) because special treatments are already required by 10 CFR 53.440 and numerous requirements in subpart F. The commenter noted that 10 CFR 53.865 should also be updated to include the guidance in 10 CFR 53.460 for Appendix B to 10 CFR Part 50 applicability only required for SR SSCs.

The commenter also suggested relocating 10 CFR 53.460(c), which relates to the confidence that human actions will be performed as assumed in the analysis, to 10 CFR 53.450, stating that it is out of place currently and would be more appropriately included there (NEI2-0054, NEI2-0111, NEI2-0051).

NRC Response: The NRC agrees, in part, with the comments.

The regulations within 10 CFR Part 53 require applicants and licensees to identify appropriate special treatments for SSCs to fulfill functional design requirements associated with either design-basis accidents or licensing-basis events other than design-basis accidents. This provides both a technology-inclusive approach and flexibility to applicants and licensees in defining the role of various SSCs and programmatic controls to meet safety criteria in Subpart B. Contrary to the comment's suggestion, the NRC expects that SR SSCs and NSRSS SSCs will receive differing regulatory treatment when appropriate, based on this flexibility.

The NRC disagrees with deleting 10 CFR 53.460(b) and revising 10 CFR 53.865 as suggested because, in combination with changes to the definition of the term "special treatment" in 10 CFR 53.020, 10 CFR 53.460(b) conveys that the regulatory treatment of NSRSS SSCs depends on the conditions under which they must perform their intended safety function. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC agrees, in part, with revising the requirement in 10 CFR 53.460(c) but not the total relocation of the requirement because the need to account for human actions may be an important attribute of certain special treatments for SSCs. Accordingly, the NRC revised the requirement in 10 CFR 53.460(c) to focus more on special treatments for SSCs related to human action versus the actual performance of the human actions.

Comment Bin 3.3.2.3.B: Two commenters stated 10 CFR 53.470 is not needed (TG21-0001, NEI2-0055). One commenter stated that it is confusing in that it is not clear what the alternative criteria are supposed to be, nor what benefit in operational flexibility would result from using the alternative criteria, and the requirement is little used in the rest of 10 CFR Part 53. The commenter also expressed concern that 10 CFR 53.470 could be used inappropriately to force more strict criteria on designs to achieve the same operational flexibility that is provided in 10 CFR Part 50 and 10 CFR Part 52 without an equivalent requirement in those parts. The same commenter suggested either deleting 10 CFR 53.470 or clarifying in the rule language that exemptions would not be needed if the NRC staff determines that margins justify deviation from the regulatory requirements. In the event that 10 CFR 53.470 remains, the commenter suggested supporting it with regulatory guidance providing information on what potential benefit is gained by the optional requirement (NEI2-0055).

Another commenter questioned the need for the section, noting that if a plant owner can accept more restrictive requirements, why can they not just operate the plant within those requirements, and asked if this is any different than what the current operating fleet has done. The commenter also stated that it seems impossible to easily incorporate any changes necessary to acquire the desired flexibility into existing design features due to present "intellectual property" interpretations. Additionally, the commenter expressed concern about 10 CFR 53.470 not requiring any reporting or NRC approval before implementing operational flexibilities (TG21-0001).

NRC Response: The NRC agrees, in part, with the comments.

As explained in the proposed and final rules, Part 53 allows an applicant or licensee to seek operational flexibilities by establishing analysis criteria that may be more restrictive than otherwise could be proposed under 10 CFR 53.220. An example is referring to estimated offsite consequences in terms of doses to a hypothetical individual that are lower than required under 10 CFR 53.220 to justify siting in relation to population centers. The NRC acknowledges that an alternative to the 10 CFR 53.470 included in the proposed rule could be that the siting criteria from RG 4.7, "General Site Suitability Criteria for Nuclear Power Stations," issued February 2024 (ML23348A082), (e.g., less than 1 rem over 30 days at a specified distance) could be adopted as part of risk performance objectives under 10 CFR 53.220 and thereby be integrated into the analyses and requirements for associated design features and programmatic controls. The comments suggest that the integration of appropriate criteria for operational flexibilities into the requirements of 10 CFR 53.220 is preferrable to having a separate provision such as the proposed 10 CFR 53.470.

The NRC agrees that either approach discussed above can adequately establish criteria for consideration of requirements in various sections of Part 53 (e.g., design, siting, and operations). The NRC cautions against simple references to the lack of such requirements in Parts 50 and 52 given those regulations do not afford the flexibilities provided in Part 53 and used conservative, generic analyses for consideration in areas such as siting relative to population density.

Accordingly, the NRC has deleted 10 CFR 53.470 in the final rule and included additional discussion in the final rule to describe how the analysis criteria under 10 CFR 53.220 and 10 CFR 53.450(e) should reflect the use of the analysis in proposing operational flexibilities such as siting relative to population density.

3.3.3. RFC: Probabilistic risk assessment (PRA) acceptability reviews

Comment Bin 3.3.3.A: Two commenters stated that guidance on risk evaluation methodologies should strike a balance between predictability and flexibility and noted that while certain guidance updates may be beneficial, new prescriptive guidance should be developed as needed to avoid limiting innovation (SCWG-0014, BI1-0007). One commenter recommended that the NRC focus on defining clear performance outcomes, allowing applicants to choose the most appropriate risk evaluation approach, and added that the NRC does not need to define acceptable methods, but instead should document decisions and lessons learned to provide clarity over time (SCWG-0014). The commenters concluded that guidance should be considered on the level of detail necessary depending on the risk evaluation method used, including if an all-hazards PRA is required, content of application guidance, and principal design criteria. The commenters recommended that the NRC update RG 1.233, RG 1.174, RG 1.200, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities," issued

December 2020 (ML20238B871), RG 1.247, “Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-informed Activities,” issued March 2022 (for trial use) (ML21235A008), and any others as needed, and consider creating additional guidance on the criteria that need to be met if risk evaluation methods other than PRA are used (SCWG-0014, BI1-0007).

One commenter also stated that clarification is needed on the definition of an “appropriate level of safety,” which is used differently in the proposed rule than in existing rules and guidance, and noted clarification is also needed on ensuring safety "comparable to what has been licensed in the past" (BI1-0007).

A commenter stated that 10 CFR Part 53 should allow a graded approach to PRA in which the applicant can choose among a range of approaches for the scope of the PRA:

- An all-modes, all-sources, all-hazards PRA that greatly informs the licensing basis.
- Non-core sources handled through traditional means and regulatory requirements (i.e., Standard Review Plan fuel handling accidents with the traditional regulatory requirements for spent fuel pools and spent fuel storage on site).
- Lower modes handled through traditional means and regulatory requirements (i.e., control rod withdrawal DBAs from lower power levels).
- Hazards handled through traditional means and regulatory requirements (Appendix S seismic requirements, Appendix R fire requirements, etc.).
- DBAs confirmed, as needed, by risk insights.

The commenter noted that all of these approaches may utilize the screening criteria in PRA standards to screen out modes, hazards, and sources while still meeting NRC requirements for PRA adequacy or acceptability.

While acknowledging that their stance that DBAs may only need to be confirmed by risk insights could be controversial for 10 CFR Part 53 and arguably not in line with the Commission directive in SRM-SECY-19-0036, the commenter wrote that an approach informed by DG-1414 and maximum credible accident analysis creates a path to a licensing basis determined by traditional DBAs confirmed by a PRA that would remain within the owner scope and be made available to the NRC for auditing. The commenter explained that under such a framework, the PRA would serve as a check on whether the traditional DBAs were in fact bounding (e.g., no risk insights would challenge assumptions made in the DBA). The commenter emphasized that reliance on more traditional means of risk assessment would further section 208 of the ADVANCE Act, which provides that risk analysis methods should encompass alternatives to probabilistic risk assessments.

The commenter expressed concern about language in slides that the NRC presented during a January 16, 2025, public meeting indicating that flexibility in PRA analysis in 10 CFR Part 53 “would be used in limited cases (e.g., seismic analysis) where state of the art knowledge of very low frequency events may not yield useful PRA results.” The commenter argued that Section 3 of the non-LWR PRA standard provides an appropriate framework for determining PRA scope that should be acceptable for all 10 CFR Part 53 applications and may justify limiting PRA scope to full power internal events or even a maximum hazard analysis of other supplemental evaluations. The commenter concluded that such an approach not only would be aligned with the Commission directive in SRM-SECY-19-0036 but also is supported by the PRA Policy Statement.

Quoting the preamble discussion for 10 CFR 53.415, in which the NRC said the requirements of that section would support “either traditional deterministic approaches for determining and protecting against external hazards or probabilistic approaches that are being developed for seismic and some other external hazards,” the commenter suggested that clarity could be gained from the NRC explicitly stating the criteria by which it determines that a hazards PRA or lower modes PRA is necessary. The commenter also asked the NRC for guidance on the statement in the preamble discussion of Subpart C that its approach to determining PRA acceptability offers appropriate flexibility for PRAs to be developed and assessed “based on the application they are used to support,” saying it should build on NRC precedent where development of a certain PRA scope is an entry condition to specific risk-informed applications (e.g., an internal flood PRA could justify deviation from standard review plan (SRP) 3.4.1 for internal flooding design). The commenter described their September 2021 white paper on “Technology-inclusive, Risk-informed, Performance-based Approaches for Development of Licensing Bases Under Part 53” as helping to provide clarity on the various means of risk-informed and performance-based methodologies complying with 10 CFR Part 53 (NEI2-0181).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees that updates to existing RGs, standard review plans, and other NRC guidance to reflect methodologies acceptable under 10 CFR Part 53 would increase regulatory certainty. The NRC continues to identify and develop additional guidance needed to support 10 CFR Part 53 and appreciates the comments’ suggestions for prioritization of such guidance.

As described in the final rule, existing processes in consensus PRA standards related to defining the needed scope and level of detail of a PRA for a given application currently provide flexibility for an applicant to choose whether risk contributors may be evaluated by being represented in a PRA logic model or PRA screening analysis, or by non-PRA approaches, as based on the needs of the application. The requirements under 10 CFR Part 53 could be satisfied using existing processes; however, the NRC recognizes additional specificity in the related requirements can provide clarity on how they can be met. In that regard and consistent with existing processes, the NRC recognizes that PRA, other SREs, or combination thereof may be used together with other generally accepted approaches for systematically evaluating engineered systems to meet the related requirements under 10 CFR Part 53. However, the use of PRA, SREs, or combination thereof would not include the exclusive use of bounding assessments or evaluations as a means to satisfy the analyses requirements under 10 CFR Part 53 because such assessments would not be sufficient to meet certain requirements, for example, under 10 CFR 53.450(b) and 10 CFR 53.450(e) related to the classifying SSCs based on safety significance and identifying significant event sequences.

Accordingly, the NRC has revised the rule language in response to these comments (see also the response to Comment Bin 3.3.2.2.E) to allow for the use of PRA, other SREs, or combination thereof together with other generally accepted approaches for systematically evaluating engineered systems to meet the related requirements under 10 CFR Part 53.

3.3.4. RFC: Earthquake engineering and flexibility in addressing seismic risk (§ 53.480)

Comment Bin 3.3.4.A: Observing that numerous requirements in 10 CFR 53.480 reference both SR and NSRSS SSCs, a commenter stated that limiting the scope of the section to SR SSCs would be more appropriate and align with 10 CFR 53.415 (NEI2-0182, NEI2-0056). The commenter argued that 10 CFR 53.480 lacks sufficient clarification on the design requirements for NSRSS SSCs and, taken together with 10 CFR 53.440(b), could imply that both SR and NSRSS structures must be designed to ASCE 43-05 (and eventually ASCE 43-19) as the only NRC-endorsed standards available (NEI2-0056).

The commenter characterized the requirement in 10 CFR 53.480(c)(vi) on soil-structure interaction as overly prescriptive and, citing NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 3.7.2, cautioned that it may not be appropriate for some sites and designs (NEI2-0182, NEI2-0057). Saying the rule should be performance-based and minimize exemptions, the commenter suggested two changes to the language, from "must take into account" to "should consider" and from "strain limits in excess of yield strain" to "inelastic behavior" (to better characterize the properties of concrete) (NEI2-0182, NEI2-0057).

Another commenter stated that the scope of 10 CFR 53.480 should be limited to SR SSCs in order to align with the existing NRC frameworks, enhance regulatory efficiency, ensure that seismic risk management remains risk-informed and performance-based, and provide necessary flexibility while maintaining safety and supporting the licensing of advanced reactors in accordance with the ADVANCE Act. The commenter added that the NRC should ensure 10 CFR 53.480 is consistent with the ADVANCE Act's goals by incorporating graded approaches for seismic design (SCWG-0002).

NRC Response: The NRC agrees, in part, with the comments.

In regard to the applicability of 10 CFR 53.480 to SR and NSRSS SSCs, the proposed and final rules describe how the rule language for this section can support a variety of approaches to address the design of nuclear plants and specific SSCs to address the risks posed by seismic events. Risk-informed approaches such as those cited in the comment include requirements for both SR and NSRSS SSCs but those requirements can be different to reflect the functions and risk significance of the various SSCs. The NRC is preparing guidance documents that include a graded approach for seismic design by grouping SSCs into different seismic design categories based on their risk significance. Accordingly, the NRC did not change the rule language in response to these comments.

Regarding the part of the comment suggesting specific changes to 10 CFR 53.480(c)(1)(vi), the NRC agrees with the suggested edits. Accordingly, the NRC has revised the rule language in response to this comment.

Comment Bin 3.3.4.B: A commenter stated that the NRC should include provisions in the rule for developing ground motion response spectra that would enable the use of alternative, risk-informed, performance-based approaches to seismic design and develop related guidance instead of utilizing the seismic design requirements in Appendix S, "Earthquake Engineering Criteria for Nuclear Power Plants," to 10 CFR Part 50. The commenter explained this would allow applicants with sufficient risk insights to grade the assumptions and inputs for the seismic analyses and classification of SSCs. The commenter added that there is risk-informed guidance through consensus codes such as ANS 2.26 and ASCE 7 that could provide a method for the use of information such as high-quality U.S Geological Survey data, which could minimize the need for expensive site characterization efforts prior to a license application submittal (USNIC2-0017).

NRC Response: The NRC agrees with the comment.

Provisions similar to those suggested in the comment were included in the proposed rule language for 10 CFR 53.480, “Earthquake engineering” in paragraph (c), “Design considerations,” and remain in the final rule.

Accordingly, the NRC did not change the rule language in response to this comment.

3.4. Subpart D: Siting Requirements (§§ 53.500-53.540)

3.4.1. External hazards (§ 53.510)

No comments are associated with this issue.

3.4.2. Other comments on Subpart D

Comment Bin 3.4.2.A: A commenter stated that the proposed rule provides no technical or regulatory basis for the decision to retain the 10 CFR Part 100 siting requirements and expressed concern regarding the adverse implications for siting of advanced reactors close to or within larger population centers to support various industrial and commercial applications. The commenter stated that importing the prescriptive and exclusionary 10 CFR Part 100 population siting requirements is inconsistent with the purpose of 10 CFR Part 53 as mandated in NEIMA and reinforced by the ADVANCE Act, and they requested that the NRC’s approach to population siting provide new applicants with flexibility to site plants closer to or within densely populated centers based on the specific reactor designs and safety attributes. The commenter suggested that the NRC’s 2023 rulemaking establishing alternative emergency planning zone (EPZ) sizing requirements for SMRs and ONTs provides the necessary technical and regulatory bases for population siting requirements in 10 CFR Part 53, without increasing risk to the public or reducing defense-in-depth, and is supported by discussion in SECY-16-0012, “Accident Source Terms and Siting for Small Modular Reactors and Non-Light Water Reactors,” issued February 2016 (ML15309A319) and SECY-20-0045, “Population Related Siting Considerations for Advanced Reactors,” issued May 2020 (ML19143A194). The commenter suggested that the NRC should remove proposed 10 CFR 53.530(c), rely on updated guidance in RG 4.7, and develop performance-based guidance to potentially allow siting of low-consequence reactors close to or within densely populated centers containing more than 25,000 residents (NEI2-0249, NEI2-0253).

The commenter reasoned that because the siting requirements in Subpart D were carried over from 10 CFR Part 100 without being modified to be performance-based in line with NEIMA, they would impose significant unnecessary regulatory burden (NEI2-0006).

The commenter questioned the need for 10 CFR 53.500, saying it essentially duplicates all the requirements in Subpart D at a high level. The commenter suggested revising the section to clarify that it is a purpose statement, outlining the collective nature of the Subpart D requirements and the outcome achieved by meeting those requirements, rather than a requirement that an applicant and licensee must meet (NEI2-0059).

The commenter also took issue with 10 CFR 53.530, which they said was copied from 10 CFR Part 100 and may not be appropriate for smaller, low-consequence reactors, and they quoted language from SECY-24-0008 in which the NRC seems to acknowledge that this requirement may be too restrictive. Because 10 CFR Part 53 intends to be performance-based and should consider microreactor deployment models as directed by the ADVANCE Act, the commenter argued, the population center distance criteria should not be prescriptive and exclusionary. The commenter suggested removing 10 CFR 53.530(c) or revising 10 CFR 53.530 as follows:

- Add a second sentence to the introductory paragraph: “For sites that establish that no plume exposure pathway EPZ is required or that the plume exposure pathway EPZ does not extend beyond site boundary in accordance with the requirements of § 53.1109(g)(2) of this chapter, the low-population zone and population center distance would coincide with the site boundary.”

- Remove the language from 10 CFR 53.530(c) discussing that reactor sites should be located away from very densely populated centers.

The commenter suggested that performance-based guidance on potentially co-locating the low population zone and population center distance with a site boundary EPZ should be developed for the population density criterion, writing that this would potentially allow siting of low-consequence reactors close to or within densely populated centers containing more than about 25,000 residents. The commenter stated its intent to further justify this position in an upcoming white paper to the NRC (NEI2-0061). Other commenters agreed with these suggestions (NEX-0026, USNIC2-0027).

A commenter objected to the proposed options set forth in SECY-20-0045 regarding site selection for SMRs, arguing that they are deterministic when NEIMA calls for risk-informed approaches and would eliminate the siting of SMRs on sites where higher powered LWRs have operated safely for years. The commenter wrote that this deterministic approach to site selection is not based on science and can frighten the public without good reason by overstating the risk of health hazards, and they disputed the idea that a 20-mile radius adds defense in depth. The commenter urged the NRC to rescind SECY-20-0045 and RG 4.7, which they said can promote fear of nuclear energy, are not risk-informed, and could be replaced with risk-informed technologies now available (MU1-0003). Similarly, another commenter asked the NRC to reconsider its preference for siting reactors in areas of low population density and to apply a more risk-informed and performance-based approach to radiation safety and adequate protection (RAD-0015).

NRC Response: The NRC agrees, in part, with the comments.

Regarding the suggestion of alternatives to the population-related siting considerations in the proposed 10 CFR 53.530, the NRC has revised the final rule to allow proposed siting based on assessments of estimated societal risks as compared to societal benefits of siting a commercial nuclear plant in a more densely populated area. The NRC disagrees with approaches for siting considering only estimated doses to individuals from licensing-basis events or siting solely on the possible need to take prompt protective actions such as evacuating people because an important part of the historical purpose of the siting provisions in 10 CFR Part 100 and the proposed Subpart D to 10 CFR Part 53 was to take into consideration the broader societal impact of reactor accidents. The changes to 10 CFR 53.530(b) and (c) provide an option for sites to be proposed using assessments of additional societal risks associated with siting a reactor in areas of higher population density (e.g., potential increases in population dose or economic consequences from reactor accidents) in comparison to the societal benefits of a specific site (e.g., ability to use existing infrastructure for a retired fossil fuel power plant). The measure of merit for a comparison of societal benefits to societal risks would likely be expressed in dollars.

The NRC agrees, in part, with that part of the comment related to 10 CFR 53.500 and has revised the rule language for the final rule to have that section serve as an introduction to Subpart D.

The NRC disagrees that the revisions to RG 4.7 and associated provisions in 10 CFR 53.530 are not risk-informed insofar as the events considered in determining the areas in which population density is assessed are the licensing-basis events identified from the probabilistic risk assessment or other systematic risk evaluations under 10 CFR 53.450(e). The changes made to 10 CFR 53.530 to provide an option for considering societal risks and societal benefits will likewise be risk-informed since such assessments consider the analyses of event frequencies and consequences under 10 CFR 53.450(e).

Accordingly, the NRC has revised the rule language in 10 CFR 53.500 and 10 CFR 53.530(b) and (c) in response to these comments.

Comment Bin 3.4.2.B: A commenter suggested that instead of effectively relocating the siting requirements from one part to another without endeavoring to establish a more modern technology-inclusive, risk-informed, and performance-based approach to siting, 10 CFR Part 53 should reevaluate that approach by considering how safety, security, EP, and siting could be better integrated to establish a more efficient framework (NEI2-0060, NEI2-0058). Another commenter agreed with this suggestion (NEX-0025, NEX-0024).

Specifically, the commenter referenced their February 11, 2021, comment letter that proposed establishing the site boundary, in lieu of the low population zone and exclusion area boundary, as the key boundary, in alignment with the SMR Emergency Preparedness rulemaking, thus streamlining the licensing basis of the facility (NEI2-0058). Another commenter agreed with this suggestion (NEX-0024).

NRC Response: The NRC disagrees with the comments.

The NRC disagrees that the siting requirements in 10 CFR Part 53 require a fundamental reevaluation. The rule is technology-inclusive and so must accommodate siting for all types of facilities, from microreactors to large-LWRs. In addition, 10 CFR Part 53 and 10 CFR Part 73 include risk-informed alternatives that can consider potential offsite consequences resulting from a variety of events and hazards for specific sites and thereby provides a more integrated regulatory framework.

However, the NRC has changed some of the siting requirements in 10 CFR 53.530 in response to comments on that section of the rule. See the NRC’s response to Comment Bin 3.4.2.A.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.4.2.C: A commenter that supported increased licensing of microreactors suggested revising the rule as follows (BI1-0018, BI1-0019):

- For consistency with the approach in 10 CFR Part 50 and 10 CFR Part 52, relocate from 10 CFR 53.530(c) to guidance the statement that reactor sites should be located away from very densely populated centers.

- Include a categorical exemption from 10 CFR 53.530 for existing sites defined as “covered sites” in the ADVANCE Act, including microreactors, coal to nuclear transitions, production facilities, utilizations facilities, and brownfield sites.

- Change the definition of population center distance from the deterministic threshold of 25,000 residents to a risk-informed, performance-based metric.

- To the extent possible, use available information and data, such as site-specific geologic, seismic, weather, and other environmental data.

- Potential impacts to the environment from a new facility should consider improvements that may occur compared to the as-found condition of the site.

- Permit the use of plant parameter envelopes and site parameter envelopes on a portion of a larger site without the need to segment the site parcel.

- Allow the use of ESPs, with or without site parameter envelopes, to finalize site approval without the need to re-evaluate the site when evaluating a CP, OL, or COL, with the ESP remaining valid unless and until significant changes in the site are identified.

Stating that the regulations should be applicable to all reactor types and deployment models that could be deployed under 10 CFR Part 53, including microreactors, a commenter asked the NRC to consider whether the inclusion of population-related siting criteria could unnecessarily restrict deployment opportunities for microreactors that meet the dose requirements, which they said have the potential to be a highly reliable power source for facilities located in large population density areas. The commenter described the siting criteria as prescriptive, exclusionary, and inconsistent with the performance-based objectives of the proposed rulemaking and concluded that their removal would address the ADVANCE Act’s directive for consideration of deployment models (WEST1-0010).

Another commenter suggested adopting siting criteria that consider envelopes of approved site characteristics for a specific design, including approaches for seismic envelopes. To allow siting closer to or in population centers, and/or co-located with or near industrial facilities, the commenter suggested removing the phrase “containing more than about 25,000 residents” from the definition of population center distance. Cautioning that an incremental approach misses the opportunity to achieve transformational changes that result in a more efficient regulatory framework to protect the public health and safety, the commenter urged the NRC to move away from an approach to siting grounded in the 1960s/1970s and instead build 10 CFR Part 53 upon a more modern, realistic, and flexible regulatory framework (USNIC2-0012).

Another commenter objected to the definition of population center distance because: (1) it is not technology-inclusive and is overly descriptive, limiting the flexibility needed to accommodate a diverse range of reactor technologies; (2) a one-size-fits-all approach does not account for the specific circumstances and characteristics of advanced reactors; and (3) the assumption that population growth is inherently problematic overlooks natural, expected trends of demographic shifts (e.g., population growth near existing plants due to workforce commute). The commenter argued that 10 CFR 53.530(a)(1) and (2) represent deterministic risk objectives that fail to account for broader, population-related considerations and do not integrate defense-in-depth (e.g., by not allowing for protective actions that are a critical part of emergency preparedness requirements). The commenter described the narrow focus of these requirements as inconsistent with a holistic, integrated approach to licensing, which should encompass the full spectrum of safety measures, including preparedness and protective actions, rather than focusing solely on fixed, prescriptive risk thresholds. Thus, the commenter suggested revising the rule to align with a more flexible, inclusive framework that accounts for the unique safety features of advanced reactors and integrates the full range of protective measures (BI1-0028).

NRC Response: The NRC agrees, in part, with the comments.

10 CFR Part 50 and 10 CFR Part 52 require compliance with 10 CFR Part 100, which includes a requirement under 10 CFR 100.21(h) that a reactor site be located away from very densely populated centers.

The NRC disagrees with changing the definition of the population center distance in 10 CFR 53.020, which is based on past legal and policy precedents. However, while the related requirement under 10 CFR 53.530(c) establishes a preference for siting reactors in areas of low-population density, the NRC acknowledges that some proposed reactor designs may be able to justify different siting scenarios based on appropriate analyses of factors that impact public health and safety.

Accordingly, the NRC has revised the rule language in response to these comments and Comment Bin 3.4.2.A. Specifically, the NRC has revised 10 CFR 53.530(c) to allow alternatives to siting a reactor away from very densely populated centers as supported by an acceptable technical basis.

3.5. Subpart E: Construction and Manufacturing Requirements (§§ 53.600-53.620)

3.5.1. Factory fuel loading requirements (§ 53.620)

3.5.1.1. Comments on factory fuel loading requirements not related to RFC

Comment Bin 3.5.1.1.A: A commenter suggested removing the term “fresh fuel” (in reference to a reactor becoming fueled at the manufacturing facility prior to shipment) from 10 CFR Part 53 for the following reasons (SG1-0001):

- Factory acceptance testing is expected to occur at the conclusion of manufacturing a microreactor at the factory, creating byproduct material in the final reactor ready for shipment, which means that the package will be slightly radioactive and need shielding during transportation.
- Fresh fuel transportation does not need meaningful shielding.
- The total applicability of 10 CFR Part 71 is cited in 10 CFR Part 53.

NRC Response: The NRC disagrees with the comment.

10 CFR Part 53 does not include specific provisions for the testing of manufactured reactors within the manufacturing facility. The NRC’s response to comments in Section 3.8.10 explains that the NRC considered adding such provisions, but comments received generally favored approaches where applicants for or holders of an ML would request exemptions from specific

requirements in 10 CFR Part 53 to allow reactor testing at the manufacturing facility. The NRC therefore elected to not make changes to the final rule language to accommodate factory testing. The introduction of byproduct materials by operational testing at the manufacturing facility will need to be addressed within any exemption requests from any part of NRC regulations.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.5.1.1.B: Regarding the proposed requirement in 10 CFR 53.620(d)(1)(i) that fuel loading of a manufactured reactor is allowed only if at least two independent physical mechanisms—each sufficient to prevent criticality assuming optimum moderation and neutron reflection conditions—are in place, a commenter argued that the requirement is unnecessary because the requirements of Subpart H of 10 CFR Part 70 already provide reasonable assurance that subcriticality will be maintained throughout all processes. The commenter thus proposed revising 10 CFR 53.620(d) as follows:

- In 10 CFR 53.620(d)(1)(i), remove “only if the manufactured reactor is configured during its loading, storage, and transport with at least two independent physical mechanisms in place, each of which is sufficient to prevent criticality assuming optimum neutron moderation and neutron reflection conditions.”
- Revise 10 CFR 53.620(d)(1)(iii) by replacing “in which the independent physical mechanisms to prevent criticality have been installed” with “possessed under a 10 CFR part 70 license.”
- Revise 10 CFR 53.620(d)(1)(iv) by replacing “the independent physical mechanisms to prevent criticality may be removed” with “the licensee may remove manufacturing controls in place to ensure subcriticality” and changing the last sentence to state that “Upon removing those controls, a manufactured reactor has commenced operation.”

The commenter also suggested related changes to other sections of the regulatory text as follows:

- Revise 10 CFR 50.160(c)(2) by replacing “removal of any one of the independent physical mechanisms to prevent criticality” with “removal of manufacturing subcriticality controls at the operating site.”
- Revise footnote 1 to 10 CFR 53.1452 by replacing “its scheduled date for initiating the physical removal of any one of the independent physical mechanisms to prevent criticality required under § 53.620(d)(1)” with “its scheduled date for initiating the removal of manufacturing subcriticality controls required under § 53.620(d)(1) through the ML.”

Lastly, the commenter suggested that all other instances in the proposed rule of “physical mechanisms” should change to “manufacturing subcriticality controls” (NEI2-0067).

Similarly, another commenter questioned why multiple requirements in 10 CFR 53.620(d)(1) related to transportation of a fueled reactor refer to “independent physical mechanisms” to prevent criticality when the equivalent requirement in 10 CFR Part 50 does not specify that they must be physical. The commenter asserted that this specificity introduces a prescriptive requirement, leads to overinterpretation of wording and intent, restricts the ability to select alternate and equally effective measures, and could preclude licensing of mobile reactors if a broad requirement for physical prevention of criticality is required during transportation (RAD-0006).

Other commenters stated that a requirement for at least two independent physical mechanisms to prevent inadvertent criticality is unnecessary because:

- the requirement goes beyond established NRC regulatory precedent and consensus standards (e.g., ANSI/ANS-19.13) that already provide adequate protection and align with defense-in-depth principles (SCWG-0003, BI1-0008);
- the requirement does not align with risk-informed, performance-based principles (SCWG-0003, BI1-0008);
- the requirements in 10 CFR Part 70 are adequate (WEST1-0007); and
- the requirement adds significant and potentially confusing layers of requirements above the double contingency principle practices proven over decades of operations with SNM (WEST1-0007).

Two commenters stated that the NRC could further risk-inform the rule in line with NEIMA and the ADVANCE Act by revising the requirement to allow for technology-inclusive approaches without impacting protection (SCWG-0003, BI1-0008).

NRC Response: The NRC agrees, in part, with the comments.

The NRC does not fully agree with the relevance of consensus codes and standards related to physics testing and criticality controls for fissionable materials outside of reactors. However, the NRC agrees that the final rule text would benefit from additional flexibilities. The final rule now requires the manufactured reactor to be configured during its loading, storage, and transport with features to prevent criticality and requires that those features be specified in the ML. The requirement provides flexibility to address the variety of reactor designs and possible approaches to prevent criticality and the range of possible conditions associated with the loading, storage, and transport of manufactured reactors. The requirement, to have in place features to prevent criticality, could support meeting the provisions in Subpart H to 10 CFR Part 70. However, the protections may go beyond those requirements to address concerns associated with fueling, storing, and transporting a nuclear reactor with the fuel arranged in what will be a critical configuration during operations.

The final rule removed the prescriptive requirement that was in the proposed rule and allows applicants to propose features to prevent criticality that are appropriate for specific reactor designs and circumstances associated with their fueling, storage, and transport. While the features to prevent criticality will be governed by various parts of NRC regulations, they will be included in the ML to manage the appropriate controls during the various phases of the manufacture, fueling, storage, transport, and deployment of the manufactured reactor. As stated in the comment, the suggested changes to 10 CFR 53.620(d) also required conforming changes to other sections in 10 CFR Part 53.

Accordingly, the NRC has revised the rule language in 10 CFR 53.620(d) and made conforming changes throughout 10 CFR Part 53 in response to these comments.

Comment Bin 3.5.1.1.C: A commenter discussed that the proposed rule missed an opportunity to address transportation of microreactors. The commenter stated that 10 CFR Part 53 begins with a pathway for the transport of a fueled microreactor and cited relevant discussion from SECY-24-0008 regarding the operating status of a fueled microreactor. The commenter expressed agreement with the SECY-24-0008 conclusion that a fueled microreactor with features to preclude criticality should not be considered “in operation,” and they suggested that more can be done to increase regulatory certainty and technology inclusivity in the context of fueled or mobile microreactors transport and licensing (NEI2-0252).

NRC Response: The NRC agrees, in part, with the comment.

The proposed and final rule includes a Commission finding in 10 CFR 53.620(d)(iii) that a manufactured reactor meeting the requirements of 10 CFR 53.620(d)(i) is not in operation.

The NRC has also revised the rule language to address other comments in this section (Section 3.5.1.1). The NRC is undertaking a separate rulemaking effort to expedite licensing of qualifying microreactors and other low safety and security consequence reactors. This rulemaking effort is consistent with the ADVANCE Act and EOs issued in 2025.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.5.1.1.D: A commenter stated that the proposed rule does not include modifications to 10 CFR Part 71 to align it with 10 CFR Part 53 and that this is evident in 10 CFR 53.620(e)(4), which requires that for a manufactured reactor pre-loaded with fresh fuel and transported to its place of operation, transportation must comply with 10 CFR Part 71 and 10 CFR Part 73. The commenter asserted that the prescriptive nature of 10 CFR 71.55 may not adequately accommodate advanced reactor designs, and 10 CFR 71.73 requirements may not sufficiently cover advanced reactor designs during transportation.

The commenter recommended the NRC consider using a technology-inclusive, risk-informed, and performance-based approach in developing packaging and transportation requirements in 10 CFR Part 71 to meet the objectives of the proposed regulatory framework. The commenter said that this approach should address the needs of factory-fueled reactors that require transportation from the factory to their operational sites (IDNL-0006).

NRC Response: The NRC agrees, in part, with the comment.

As discussed in the response to Comment Bin 3.5.1.1.B, the NRC has revised the requirements in 10 CFR 53.620(d) related to features to prevent criticality in the final rule. This change offers additional flexibility in 10 CFR Part 53 and may facilitate the alignment of design features and other measures needed to comply with requirements in 10 CFR Part 71. However, the NRC acknowledges that applicants will need to carefully assess the various regulations of the NRC and other agencies and may propose exemptions from specific regulations where appropriate and justifiable.

Additional rulemakings may be appropriate as the designs and deployment models evolve. For example, the NRC is undertaking a separate rulemaking effort to expedite licensing of microreactors and other low safety and security consequence reactors. This rulemaking effort is consistent with the ADVANCE Act and EOs issued in 2025.

Accordingly, the NRC did not change the rule language in response to this comment.

3.5.1.2. RFC: Applicability of factory fuel loading requirements by size or type of reactor

Comment Bin 3.5.1.2.A: One commenter stated that the rule should clearly and efficiently allow for factory fuel loading of reactors with factory-focused inspections and testing of production units. The commenter suggested incorporating SECY-24-0008 and making such approaches acceptable for any technology that can use them, not just microreactors. The commenter supported the staff's recommended options 1b, 2b, and 3b, which would allow the staff to employ risk insights and performance-based approaches to regulating commercial factory-fabricated reactors, and said options 1a, 2a, and 3a, which mostly rely on established policies and processes for power reactor licensing, may be appropriate in certain circumstances (USNIC2-0014).

NRC Response: The NRC agrees, in part, with the comment.

10 CFR Part 53 includes provisions for the loading of fuel into manufactured reactors at the manufacturing facility. The associated provisions do not have specific exclusions that limit them to microreactors and are similar to the options described in SECY-24-0008 for how factory fuel loading might be accomplished under 10 CFR Part 50 and 10 CFR Part 52.

Regarding allowing operational testing of manufactured reactors within the manufacturing facility (Options 3a and 3b in SECY-24-0008), the response to the comments in Section 3.8.10 explains that the NRC has not included specific provisions for such testing in 10 CFR Part 53 but instead agrees with the comment’s suggestion that applicants for or holders of manufactured licenses would follow the approach outlined in SECY-24-0008 and request specific exemptions from various requirements in 10 CFR Part 53 based on particulars of the reactor design and testing plans.

Accordingly, the NRC did not change the rule language in response to this comment. However, the NRC did revise the rule language in response to a related comment on appropriate measures to prevent criticality in fueled manufactured reactors. See the response to the comments in Section 3.5.1.3.

3.5.1.3. RFC: Inclusion of Subpart H to 10 CFR Part 70 requirements for factory fuel loading

Comment Bin 3.5.1.3.A: A commenter said there is a gap with regard to factory testing of fueled microreactors and that this topic would be addressed more efficiently by relying on existing guidance instead of adding new requirements. The commenter also asked for more clarity in the rule on the relationship between requirements in 10 CFR Part 53 and 10 CFR Part 70, which includes performance requirements for radiological, chemical, fire, and criticality safety. The commenter cautioned that attempts to either bypass or restate the requirements of 10 CFR Part 70 in 10 CFR Part 53 could overlook requirements that are essential to factory safety and safeguards, result in contradictions between the two parts, and lead to confusion regarding which regulation is operative.

The commenter noted some proposed requirements that they consider duplicative:

- Requiring licenses issued under 10 CFR Part 70 for loading fuel into a manufactured reactor to comply with that part's Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material."
- 10 CFR 53.620(e)(2), which appears to be duplicative of 10 CFR 53.620(e)(4).

The commenter also noted some proposed requirements that they consider unduly restrictive:

- Limiting shipment of a manufactured and loaded microreactor to destinations with a COL, which should be revised to include deployment sites for which the NRC has issued an export license under 10 CFR Part 110.
- Absent a safety finding, fabrication should be able to start any time when the ML is in timely renewal.
- A reactor in which there are two independent features to preclude criticality is not "designed or used to sustain nuclear fission."
- Limiting the number of microreactors that a manufacturing facility can produce over its lifetime, while the rule instead should limit, based on safety and security analyses, the quantity of SNM onsite and the number of reactors fabricated and being loaded with fuel at a given time.
- Not authorizing changes to an ML, as the proposed rule appears to do, which would not allow for technological innovation after feedback from reactor operations.

The commenter suggested that any attempt to control the possession and use of SNM should be relegated, by reference in 10 CFR Part 53, to the requirements of 10 CFR Part 70, with the 10 CFR Part 53 ML findings limited to those attributes that are relevant to the ultimate reactor operational safety and safeguards. The commenter described an approach in which the 10 CFR Part 53 finding would only authorize assembly and fueling at a manufacturing facility licensed under 10 CFR Part 53 but would require a separate safety finding consistent with 10 CFR Part 70 for all SNM operations in a factory setting, including reactor fueling.

Finally, the commenter requested additional clarification in Subpart E of this rule to differentiate the 10 CFR Part 53 requirements for manufactured reactors that do not include in-factory fueling activities from the requirements addressing SNM and radioactive material activities for a manufactured reactor fueled at a factory (NEI2-0184).

Another commenter agreed that the requirement limiting shipment to only destinations with a COL should be revised to include deployment sites for which the NRC has issued an export license under 10 CFR Part 110, writing that the proposed requirement limits U.S. reactor vendors (going against the goals of the ADVANCE Act) or requires them to have fabrication facilities outside the United States (WEST1-0008).

NRC Response: The NRC agrees, in part, with these comments.

As explained in the proposed and final rules, the loading of fuel into manufactured reactors in a factory setting will involve several parts of NRC regulations in 10 CFR. The primary connection with 10 CFR Part 53 is the manufactured reactor and ensuring that its subsequent operation will not present undue risk to public health and safety. The possession of special nuclear material will require a license under 10 CFR Part 70. Section 10 CFR 53.620(d) makes Subpart H of 10 CFR Part 70 applicable and largely controlling of the fuel loading activities within the manufacturing facility instead of using the requirements for design, construction, and operations under 10 CFR Part 53.

In recognition that the manufactured reactor does differ from most fuel cycle facilities in that the fuel is loaded into what will be a critical configuration for plant operation, additional measures are included in 10 CFR 53.620, including the need for features to prevent criticality that are specified in the ML. The NRC has revised the requirements in 10 CFR 53.620(d)(1) related to criticality prevention in response to Comment Bin 3.5.1.3.C.

The NRC sees how paragraph 10 CFR 53.620(e)(4) can be viewed as being duplicative of the more general requirements in paragraph 10 CFR 53.620(e)(2). However, the distinction is that 10 CFR 53.620(e)(2) is a requirement on licensees, and 10 CFR 53.620(e)(4) is a requirement for the content of an ML. No change was made in response to the comment in order to maintain the emphasis on additional requirements that apply to the transport of a fueled manufactured reactor.

The NRC agrees with allowing transport of a manufactured reactor to a destination covered by 10 CFR Part 110, as explained in the response to Comment Bin 3.5.2.F, and accordingly has changed the rule language for the final rule.

The NRC agrees with the suggestion that the holder of an ML may continue to manufacture manufactured reactors so long as a timely application for renewal has been filed. The NRC has removed the restriction that stated that manufacturing could not begin with less than 6 months before the expiration of the license. See the NRC’s response to Comment Bin 3.8.6.B.

The NRC agrees, in part, that changes to the design of a manufactured reactor should be allowed. See the NRC’s response to Comment Bin 3.9.3.B.

Accordingly, the NRC revised the rule language as described in the referenced Comment Bin responses, but the NRC did not make additional changes to the rule language in response to these comments.

Comment Bin 3.5.1.3.B: A commenter asserted that 10 CFR Part 70 sufficiently governs the handling, processing, and loading of nuclear fuel, ensuring appropriate safety and security measures are in place, and thus suggested removing 10 CFR 53.620(d) as it is unnecessary and redundant. The commenter reasoned that while the NRC has not previously applied 10 CFR Part 70 to factory fuel loading of a manufactured reactor, it provides an established, structured approach, nor has the NRC previously applied different standards in this context (SCWG-0017, SCWG-0021).

NRC Response: The NRC agrees, in part, with the comments.

See the response to Comment Bin 3.5.1.1.B regarding the NRC revisions to the rule language for 10 CFR 53.620(d), which provides flexibility in how an applicant or licensee defines features to prevent criticality for fueling, storing, and transporting a fueled manufactured reactor. The requirements in 10 CFR 53.620(d) do rely heavily on the regulations in 10 CFR Part 70 to address the handling of special nuclear material, the loading of fuel into manufactured reactors, and the subsequent storage of the fueled manufactured reactor pending its transport from the manufacturing facility.

However, the NRC does not agree that the references to 10 CFR Part 70 render 10 CFR 53.620(d) unnecessary because the provisions in 10 CFR Part 53 provide the necessary structure for the regulation of the manufactured reactor under those sections of the AEA and other NRC regulations governing commercial nuclear plants. 10 CFR 53.620(d) also confirms that a manufactured reactor is not in operation while the mechanisms to prevent criticality are in place even after fuel load and therefore can be possessed with just the ML and not the operating licenses traditionally used for loading of fuel into a nuclear reactor under 10 CFR Parts 50 and 52.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.5.1.3.C: A commenter expressed concern that the proposed rule departs from the NRC-endorsed voluntary consensus standard ANSI/ANS-8.1-2014 (R2023), "Nuclear Criticality Safety in Operations with Fissionable Material Outside Reactors," without justification. The commenter wrote that the requirement for at least two independent physical mechanisms that will each prevent criticality is inconsistent with ANSI/ANS-8.1-2014 (R2023), goes beyond what 10 CFR Part 70 requires for reasonable assurance of adequate protection, and is not performance-based as mandated by NEIMA and the ADVANCE Act. The commenter argued that the existing process analysis requirement in ANSI/ANS-8.1-2014 (R2023) and double contingency principle in 10 CFR Part 70 are the foundations of criticality safety for all 10 CFR Part 70 facilities, while the proposed requirement would add a burdensome, prescriptive level of control that bars non-physical methods of control that would meet the existing regulation in 10 CFR Part 70. Quoting OMB Circular A-119, which states that "all Federal agencies must use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical," the commenter explained that while the NRC's endorsement of ANSI/ANS-8.1-2014 (R2023) was not without exception, it did not take exception to the performance process analysis requirement or the double contingency recommendation. The commenter requested that the NRC revise the rule to require the operations covered by 10 CFR 53.620(d) to follow the ANSI/ANS-8 series of standards, particularly ANSI/ANS-8.1-2014 (R2023), for ensuring criticality safety at 10 CFR Part 70 facilities (ANS-0001).

Another commenter wrote that for a microreactor with two methods to control criticality (thus satisfying the double contingency principle), the safety evaluation should show that there is no way for an inadvertent criticality event at fuel load, even during an accident or natural phenomena, and as such the NRC should not treat it as a nuclear reactor. Stating that the requirements of 10 CFR Part 70 should be adequate for safely loading fuel into a reactor at the factory, the commenter argued that there is no need to require, as 10 CFR 53.620(d)(1)(i) does, also having in place at least two independent criticality prevention mechanisms. The commenter asserted that this requirement not only is unnecessary but also adds significant and potentially confusing layers of requirements above long-established double contingency principle practices and could preclude the otherwise safe loading of certain reactor types without the need to disassemble at the use site to remove physical mechanisms.

Objecting to the requirement for two separate mechanisms, the commenter quoted the definition in 10 CFR 70.4 of the double contingency principle, which states that "process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible." The commenter then noted that as described in NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications —Final Report," issued June 2015 (ML15176A258), one mechanism can provide control of two separate parameters, or a single process can be controlled such that at least two independent failures involving the parameter would be required before a criticality accident is possible. Lastly, the commenter remarked that adequate guidance for factory fueling activities can be developed as necessary to provide clarity for 10 CFR Part 70 license holders that will manage them (NEI2-0188).

NRC Response: The NRC agrees, in part, with the comments.

See the response to Comment Bin 3.5.1.1.B regarding the NRC revisions to the rule language for 10 CFR 53.620(d), which provides flexibility in how an applicant or licensee defines features to prevent criticality for fueling, storing, and transporting a fueled manufactured reactor. In making this change to 10 CFR 53.620(d) and the conforming changes, the NRC is open to reviewing proposals and including requirements in manufacturing licenses but does not necessarily agree that criticality controls for all manufactured reactors with fuel loaded into critical configurations for the purpose of operations are sufficiently addressed by the referenced standards related to the handling of fissionable material outside of reactors.

Regarding the suggestion that fueled manufactured reactors need not be considered utilization facilities, see the NRC's response to Comment Bin 3.8.9.A.

Accordingly, the NRC did not change the rule language in response to these comments.

3.5.1.4. RFC: Security programs for a fueled manufactured reactor (§ 53.620(d)(2)(i))

Comment Bin 3.5.1.4.A: A commenter suggested handling the safeguards and security aspects of a manufacturing facility authorized to possess SNM independently of 10 CFR Part 53 and incorporated into the 10 CFR Part 70 possession license. The commenter described their understanding that Category III safeguards measures for protecting SNM are currently adequate in 10 CFR Part 73 and 10 CFR Part 74 and that the NRC is treating Category II possession on a case-by-case basis due to the small number of applicants seeking to possess such quantities. The commenter concluded that while long-term changes to 10 CFR Part 73 and 10 CFR Part 74 may be warranted, this should be handled in existing regulations related to material possession rather than codified in 10 CFR Part 53 (NEI2-0191).

NRC Response: The NRC agrees, in part, with this comment.

The NRC intends to license SNM at a manufacturing facility under 10 CFR Part 70. This will require the licensee to protect the SNM under the requirements of 10 CFR 73.67 for Category II and Category III SNM. Once the fuel is loaded into the reactor this material will be protected per 10 CFR 53.620(d) which likewise points to 10 CFR 73.67 for physical protection against radiological sabotage.

The NRC considers physical protection for Category III adequate.

Prior to loading the fuel into the manufactured reactor, for Category II SNM the NRC intends to continue its practice of evaluating the physical protection needed to ensure adequate protection on a site-specific, case-by-case basis informed by material attractiveness concepts.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.5.1.4.B: A commenter supported requiring security programs for all MLs where fuel will be loaded into reactors, with the security requirements based on the categorization of the fuel type regardless of where that fuel is stored, and suggested imposing additional security requirements for pre-loaded reactors at manufacturing facilities to preclude clandestine operation of the reactors that could result in the production of SNM of higher strategic significance than the fresh fuel. The commenter also advocated the development of more stringent supplemental security measures for high-assay low-enriched uranium (HALEU) in quantities above 20 kilograms of contained uranium-235 to protect against the design-basis threat (DBT) of theft, referencing a recent article on the weapons potential of HALEU (UCS-0008).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that security programs should be required for all manufacturing licenses where fuel will be loaded into reactors. Currently, 10 CFR 73.67 only requires a security plan for licensees who possess, use, transport, or deliver to a carrier for transport SNM of moderate strategic significance (Category II), or 10 kg or more of SNM of low strategic significance. However, the physical security program for fueled manufactured reactors will require a security plan for any ML authorizing possession of a manufactured reactor into which fuel has been loaded at the manufacturing facility, regardless of fuel type, enrichment, and quantity. In addition, RG 5.97, “Guidance for Technology-Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants,” has been updated to include a section on security requirements for the possession and loading of fresh fuel into a manufactured reactor.

Regarding the comment’s suggestion for the development of more stringent supplemental security measures for high-assay low-enriched uranium (HALEU), the regulations in 10 CFR 73.67(d) and (e) for the protection of Category II quantities of SNM represent the minimum requirements for physical protection. The NRC uses a risk-informed site-specific physical security analysis to determine if additional security requirements are needed in addition to the requirements in 10 CFR 73.67 to ensure the adequate protection of Category II quantities of SNM. The NRC has determined that this graded approach ensures that any licensed facility will be in accord with the common defense and security.

Accordingly, the NRC did not change the rule language in response to this comment; the NRC revised RG 5.97 (formerly DG-5076) in response to this comment.

3.5.1.5. RFC: Cybersecurity programs for a fueled manufactured reactor (§ 53.620(d)(2)(i))

Comment Bin 3.5.1.5.A: Because existing cybersecurity requirements for possession licenses are adequately implemented, a commenter explained, there is minimal value in codifying the requirements into 10 CFR Part 53 for possession and fuel loading activities conducted under a 10 CFR Part 70 license at the manufacturing facility. However, the commenter noted, there may be components of cybersecurity that need to be implemented at the manufacturing facility to prevent issues from manifesting at the reactor operating site under the OL or COL (NEI2-0192). Another commenter expressed support for the comment (NEX-0017).

NRC Response: The NRC disagrees with the comments.

The NRC disagrees that cybersecurity requirements for possession licenses are currently adequately implemented as there are no existing cybersecurity requirements for possession. Furthermore, the NRC disagrees that there is minimal value in codifying cybersecurity requirements under 10 CFR Part 53. Cybersecurity needs to be implemented at the manufacturing facility to prevent issues from manifesting during operations as stated by the comment.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.5.1.5.B: In response to an NRC request for comment, a commenter stated that they expect to utilize digital technologies to the maximum extent for physical security controls, radiation monitoring, and criticality controls at a manufacturing facility, writing that such systems have demonstrated maturity and benefits in performance and capability. The commenter suggested that ML holders should be required to protect digital systems that are involved in the fuel loading operations, while digital systems that are part of the manufacturing facility but do not interact with fueling operations should not require NRC oversight regarding protection (RAD-0008).

NRC Response: The NRC agrees, in part, with the comment.

While not being as prescriptive as suggested in the comment, the NRC has revised the rule text for 10 CFR 53.620(d)(2)(i)(C) to ensure only those digital assets that are necessary for the possession and loading of fuel are within scope. The associated guidance (RG 5.96, “Establishing Cybersecurity Programs for Commercial Nuclear Plants Licensed Under 10 CFR Part 53”) provides a method that the NRC deems acceptable for implementing the requirements of 10 CFR 53.620(d)(2)(i)(C) for establishing, implementing, and maintaining a cybersecurity program at a manufacturing facility that would be licensed under 10 CFR Part 53.

Comment Bin 3.5.1.5.C: A commenter reasoned that if there are credible pathways for cyberattacks that could turn a manufactured reactor into a radiological weapon in storage or transport, then there must be provisions to preclude such events, consistent with the objectives of the security measures designed to prevent physical attacks (UCS-0009).

NRC Response: The NRC agrees with the comment.

The comment supports the inclusion of cybersecurity requirements in the proposed rule and suggests no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

3.5.1.6. RFC: Design of physical security program to protect against radiological sabotage (§ 53.620(d)(2)(i)(B))

Comment Bin 3.5.1.6.A: A commenter noted that 10 CFR 70.22(j)(1) requires a "licensee safeguards contingency plan for dealing with threats, thefts, and radiological sabotage, as defined in part 73 of this chapter" for possession of special nuclear materials licensed under 10 CFR Part 70. The commenter stated that physical security requirements can provide reasonable assurance that a malevolent act by an intruder or insider threat would not lead to a criticality event.

The commenter further suggested revising the security requirements in 10 CFR 53.620 to ensure that an individual cannot achieve an unintended criticality event at fuel load if the individual either makes sufficient changes to a reactor's control systems or moves a sufficient quantity of SNM to an unsafe, moderated geometry. The commenter suggested that during other phases security should fall under separate licenses (e.g., 10 CFR Part 73 for transportation) (NEI2-0193).

NRC Response: The NRC disagrees with the comment.

Regarding safeguards contingency plans, 10 CFR 70.22(j)(1) is applicable to licensees or applicants that will possess Category I quantities of SNM. For these licensees or applicants, a safeguards contingency plan is required under Appendix C, "Licensee Safeguards Contingency Plans," to 10 CFR Part 73. Due to the required layers of defense-in-depth—such as the material control and accounting (MC&A) plan, insider mitigation program, and criticality controls—it is generally not anticipated that a manufacturing licensee would need to implement a safeguards contingency plan.

Regarding the concern for diverting sufficient quantities of SNM to induce an unintended criticality, the MC&A plan is designed to prevent the malevolent actor from amassing a large quantity of Category II or III SNM, undetected, for malevolent purposes. The MC&A program allows the licensee to monitor the movement of SNM within the facility through periodic inspections and account for SNM to ensure that SNM has not been diverted. The NRC does not issue separate SNM licenses for a fixed site or for transport of SNM. Licensing of a site is accomplished under one license including meeting any transport security of that SNM for shipment to another NRC licensee/receiver.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.5.1.6.B: A commenter supported including security requirements to protect against radiological sabotage of reactors pre-loaded with unirradiated fuel, reasoning that they could be converted into extremely dangerous radiological weapons, especially in busy or densely populated areas. Stating that the range of scenarios would include stable operation of the reactor or a violent reactivity insertion that could cause a massive power excursion and explosion, the commenter wrote that all relevant technical factors should be taken into account in developing the security requirements for ensuring denial of access or denial of task, but they described security categorization of the fuel as of limited relevance for these scenarios, because whatever the fuel, the core will presumably be in a configuration that would allow for reactor startup once criticality controls are removed. However, the commenter added, some reactor types (e.g., fast reactors) may be more conducive to rapid reactivity insertion events and, thus, may warrant additional security measures (UCS-0010).

NRC Response: The NRC agrees, in part, with the comment.

The comment is generally supportive of the requirements in 10 CFR Part 53. NRC security requirements are designed to protect against acts of radiological sabotage and to prevent the theft of special nuclear material and accommodate a wide range of designs and configurations.

Accordingly, the NRC did not change the rule language in response to this comment.

3.5.1.7. RFC: Additional security measures for transportation of a fueled manufactured reactor (§ 53.620(d)(2)(i))

Comment Bin 3.5.1.7.A: A commenter disputed the need for additional security measures for transportation of a fueled reactor, compared to existing requirements for transporting SNM, given that the increased shipment size of a fueled reactor, the inaccessibility of SNM in a fueled reactor, and the increased rate of detection suggest the risk of diversion is lower for SNM from a fueled reactor compared to approved transportation packages (RAD-0009).

Another commenter suggested that transportation security requirements should be codified in 10 CFR Part 71 or 10 CFR Part 73 rather than in 10 CFR Part 53 (NEI2-0194).

NRC Response: The NRC agrees, in part, with these comments.

Regarding additional security measures, the NRC agrees that supplemental security measures should not be necessary for Category II or Category III quantities of SNM transport based on quantity of material, the shape and form as well as the physical measures in place that limit access to the material, and the ability to detect unauthorized access.

Regarding the location of transportation security requirements, the NRC agrees that these requirements should be in 10 CFR Part 73. 10 CFR 53.620(d)(2)(i) requires an ML holder to meet the performance objectives in 10 CFR 73.67. Requirements in 10 CFR 73.67(e) and 10 CFR 73.67(g) include provisions for security of Category II and Category III quantities of SNM, respectively, during transportation.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.5.1.7.B: A commenter stated that alternative security measures to preclude deliberate criticality scenarios also should apply to transportation, along with enhanced security requirements for transport of quantities of HALEU of high strategic significance (UCS-0011).

NRC Response: The NRC disagrees with this comment.

The language in 10 CFR 53.620(d)(2)(i) requires an ML holder to meet the performance objectives in 10 CFR 73.67. Requirements in 10 CFR 73.67(e) and 10 CFR 73.67(g) include provisions for security of category II and category III quantities of SNM, respectively, during transportation. For new applications using HALEU / Category II SNM, the NRC intends to continue its practice of evaluating the physical protection needed to ensure adequate protection during transport on a case-by-case basis, informed by material attractiveness concepts.

Accordingly, the NRC did not change the rule language in response to this comment.

3.5.1.8. RFC: Additional security measures for access authorization (§ 53.620(d)(2)(i))

Comment Bin 3.5.1.8.A: A commenter suggested relegating security measures for a manufacturing facility for access authorization to the 10 CFR Part 70 license and existing requirements and methods rather than introducing duplicative and potentially contradictory requirements in 10 CFR Part 53 (NEI2-0195).

NRC Response: The NRC disagrees with this comment.

Access authorization requirements are needed for a fueled manufactured reactor in addition to maintaining the requirements for special nuclear material. The 10 CFR Part 53 final rule contains requirements for access controls and access authorization for an ML holder under 10 CFR 53.620(b)(1) and (d)(2)(i)(D). The inclusion of access authorization requirements is necessary to provide reasonable assurance that individuals with unescorted access are trustworthy and reliable, so as not to constitute an unreasonable risk to public health and safety or the common defense and security, regardless of the reactor technology.

Accordingly, the NRC did not change the rule language in response to this comment.

3.5.2. Other comments on Subpart E provisions (§§ 53.600-53.610, comments on §§ 53.620 not related to factory fuel loading)

Comment Bin 3.5.2.A: A commenter expressed general support for Subpart E of the proposed rule, stating that it makes sites more secure by connecting the construction and manufacturing requirements to the safety criteria. The commenter highlighted 10 CFR 53.610(a) as giving the public confidence in the proposed rule by ensuring safety through quality assurance requirements (NP-0002).

NRC Response: The NRC agrees with this comment.

The comment supports the proposed rule and suggests no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.5.2.B: Questioning why 10 CFR 53.605 was included in the rule as it duplicates 10 CFR Part 21, a commenter noted that in 2012 the NRC and industry considered removing 10 CFR 50.55(e) as unnecessary given 10 CFR Part 21, an argument the commenter said remains valid. Therefore, the commenter wrote, removing 10 CFR 53.605 is consistent with the NRC’s position in 2012 (ML13163A401) that “[t]he underlying purpose of 10 CFR 50.55(e) is fully achieved through the implementation of 10 CFR Part 21 and other regulatory processes” and it “should be deleted and can be deleted without any reduction to the health and safety of the public” (NEI2-0063).

NRC Response: The NRC disagrees with this comment.

The provisions in 10 CFR 53.605 are equivalent to the existing provisions in 10 CFR 50.55(e) for plants constructed under a 10 CFR Part 50 or 10 CFR Part 52 license. The document referred to in the comment and the statements within do not represent an NRC position. The document represented industry feedback on the draft regulatory basis to clarify 10 CFR Part 21, “Reporting of Defects and Noncompliance,” from December 2012 (ML12248A200). The rulemaking effort for which that draft regulatory basis was developed was ultimately terminated by the NRC.

Two key differences remain between the requirements of 10 CFR Part 21 and those in 10 CFR 50.55(e) and 10 CFR 53.605; namely, requirements to report a significant breakdown in any portion of the quality assurance program and requirements related to the holding of records by suppliers. Given the lack of construction experience for many of the potential commercial nuclear plants to be licensed under 10 CFR Part 53, as well as planned changes to the NRC’s construction oversight activities under the agency’s Advanced Reactor Construction Oversight Program, the conclusions of the cited white paper may not be directly applicable to construction activities under 10 CFR Part 53. Inferences about their applicability cannot be made until sufficient experience is gained for reactors licensed under 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.5.2.C: A commenter suggested deleting 10 CFR 53.610(a)(4), which requires procedures to evaluate and provide construction experience applicable for the planned and ongoing construction activities, as the NRC should not be regulating construction knowledge acquisition or construction efficiency, competitors may not openly share information, and there is neither time nor money to change already planned construction crew actions. With respect to the regulation of construction knowledge acquisition and construction efficiency, the commenter added that perhaps Congress could do this (TG6-0001).

Meanwhile, a few commenters suggested removing 10 CFR 53.610 from the proposed rule entirely (HPT24-0001, HPT24-0002, SCWG-0016, BI1-0030). One of the commenters questioned the NRC’s claims that these requirements generally reflect or are equivalent to requirements in current 10 CFR Part 50 and 10 CFR Part 52 and characterized the entire section as disjointed with no logical reason for existing. The commenter provided feedback on specific provisions as follows (HPT24-0002):

- Paragraph (a) is unbounded, with no success criteria, which subjects the applicant to costly and unnecessary burdens from staff-determined “noncompliance”; the commenter warned that this approach is outside the law for reasoned decision-making, citing *Michigan v. EPA*, 576 U.S. 743, 750 (2015), and said it is unclear how this provision constitutes being “risk-informed” under NEIMA.

- Paragraph (b)(1)(i) involves SNM, which is covered by 10 CFR Part 73, and there is no compelling reason to augment that; in general, SNM cannot be stored in a facility that is not ready to fully accept and protect the material.

- Paragraph (b)(1)(ii) should not be codified as these requirements are standard construction practices. As with paragraph (a), it is unbounded, with no success criteria, which subjects the applicant to costly and unnecessary burdens from staff-determined “noncompliance”; the commenter again warned that this approach is outside the law for reasoned decision-making, citing *Michigan v. EPA*.

- Paragraph (b)(1)(iii) should not be codified as these requirements, too, are standard construction practices.

- Paragraph (c) involves inspections and tests covered by Appendix B to 10 CFR Part 50, start-up testing activities are subject to their own efforts generally associated with industry codes and standards, and the sections cross-referenced in paragraph (c)(2) (i.e., 10 CFR 53.1440 and 10 CFR 53.1387) have no analog in existing requirements.

Multiple commenters suggested using the existing quality assurance framework under Appendix B to avoid duplicative requirements and supply chain inefficiencies. The commenters also encouraged the NRC to consider accepting alternative quality assurance programs (e.g., internationally recognized standards like ISO 9001) if they meet the necessary safety and reliability criteria, saying this approach would enhance international alignment and maintain regulatory consistency without compromising safety. The commenters added that existing quality assurance requirements under 10 CFR Part 50 and 10 CFR Part 52 should be transferable to 10 CFR Part 53 (SCWG-0016, BI1-0030).

NRC Response: The NRC disagrees with these comments.

The requirements within 10 CFR Part 53 to evaluate the applicability of other national and international experiences related to design, construction, and operation reflect lessons learned from past successes and failures to develop and deploy nuclear power plants. The specific requirement in 10 CFR 53.610(a)(4) mirrors the requirements introduced into 10 CFR Part 50 following the accident at Three Mile Island.

Regarding the parts of the comment related to the general topics of NRC regulations covering construction activities, the proposed and final rules explained the overall structure of 10 CFR Part 53 and the systems engineering type approach of having requirements addressing the various stages of a project life cycle. The construction requirements in Subpart E of 10 CFR Part 53 are an important part of implementing the design and programmatic requirements identified from the design process and analyses under Subpart C of 10 CFR Part 53. The NRC disagrees with the premise that Subpart E to 10 CFR Part 53 does not reflect the risk-informed and performance-based approaches that are provided by the integration of these concepts throughout the various subparts or that the construction phase of a project need not be addressed within the regulations.

Regarding the references to other regulations such as those in 10 CFR 73, the NRC agrees in part that such requirements need not be duplicated but has maintained the references in the final rule to help stakeholders identify and understand the interrelationships among various NRC regulations. The NRC disagrees that requirements under 10 CFR 53.610 are simply duplicative of the quality assurance requirements of Appendix B to 10 CFR Part 50. As explained in Section IV, “Part 53 Framework,” of the FRN, the requirements of 10 CFR 53.610 are also needed to address potential special treatment of non-safety-related but safety-significant (NSRSS) SSCs (see also response to Comment Bin 3.5.3.A).

Regarding the statement on the need for 10 CFR 53.610(b)(1)(ii), the NRC disagrees that it is inappropriate for regulations to address prudent measures related to possible interactions between construction activities and collocated operating commercial nuclear reactors. The requirement is equivalent to the regulation in 10 CFR 52.79(a)(31).

Regarding the comment on 10 CFR 610.(b)(1)(iii), the NRC disagrees that the requirement is not needed insofar as it was added to address problems encountered with past construction projects and related licensing issues on whether preconstruction activities such as installing dewatering systems trigger the need for a CP permit or a finding under 10 CFR 53.1452(g) (see also the NRC’s response to Comment Bin 3.5.3.A).

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.5.2.D: Citing 10 CFR 53.610(a)(6)(ii), which requires appropriate programmatic controls to provide special treatment for NSRSS SSCs, a commenter shared their understanding that the standard practice in construction is to build an item according to the plans, drawings, codes, and standards of the agreed-upon issue date. If those requirements are met, the commenter said, then the item is acceptable, and if they are not met, then you may need to remove the non-compliant item and try again, sometimes at your own expense. Given that, the commenter questioned when there would be a need for “special treatment” (TG7-0001).

NRC Response: The NRC disagrees with the comment.

The NRC disagrees with the assertion that special treatment requirements would not be needed if standard construction practices are followed. As explained in Section IV, “Part 53 Framework,” of the FRN, special treatment refers to measures (e.g., quality assurance, testing, monitoring) taken beyond the procurement and installation of commercial grade products to provide confidence that the SSC will comply with the applicable functional design criteria. The possible identification and implementation of special treatments for both SR and NSRSS SSCs is an integral part of the design process, analyses, construction and manufacturing, and maintenance activities under Subpart F to 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.5.2.E: A commenter wrote that the requirements in 10 CFR 53.610 overlap and sometimes duplicate, in full or in part, QA requirements in Appendix B to 10 CFR Part 50 and recommended the following revisions (NEI2-0064):

- Revise paragraph (a) to refer to the Appendix B requirements—instead of setting forth specific requirements—to make the requirements clearer and more consistent.
- Reorganizing paragraph (a) to group all the required programs under a single paragraph, with a subordinate paragraph for each program, and separating this from the other requirements in paragraph (a) related to organization and procedures.
- Relocate paragraph (b)(1)(i)(C) to Subpart F (alongside other training programs).

The commenter also suggested multiple revisions to make 10 CFR 53.620 clearer, more consistently interpreted, and less burdensome:

- Because its requirements overlap with each other and sometimes duplicate, in full or in part, QA requirements in Appendix B to 10 CFR Part 50 (e.g., paragraphs (a)(1) through (3) and (6) are duplicative of Appendix B), paragraph (a) should refer to the Appendix B requirements rather than setting forth specific requirements (NEI2-0066).

- Reorganize paragraph (a) to group all the required programs under a single paragraph, with a subordinate paragraph for each program, and separate this from the other requirements in paragraph (a) related to organization and procedures (NEI2-0066).
- Relocate paragraph (c)(4) to Subpart F (alongside other training programs) (NEI2-0066).
- Remove paragraph (e)(2) as duplicative of paragraph (e)(4) (NEI2-0069).

NRC Response: The NRC disagrees with these comments.

As explained in Section IV, "Part 53 Framework," of the FRN, the requirements of 10 CFR 53.610 for construction and 10 CFR 53.620 for manufacturing go beyond SR SSCs addressed by the quality assurance programs under 10 CFR 53.460 and Appendix B to 10 CFR Part 50 for safety-related SSCs in order to also address potential special treatment of NSRSS SSCs. So, whereas the comment is correct that there is some duplication of requirements for safety-related SSCs, it does not suggest an alternative way to address manufacturing requirements for NSRSS SSCs.

Regarding the part of the comment on reorganizing requirements in 10 CFR 53.610 and 10 CFR 53.620, the NRC does not see an obvious improvement in clarity that would warrant making a change from the language in the proposed rule. Regarding the relocation of 10 CFR 53.610(b)(1)(i)(C) and 10 CFR 53.620(c)(4), the NRC disagrees insofar as the programs may be needed for construction or manufacturing activities not related to the operation of a manufactured reactor and therefore not within the scope of Subpart F to 10 CFR Part 53.

Regarding the part of the comment on 10 CFR 53.620(e)(2) and (e)(4), see the response to Comment Bin 3.5.1.3.A.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.5.2.F: A commenter said that to align with the AEA's authorization of export of utilization facilities, NRC should revise paragraph 10 CFR 53.620(e)(1) to allow transport to international destinations for microreactors manufactured in the United States under a 10 CFR Part 53 ML license, with the requirement that the ML holder must obtain an NRC export license under 10 CFR Part 110; otherwise the ML holder would have to request an exemption to export each reactor (NEI2-0068).

NRC Response: The NRC agrees with this comment.

Accordingly, in response to this comment, the NRC has revised the rule language to specifically allow the transport of a manufactured reactor from the manufactured facility for the purpose of export under 10 CFR Part 110.

3.5.3. <u>RFC: Control of construction so as not to impact other features important to design (§ 53.610(b)(1)(iii))</u>

Comment Bin 3.5.3.A: A commenter stated that 10 CFR 53.610(a)(1) through (4) and (6), which are arguably redundant of QA requirements in Appendix B to 10 CFR Part 50, are sufficient to meet the intent of 10 CFR 53.610(b)(1)(iii). Specifically, the commenter explained, Criterion III (Design Control) of Appendix B to 10 CFR Part 50 requires the translation of design basis requirements for SSCs into procedures, meaning that features related to protection of the plant from external hazards (e.g., dewatering, slope stability, backfill, compaction) would be addressed through Criterion III. The commenter thus suggested deleting 10 CFR 53.610(b)(1)(iii) as duplicative (NEI2-0183).

NRC Response: The NRC disagrees with this comment.

As explained in Section IV, "Part 53 Framework," of the FRN, the requirements of 10 CFR 53.610 go beyond SR SSCs addressed by the quality assurance programs under 10 CFR 53.460 and Appendix B to 10 CFR Part 50 for safety-related SSCs to also address potential special treatment of NSRSS SSCs. So, whereas the comment is correct that there is some duplication of requirements for safety-related SSCs, it does not suggest an alternative way to address construction requirements for NSRSS SSCs.

Regarding the part of the comment related to preconstruction activities and duplication of quality assurance requirements, the NRC disagrees insofar as the comment does not address NSRSS SSCs or the desire to ensure that preconstruction activities such dewatering, ensuring slope stability, backfill, compaction, and controlling seepage do not unnecessarily require issuance of a CP or a finding under 10 CFR 53.1452(g) for a COL to initiate those types of site activities.

Accordingly, the NRC did not change the rule language in response to this comment.

3.6. Subpart F: Requirements for Operation (§§ 53.700-53.910)

3.6.1. Controls of SSCs (§§ 53.700-53.720: technical specifications and plant controls, maintenance, repair, inspection programs, plant reliability programs, and response to seismic events)

Comment Bin 3.6.1.A: A commenter asked if the operational objectives in 10 CFR 53.700 are for all advanced reactors because 10 CFR 53.800 specifically mentioned self-reliant mitigation facilities. The commenter suggested that NRC clarify that all sections of 10 CFR 53.700 apply unless otherwise noted because 10 CFR 53.800 references that subsections are used in lieu of specific sections of 10 CFR 53.700 (NEI2-0070).

The commenter also said that each holder of an OL or COL under 10 CFR 53.700(a)(1) must maintain the capabilities, availability, and reliability of plant SSCs to ensure that the safety functions identified in 10 CFR 53.230 will be performed if called upon during LBEs. The commenter wrote that 10 CFR 53.230 states that plant SSCs, personnel, and programs should provide measures for defense in depth in accordance with 10 CFR 53.250. The commenter recommended that the NRC clarify how much defense in depth is required or include a regulatory reference to ensure a consistent interpretation (NEI2-0071).

In 10 CFR 53.700, another commenter recommended changing "responsibilities of plant personnel" to "responsibilities of personnel, (both plant and off site)" (TG8-0001).

NRC Response: The NRC agrees, in part, with the comments.

The NRC has revised the rule language to clarify that 10 CFR 53.700 provides a purpose and outline for Subpart F to 10 CFR Part 53 and that actual requirements are provided in specific sections. The sections are organized by those related to maintaining plant equipment, those related to personnel, and those related to plant programs.

The NRC disagrees with the suggestion of more prescriptive requirements for defense in depth to clarify how much defense in depth is required. As explained in 10 CFR 53.250(a), defense in depth is required to compensate for uncertainties in the analysis of the safety criteria such that there is reasonable assurance that the safety criteria in this subpart are met over the life of the plant. Appropriate measures to provide defense in depth are therefore dependent on the uncertainties associated with specific reactor technologies or designs and it would be counterproductive to generically define required defense-in-depth measures in a manner similar to the deterministic approach in 10 CFR Part 50. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC agrees with the suggestion that the use of “plant personnel” in the proposed rule could be read as limiting the potential role of operators or engineering expertise in remote locations. Accordingly, the NRC has revised the rule language to the broader term “personnel” in 10 CFR 53.700 and made similar conforming changes to 10 CFR 53.805(a)(4) and 10 CFR 53.830. The NRC also made similar conforming changes to Division of Reactor Oversight (DRO)-ISG-2023-02, “Interim Staff Guidance Augmenting NUREG-1791, “Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m),” for Licensing Commercial Nuclear Plants under 10 CFR Part 53,” and DRO-ISG-2023-03, “Development of Scalable Human Factors Engineering.” Additionally, the NRC made a conforming change to the rule text in 10 CFR 53.710 on authority for configuration changes for NSRSS SSCs in the final rule to refer to “within the licensee’s organization” instead of the “within the commercial nuclear plant,” which is what appeared in the proposed rule.

Comment Bin 3.6.1.B: A commenter wrote that 10 CFR 53.710 is overly prescriptive, decoupled from operational reality, and should be replaced with an approach consistent with NEIMA. The commenter added that large numbers of components and structures are typically involved with SR and special treatment systems, and applying technical specifications at these levels will create unnecessary operational burdens. The commenter provided revised rule language which they said mirrors 10 CFR 50.36 (HPT31-0001, HPT31-0002).

NRC Response: The NRC disagrees with the comments.

Regarding the scope and requirements for technical specifications, the NRC disagrees insofar as the number of SSCs subject to technical specifications under 10 CFR 53.710 is limited to safety-related SSCs and therefore clearly defined and likely fewer in number than required under 10 CFR 50.36. The required content of technical specifications under 10 CFR 53.710(a) is similar to that required under 10 CFR 50.36. The use of consistent rule language is intentional and will facilitate guidance development and application of lessons learned from many years of developing and improving technical specifications for plants licensed under 10 CFR Parts 50 and 52.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.6.1.C: A commenter suggested revising 10 CFR 53.710 to read "when combined with corresponding programmatic controls, digital controls, and human actions" and “Identify who within the commercial nuclear organization has authority to make configuration changes” (TG8-0004).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that digital controls may play an important role for future commercial nuclear plants but believes that they are already appropriately addressed within the requirements to identify SSCs and determine appropriate safety categorization and special treatments. However, as explained in the response to Comment Bins 3.6.1.A and 3.6.1.D, the NRC did revise the rule text in 10 CFR 53.710.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.1.D: A commenter said that the use of the term “controls” through 10 CFR 53.710 is not consistent with the definition of the term in 10 CFR 53.725(c) and recommended that the NRC replace “controls” with “measures.” The commenter also suggested reviewing 10 CFR Part 53 for other uses of “controls” to ensure consistent use (NEI2-0072).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that use of the word “measures” in 10 CFR 53.710 instead of “controls” could avoid confusion since “controls” are later defined for those sections covering personnel and plant operations.

Accordingly, the NRC has revised the rule language in 10 CFR 53.710 to use “measures” or “control measures” in the final rule. The NRC reviewed other sections of 10 CFR Part 53 and found that other uses of the word “controls” were sufficiently clear in the context of those sections (e.g., the use of programmatic controls, availability controls) and did not revise the rule text outside of 10 CFR 53.710 in response to this comment.

Comment Bin 3.6.1.E: A commenter said that 10 CFR 53.720 refers to operating basis earthquake ground motion or significant plant damage and said that “significant plant damage” should be defined or clarified as it is arbitrary. The commenter said that limiting conditions for operation are already defined for SR SSCs in 10 CFR 53.710, so the intent of significant plant damage is likely duplicative (NEI2-0073).

A commenter wrote that the NRC should not be involved in controlling, hindering, or preventing a licensee from shutting down the reactor as a result of a seismic event as the licensee is directly responsible for protecting the public and has superior technical expertise. The commenter added that the U.S. government would assume all liabilities if the NRC intervened in preventing licensee shutdown of a reactor. The commenter proposed revising 10 CFR 53.720 to read as follows (HPT30-0001):

> If vibratory ground motion exceeding that of the operating basis earthquake ground motion or significant reactor damage due to vibratory ground motion occurs, then the licensee must shut down the commercial nuclear plant. Prior to

> resuming operations, the licensee must demonstrate to the NRC that those features necessary for continued operation without undue risk to the health and safety of the public have been repaired or demonstrated as being operational.

A commenter wrote that it is necessary for safety, security, and proper procedures to be in place to counteract the possibility of seismic events which the proposed rule acknowledges (NP-0003).

NRC Response: The NRC agrees, in part, with the comments.

The NRC disagrees with the suggested changes to 10 CFR 53.720, such as defining "significant plant damage." The rule language in 10 CFR 53.720 is consistent with the existing requirements in Appendix S to 10 CFR Part 50. In both places, the rule language requires a plant shutdown if vibratory ground motion exceeds that of the operating basis earthquake ground motion or if significant plant damage occurs. The use of the same language is intentional and is discussed in more detail in RG 1.166, "Pre-Earthquake Planning, Shutdown, and Restart of a Nuclear Power Plant Following an Earthquake," which is used for the evaluation of plant damage and subsequent restart activities following an earthquake. Use of rule language in 10 CFR 53.720 similar to that in 10 CFR Part 50 allows for the adaptation of the longstanding guidance in RG 1.166 for use by 10 CFR Part 53 licensees.

Regarding the comment concerning the NRC preventing a licensee from shutting down a plant following a seismic event, both 10 CFR 53.720 and Appendix S to 10 CFR Part 50 require a licensee to consult with and propose a plan to the NRC to accomplish the shutdown if a shutdown is hindered by the unavailability of plant equipment resulting from the earthquake. This requirement does not imply the NRC would assume control of the facility but does reflect the seriousness of conditions when safety functions have been compromised by a seismic event.

The NRC agrees with the general support of the approach taken for earthquake engineering in 10 CFR 53.480 and operational response to a seismic event under 10 CFR 53.720. The NRC notes that the comment did not suggest changes to the rule language.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.6.1.F: A commenter wrote that the requirements in 10 CFR 53.715 are not equivalent to the subsections in 10 CFR Part 50 that are referenced. The commenter wrote that linking SSC conditions, incorporating industry wide-experience, and assessing increased risk are all not measurable. The commenter proposed revising 10 CFR 53.715 to read as follows (HPT34-0001):

> (a) Condition monitoring program an applicant developed program must be deployed to periodically monitor the condition of safety-related and important-to-safety-related structures, systems and components (SSC) against licensee established goals that provide additional reasonable assurance that these SSC items can perform their safety function. The program goals must be consider the risk associated with the SSC's nuclear safety function. Risk is linked to the applicant developed probabilistic risk analysis. The licensee must identify any key consensus industry codes/standards employed to develop the monitoring program and goals. Appropriate corrective actions must be taken if the condition

monitoring program or maintenance activities indicate goal non-compliance issues.

(b) The program goals must be reviewed at least every 24 months and adjusted as considered appropriate by the licensee.

(c) Before performing maintenance or surveillance/testing activities on safety-related and important-to-safety SSC', must assess the impact on the associated conditioning monitoring program goal(s) and take appropriate cautionary actions as considered necessary.

NRC Response: The NRC disagrees with the comment.

The rule language for 10 CFR 53.715 is based largely on the corresponding requirements in 10 CFR 50.65, except where the requirements are addressed by other sections in 10 CFR Part 53. The use of consistent rule language is intentional and will facilitate guidance development and application of lessons learned from many years of experience implementing 10 CFR 50.65 for plants licensed under 10 CFR Parts 50 and 52. Some of the suggestions in the comment align with 10 CFR 50.65 but do not reflect performance monitoring in other sections of 10 CFR Part 53, such as 10 CFR 53.710(b), that addresses control measures on plant operations, including availability controls, to ensure that plant configurations and special treatments for SR SSCs and NSRSS SSCs provide the capabilities, availability, and reliability required to demonstrate compliance with the criteria of 10 CFR 53.220 and 10 CFR 53.450(e).

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.1.G: A commenter wrote that Subpart F includes multiple reliability assurance programs with multiple panels created under current LMP guidance in NEI 18-04; however, the commenter stated that early users have found that multiple programs with multiple panels covering the same reliability scope does not increase the safety of the plant design. The commenter asked that the NRC revise 10 CFR Part 53 in a way that does not require the establishment of multiple panels (SG2-0001).

NRC Response: The NRC agrees, in part, with the comment.

The NRC is aware that the risk-informed, performance-based, and technology-inclusive framework for 10 CFR Part 53 and the related consensus codes and standards result in the need for expert panels in multiple areas related to the design and operation of commercial nuclear plants. The use of such multidisciplinary expert panels is an important element of risk-informed approaches and is equally a challenge when risk-informed alternatives are widely adopted under 10 CFR Parts 50 and 52. However, the requirements in 10 CFR Part 53 do not dictate how applicants and licensees organize such expert panels in terms of fulfilling the role for singular or multiple design and operational programs.

Accordingly, the NRC did not change the rule language in response to this comment

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Comment Bin 3.6.1.H: A commenter provided an example of a pressurized water reactor with a physical containment building that was able to contain events such as a hydrogen burn or an explosion but wrote that today that kind of approach no longer exists in favor of functional containment (TG17-0003).

NRC Response: The NRC acknowledges the information provided by the commenter and notes that 10 CFR Part 53 does not disallow the use of more traditional types of containment structures associated with nuclear power plants licensed under 10 CFR Part 50 or 10 CFR Part 52. Moreover, regardless of the approach taken by a given applicant to support their safety analyses, the regulatory framework under 10 CFR Part 53 ensures an equivalent level of safety to that of operating commercial nuclear plants while providing flexibility for licensing and regulating a variety of technologies and designs.

Accordingly, the NRC did not change the rule language in response to this comment.

3.6.2. Staffing, training, personnel qualifications, and human factors engineering (§§ 53.725-53.830)

3.6.2.1. Comments on staffing, training, personnel qualifications, and human factors engineering requirements not related to RFC

Comment Bin 3.6.2.1.A: A commenter made the following recommendations in reference to the text in 10 CFR 53.725:

- Complete the wording of “are either of the class.”
- Rewrite 10 CFR 53.725(a) entirely using terms such as “continuously staffed” and “not continuously staffed.”
- In 10 CFR 53.725(c), change “reference plant” to “reference plant design” if the plant has not been built.
- In 10 CFR 53.725(c), change “commercial nuclear plant automatically changing its output” to “commercial nuclear plant manually or automatically changing its output”.

The commenter also wrote that, generally, “licensee” has only been applied to the organization holding the plant license and not operating staff holding individual licenses. The commenter wrote that using the term “operator” if the person is licensed will cause confusion and recommended using "licensed operator" or "licensed reactor operator.”

The commenter asked if an “interaction-dependent-mitigation facility” is a continuously staffed reactor. The commenter asked why “performance testing” is only tied to a simulation facility (TG8-0002).

NRC Response: The NRC agrees, in part, with the comment.

The NRC partially agrees with the comment “complete the wording of ‘are either of the class’.” Although the sentence is grammatically correct as written, the NRC determined that revising the sentence improves clarity. Accordingly, the NRC restructured this sentence.

The NRC disagrees with rewriting “10 CFR 53.725(a) entirely using terms such as ‘continuously staffed’ and ‘not continuously staffed’.” The terms are not interchangeable or analogous with self-reliant-mitigation facilities and interaction-dependent-mitigation facilities. Self-reliant-mitigation facilities may or may not be continuously staffed, as this would be facility-dependent. Additionally, the staffing plan of the facility would determine whether an interaction-dependent-mitigation facility is a continuously staffed reactor. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC partially agrees with the comment "in 10 CFR 53.725(c) change 'reference plant' to 'reference plant design' if the plant has not been built." The NRC agrees that there is a need for language to be added to the definition of "reference plant" to provide clarification for when a plant has yet to be constructed. Accordingly, the NRC has revised the rule language to provide clarification.

The NRC disagrees with the comment "in 10 CFR 53.725(c) change 'commercial nuclear plant automatically changing its output' to 'commercial nuclear plant manually or automatically changing its output'." The term "load following", as defined in 10 CFR 53.725(c), is intended only to apply when the plant automatically changes the load using an automated intermediary system, which requires additional regulatory requirements. A manual load change would be considered a normal load change and would not be considered load following. A manual load change does not require additional regulatory requirements. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC disagrees with the comments that "generally, 'licensee' has only been applied to the organization holding the plant license and not operating staff holding individual licenses" and that "using the term 'operator' if the person is licensed will cause confusion." The current regulations in 10 CFR Part 55 use the terminology of "licensee" to refer to an individual and uses "facility licensee" to refer to the facility. This terminology is both well-known and widely used. Changing terminology could create confusion for those who are intimately familiar with the current terminology in 10 CFR Part 55. Accordingly, the NRC did not change the rule language in response to these comments.

Regarding why performance testing is only tied to a simulation facility, the definition of "performance testing" is only applicable to the operator licensing section as noted in 10 CFR 53.725(c) for definitions. The definition of "performance testing" is limited to simulators for the operator licensing section because the simulator is the only equipment used for the training and qualification of the operators. This question did not suggest changes to the rule. Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.B: A commenter wrote that many of the elements of 10 CFR 53.730 are elements of a "state-of-the-art human factors engineering" as defined in NUREG-0711, and if specific elements are required to meet the requirements, then the industry will not be able to maintain the "state-of-the-art" without a future rulemaking. The commenter suggested that 10 CFR 53.730 should mirror the approach in 10 CFR Part 50 which maintains a requirement for a human factors engineering (HFE) program but is not prescriptive in nature (NEI2-0074, NEI2-0048). Another commenter expressed agreement with these comments (NEX-0027).

NRC Response: The NRC disagrees with the comments.

The NRC disagrees that 10 CFR 53.730 prescribes elements of "state of the art human factors engineering" that would require a future rulemaking to enable the facility to maintain the "state of the art." The requirement of 10 CFR 53.730(a) that the applicant must show they meet state-of-the-art during the licensing process is consistent with previous regulations, specifically 10 CFR 50.34(f)(2)(iii). Changes are then considered using the change control process. If the change requires a license amendment, then the design change must also include state-of-the-art principles. The scope of human factors reviews is comparable to previous regulations with a few, carefully considered, differences:

- The concept of operations of existing plants is similar and well-known such that the staff can make reasonable assumptions about how operators will interact with systems to support the HFE review without requiring a specific submittal. This is not the case for facilities licensed under 10 CFR Part 53 and would thus require such a submittal.
- The Function Requirements Analysis and Function Allocation element was moved from guidance into regulations for 10 CFR Part 53 because it is necessary for modern designs as information from these analyses is critical to understanding the operator's role and therefore the staffing plan.
- The NRC currently considers important operator actions outside the control room when they meet the criteria for important human actions as defined by the accident analysis for facilities licensed under 10 CFR Part 50 or 52. Adding this helps clarify what is already in practice and supports designs without a traditional control room that may still have important actions outside of the control room.

These changes move small portions of the HFE process from guidance into the regulations due to the novel concept of operators, approaches to automation, and control room/ex-control room strategies under consideration with these designs that were not under consideration during the development of 10 CFR Parts 50 and 52.

In addition, in response to the statement that 10 CFR 53.730 should simply mirror the HFE approach in 10 CFR Part 50, note that the training, examination, and proficiency program requirement of 10 CFR 53.730(g) is not related to the "state of the art" HFE but instead is a necessary requirement for the facility to maintain programs to train, qualify, and maintain the qualification of licensed operators.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.6.2.1.C: A commenter wrote that 10 CFR 53.730(f)(4) has a requirement for staffing plans with a specific minimum for how many persons are required to perform equipment surveillance and maintenance which is excessive and overburdensome. The commenter recommended removing "numbers" and replacing it with "…how the positions and responsibilities…" (NEI2-0076). Another commenter expressed agreement with this approach (NEX-0029).

NRC Response: The NRC agrees with the comments.

The NRC agrees with the recommendation to remove the "numbers" from the 10 CFR 53.730(f)(4) proposed requirement for the staffing plan to include specific minimum numbers for how many people are required to perform equipment surveillance and maintenance.

Accordingly, the NRC revised 10 CFR 53.730(f) to remove the requirement to provide specific numbers of support personnel in the staffing plan submittal in response to this comment.

Comment Bin 3.6.2.1.D: A commenter recommended revising and moving 10 CFR 53.730(a) and (b) to 10 CFR 53.415 and retitling the section “Man/Machine Interface” (in subsequent text in the comment, the commenter labeled this new section as 10 CFR 53.445 and also 10 CFR 53.400). The revised rule text would “(1) explicitly identify the intent of the human engineering (man/machine interface), (2) establish acceptance criteria, and (3) properly limit the scope of the section.”

The commenter wrote that 10 CFR 53.730(a) is unbounded with no success criteria and that the requirements would encompass the entire power plant which is “astoundingly excessive.” The commenter recommended the addition of a new subsection to encompass the defense-in-depth portion of the reactor's man-machine interface.

The commenter suggested deleting 10 CFR 53.730(b)(7), writing that proper man/machine interface requirements always apply to the reactor, and added that they are not aware of what a self-reliant mitigation facility is. The commenter recommended removing 10 CFR 53.730 (c) and (d) in its entirety, writing that there is no human factor counterpart in 10 CFR Part 50. The commenter added that the rule text as written is illegal and contradicts the requirements of NEIMA. The commenter also expressed confusion over the meaning of a self-reliant mitigation facility (HPT15-0001, HPT15-0002, HPT15-0003).

However, a subsequent submission from the commenter suggested deleting the entirety of 10 CFR 53.730 instead of moving it. The commenter wrote that, for most requirements in the section, there is no equivalent requirement in 10 CFR Part 50. The commenter added that the requirements in 10 CFR 53.730 are open ended with no discernable acceptance criteria and specifically asserted that 10 CFR 53.730(g) is duplicative to 10 CFR 53.815 and 53.830 (HPT20-0001, HPT20-0002).

NRC Response: The NRC agrees, in part, with the comments.

The NRC disagrees with revising and moving 10 CFR 53.730(a) and (b) to 10 CFR 53.415. The Man/Machine Interface (referred to as the Human System Interface, or HSI, in NRC guidance documents) is included in the staff’s review. Reviewing HSI alone is inadequate for determining safe and reliable performance in all settings that human activities are expected for supporting the continued availability of plant safety or emergency response functions. Contextual information, such as the concept of operations, is necessary to properly evaluate the HSI. For example, some designs are considering combining the operator role with other site roles, which may mean that the operator is no longer continuously at-the-controls or in the main control room. In such cases, looking solely at the alarm system interface is inadequate without also considering that the operator would not be able to hear those alarms while in the plant. Human factors regulations ensure that human factors principles are appropriately considered and applied. The new regulation allows for scaling of these efforts informed by risk insights as described in DRO-ISG-2023-03, “Development of Scalable Human Factors Engineering Review Plans,” issued October 2024 (ML22266A072), and thus limit the scope of the review based upon the specific design.

The NRC disagrees with the statement that 10 CFR 53.730(a) is unbounded and without success criteria such that the requirements are excessive. The human factors regulations are necessary to ensure that human factors principles are appropriately considered and applied. The NRC expects that many designers will limit the human role via inherent and highly reliable passive safety features, such that the self-reliant mitigation facility criteria will be met. For those designs, the NRC expects little additional HFE review to be necessary, thus providing for a scalable review that is technology-inclusive and risk-informed that performs only those HFE reviews that are necessary to ensure safety. The guidance provided in DRO-ISG-2023-03 reduces the effort needed to conduct license reviews for facilities licensing under 10 CFR Part 53 and is expected to expedite the technical review time and lower costs by focusing on novel features and risk-important features of the design.

The NRC disagrees with the deletion of 10 CFR 53.730(b)(7). The scope of the human factors reviews is comparable to previous reviews conducted under the regulations in 10 CFR Parts 50 and 55 with a few carefully considered differences. In total, the expectation is that the reviews will be more efficient and effective when compared to reviews performed under 10 CFR Part 50 due to the risk-informed, scalable nature of the reviews under 10 CFR Part 53.

Regarding the statement that 10 CFR 53.730(c) does not have an explicit counterpart in 10 CFR Part 50, 10 CFR Part 53 was developed to be technology-inclusive and have the requisite flexibility to address different concepts of operation when compared to the prescriptive requirements of 10 CFR Part 50, which is predicated upon a single concept of operations. Adding in the flexibility for the facility to determine the appropriate concept of operations based on their design rather than being forced to follow a concept of operations that may not be appropriate for their design leads to a need for a new requirement for that facility to provide the NRC with that concept of operations to help inform the NRC review. This concept of operations is foundational to the review of operator licensing, staffing, and human factors program elements. Therefore, the NRC will retain this requirement.

Regarding 10 CFR 53.730(d), the NRC acknowledges that there is no direct equivalent in 10 CFR Part 50, but this is a direct result of the fact that there is no equivalent in 10 CFR Part 53 to 10 CFR 50.54(m), which prescribes the type and level of staffing for operating reactors. The NRC acknowledges that novel designs may have reductions in risk and few, if any, credited important human actions. The information gained from the Function Requirements Analysis and Function Allocation analyses is critical to understanding the operator’s role in these new paradigms, understanding how the inherent and passive features are used to limit the need for operators, and to help the staff understand the justification for a proposed staffing plan.

Information pertaining to a self-reliant mitigation facility (SRMF) is located in 10 CFR 53.800. A commercial nuclear plant is classified as a SRMF if the NRC determines as part of its approval of the OL or COL for that plant that the design of the plant demonstrates compliance with the criteria in 10 CFR 53.800(a)(1) through (a)(5). A SRMF is of a class such that the licensee must comply with the requirements of 10 CFR 53.800 through 10 CFR 53.820 in lieu of the requirements in 10 CFR 53.760 through 10 CFR 53.795. Additionally, SRMFs will be operated by generally licensed reactor operators (GLROs), a new classification of operators as outlined in 10 CFR 53.810. The training, examination, and proficiency programs for GLROs can be found in 10 CFR 53.815 whereas facility licensee requirements related to GLROs can be found in 10 CFR 53.805.

The NRC agrees, in part, that many portions of 10 CFR 53.730 do not have an equivalent requirement in 10 CFR Part 50. The NRC provides requirements for operator licensing in 10 CFR Part 55 for facilities licensed under 10 CFR Parts 50 or 52 and therefore those requirements would not be in 10 CFR Part 50. For example, the requirements in 10 CFR 53.730(g), which address the initial training and examination programs and the requalification program, are analogous to 10 CFR 55.31, 55.33, and 55.59, which address the requirements for the initial application for an operator license and the requalification of operators. Furthermore, the requirements in 10 CFR 53.775 and 53.780 apply to individually licensed senior reactor operators (SROs) and reactor operators (ROs) at interaction-dependent mitigation facilities, and 10 CFR 53.815 and 53.830 apply to GLROs at self-reliant mitigation facilities whereas 10 CFR 53.730 applies to all facilities irrespective of their classification. As 10 CFR 53.730 addresses the requirements for personnel in ensuring safe operations as it applies to each facility applicant for or holder of an OL or COL, the requirements in this section are different than the requirements in 10 CFR 53.815 and 53.830, which apply to the requirements for an individual operator; therefore, 10 CFR 53.730 is not duplicative and cannot be deleted.

The NRC disagrees that 10 CFR Part 50 does not have requirements for a staffing plan; the minimum required number of licensed operators per shift are prescribed in 10 CFR 50.54(m). In contrast, 10 CFR 53.730(f) allows applicants to determine the staffing needs of their facility and submit a staffing plan to the NRC for approval. This is a performance-based staffing requirement which allows, in part, an applicant to propose the minimum number, positions, and qualifications of licensed operators across all modes of operation. The approach results in a staffing level that is appropriate for the facility’s design, concept of operations, and workload levels for licensed operators.

Regarding the statement that the requirements in 10 CFR 53.730 are open-ended with no discernable acceptance criteria, 10 CFR 53.730 establishes the risk-informed, technology-inclusive technical requirements for applicants for or holders of OLs or COLs within specific areas as it relates to defining, fulfilling, and maintaining the role of personnel in ensuring safe operations. Because 10 CFR 53.730 is technology-inclusive, it is not feasible to write specialized criteria, which would be dependent upon a given design; however, the requirements provide the generalized acceptance criteria, which are to be applied by the facility licensee based on their reactor design. Guidance to the staff, including acceptance criteria, for operator examination programs, staffing, and scalable human factors is provided in DRO-ISG-2023-01, “Operator Licensing Programs,” issued October 2024 (ML22266A066), DRO-ISG-2023-02, “ISG Augmenting NUREG-1791, 'Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m),' for Licensing Plants under Part 53,” issued October 2024 (ML22266A068), and DRO-ISG-2023-03, respectively. Additional guidance for an acceptable method for meeting the regulatory requirements for training programs is provided in NUREG-1220, Revision 1, “Training Review Criteria and Procedures,” issued January 1993 (ML102571869).

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.6.2.1.E: A commenter stated that it is unclear why oversight of an RO is insufficient in 10 CFR 53.735(b) and the interaction-dependent-mitigation facility would require an SRO. The commenter recommended that 10 CFR 53.735(b) use the same language as 10 CFR 53.735(a) and read, “Under the direction and in the presence of an operator, senior operator or generally licensed reactor operator, as appropriate…” (NEI2-0078).

NRC Response: The NRC disagrees with the comment.

SROs are able to provide oversight for fuel handling for the current reactor fleet because they are tested on fuel handling facilities and procedures under 10 CFR 55.43(b)(7). Although 10 CFR 53.780(b) does not explicitly discuss the content of examinations for RO and SRO applicants, draft guidance located in DRO-ISG-2023-01 provides guidance to the staff in the review and approval of these examination programs. Per this guidance, SROs and GLROs are expected to be tested on fuel handling facilities and procedures whereas ROs are not. This guidance is based on only SROs and GLROs performing this function. Additionally, GLROs are considered equivalent to SROs as both can direct the licensed activities of other operators and ROs cannot, hence the reduced testing of ROs.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.F: A commenter wrote that, unlike 10 CFR 55.31, 10 CFR Part 53 does not specify the minimum number of control manipulations to be performed. Given this, the commenter asked the NRC to clarify if it intends to revise NRC Form 398 to remove the requirement to perform at least five significant control manipulations. The commenter added that the number of required control manipulations needed to be performed should be determined through the systems approach to training (SAT)-based methodology and based on the design and operating characteristics of the reference plant (NEI2-0081).

Additionally, the commenter wrote that NRC Form 398 should be updated to reflect 10 CFR Part 53 allowances (NEI2-0080). The commenter also wrote that NRC Form 398 is referred to as Form NRC 398 throughout 10 CFR 53.775, which should be corrected to NRC Form 398 (NEI2-0079).

NRC Response: The NRC agrees, in part, with the comments.

NRC Form 398 was erroneously referred to as “Form NRC 398” in 10 CFR Part 53. In addition, NRC Form 396 is also impacted by 10 CFR Part 53 and was erroneously referred to as “Form NRC 396” in the proposed rule language throughout Subpart F.

Accordingly, the NRC corrected the erroneous use of “Form NRC 398” and “Form NRC 396” throughout 10 CFR Part 53, Subpart F, in response to these comments. The NRC also updated both NRC Form 398 and NRC Form 396 to conform with the requirements in 10 CFR Part 53 in addition to the requirements in 10 CFR Part 55 in response to these comments. However, NRC Form 398 will still require five reactivity control manipulations for operators licensing under 10 CFR Part 55 as 10 CFR 55.31(a)(5) requires the completion of at least five reactivity control manipulations.

Comment Bin 3.6.2.1.G: A commenter wrote that the NRC should revise 10 CFR 53.730(g), 10 CFR 53.780(a)(1) and (c)(1)(ii), and 10 CFR 53.830(b) and (c)(1)(ii) to provide clarification as to if facility licensee training programs accredited by the National Nuclear Accrediting Board (NNAB) would be considered a "Commission-approved training program." The commenter suggested that this could be provided in the definition section and suggested including similar wording to that contained in NUREG-1021, Revision 1, “Operator Licensing Examiner Standards,” issued October 1984 (ML15027A416). The commenter suggested providing clarification guidance in DRO-ISG-2023-01, as well. Additionally, the commenter wrote that 10 CFR 53.830(b) should be revised, or guidance should be provided, to clarify if training programs must be approved by the NRC before initial use (NEI2-0077, NEI2-0082, NEI2-0106).

NRC Response: The NRC disagrees with the comments.

Regarding NNAB accreditation, the Commission has not had the opportunity to review an NNAB accreditation program for training licensed operators at advanced reactor facilities or an opportunity to determine if such a program is sufficient to warrant Commission approval. Once such a program is provided to the Commission, the NRC will review the program and, if warranted, provide such approval at that time. For facilities that plan to use the current NNAB accreditation process, Commission approval of that process is already documented as discussed in the comment and additional approval is not required.

Regarding the comment associated with 10 CFR 53.830(b), training programs for commercial nuclear plant personnel, other than licensed operators whose training is covered under other parts, are not required to be Commission-approved. This is similar to the current training requirement documented in 10 CFR 50.120, which also does not require Commission approval. Commission approval is only required for licensed operator initial and requalification training programs, whether those are for individually licensed ROs/SROs or GLROs. Not using "Commission-approved" in 10 CFR 53.830(b) was deliberate as such approval is not required.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.6.2.1.H: A commenter recommended that the NRC delete the requirement to maintain answers given by a specifically licensed operator during initial and requalification examinations under 10 CFR 53.780(b)(5) and 10 CFR 53.780(c)(3) or GLRO participation during training and examination programs under 10 CFR 53.815(c). The commenter cited operating experience from the U.S. Navy where exam answers are not maintained as part of the qualification record. The commenter also stated that this requirement increases the number of records that need to be maintained. The commenter suggested that the NRC could instead clarify the basis behind maintaining the answers given by the applicant on the initial examination (NEI2-0086, NEI2-0090, NEI2-0103).

NRC Response: The NRC disagrees with the comments.

The retention of records in 10 CFR Part 53 as outlined in 10 CFR 53.780(b)(5), 10 CFR 53.780(c)(3), and 10 CFR 53.815(c) is analogous to the retention of records in 10 CFR Part 55 and in NUREG-1021. The NRC currently maintains the records for 10 CFR Part 55 initial licensing examinations as outlined in NUREG-1021, whereas for requalification examinations the facilities maintain these records as outlined in 10 CFR 55.59(c)(5). Unlike 10 CFR Part 55, 10 CFR Part 53 has the facilities maintaining all records.

Retention of this information allows the NRC to audit the information as necessary. Successful completion of the initial examination informs the licensing decision for the initial licensing of operators. This information needs to be retained in case it is needed later (such as ensuring the establishment of uniform conditions for operator licensing or in support of an audit of the NRC's licensing decisions). For requalification, successful completion of the requalification examination is required for operator license maintenance. The NRC needs this information retained and available so that the NRC can confirm, via inspection, that these operators are meeting that requirement.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.6.2.1.I: A commenter wrote that in 10 CFR 53.780(c)(2)(ii)(B) the NRC needs to more clearly define what the expectation is regarding a representative of the Commission being “afforded the opportunity to be present.” The commenter recommended deleting the requirement or further clarifying it in guidance (NEI2-0087).

NRC Response: The NRC agrees, in part, with the comment.

The NRC disagrees with deleting 10 CFR 53.780(c)(2)(ii)(B). The NRC needs to know when requalification examinations will be administered to enable inspection, including observation of examination activities. To be able to schedule the necessary staff resources, the NRC needs to be informed ahead of the scheduled examination. Therefore, the regulatory requirement to inform the NRC ahead of the scheduled examination in sufficient time to allow the staff to be present is warranted.

However, the NRC agrees that additional guidance regarding what this phrase means is warranted. Accordingly, the NRC revised DRO-ISG-2023-01 in response to this comment. Specifically, the NRC included clarification of the phrase “afforded the opportunity to be present.”

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.J: A commenter wrote that the NRC should delete the word “promptly” from 10 CFR 53.780(b)(4) as the NRC can provide expectation in guidance documents as to “how early” a graded examination documentation for each applicant must be provided to the Commission (NEI2-0085).

The commenter said that the definition of “prompt” is unclear in 10 CFR 53.780(c)(2)(ii)(D) and recommended that the NRC also clarify the entity the summary of examination results is being provided to (NEI2-0089).

Finally, the commenter recommended that the NRC delete the word “promptly” from 10 CFR 53.780(e)(iii) and 10 CFR 53.815(e)(2)(iii), writing that the corrective action timeline may be impacted by a variety of factors, and the timeline of the repair is the responsibility of the simulation facility owner and not the NRC (NEI2-0091, NEI2-0105).

NRC Response: The NRC agrees, in part, with the comments.

Regarding use of the term “promptly” in 10 CFR 53.780(b)(4), the NRC agrees that there is no need to use the term “promptly” because the NRC will not make any licensing decisions on received applications until this examination material is received and reviewed by the NRC. Therefore, the impact of a delayed submittal will be that the license decisions are delayed. The facility licensee has a material interest in timely licensing decisions and therefore will likely ensure submittal of the examination grading to support efficient licensing decisions. Accordingly, the NRC updated the rule language to remove this term for submitting grading documentation for initial licensing examinations for specifically licensed operator applicants as a result of this comment.

Regarding the use of the term "promptly" in 10 CFR 53.780(c)(2)(ii)(D), the NRC agrees in part with the comment. The NRC needs to receive this information without delay to confirm that the licensed operators at the facility are maintaining the requisite skills and abilities to safely operate the facility, as evidenced by passing the examination. The NRC agrees that clarification of the term in guidance is warranted and updated DRO-ISG-2023-01 to provide this clarification. Regarding the entity to which to provide the summary of examination results, this will be updated in guidance documents once determined. Accordingly, the NRC did not change the rule language in response to this comment.

Regarding the use of the term "promptly" associated with the correction of hardware and software modeling changes to correct simulator deficiencies in 10 CFR 53.780(e)(3)(iii) and 10 CFR 53.815(e)(2)(iii), the NRC disagrees with the comment to remove this term. The concern is for potential negative training due to the uncorrected simulator deficiency which could impact the ability of the operators to safely operate the actual plant. If the operators are trained that the plant will act one way due to the deficiency and the plant acts differently during an actual event, this could impact operator response to the actual event. This would mean that simulator deficiencies are prioritized for correction based on the significance of the issue, while recognizing that there may be factors that would warrant a delay in the correction, such as part availability. Such a delay would still be considered "prompt" for the purposes of this regulation. Accordingly, the NRC did not change the rule language as a result of these comments regarding 10 CFR 53.780(e)(3)(iii) and 10 CFR 53.815(e)(2)(iii).

Comment Bin 3.6.2.1.K: A commenter recommended deleting 10 CFR 53.780(f) or, if this is not possible, limiting the waiver of examination to two years (TG9-0001).

NRC Response: The NRC agrees in part with this comment. As the NRC explained in the proposed and final rules, the intent of this waiver in 10 CFR 53.780(f) is for a waiver of the initial examination requirements and is not intended for continued use associated with failure to complete required requalification examinations. In keeping with a risk-informed and technology-inclusive approach, specific prescriptive criteria, such as the two-year limit found in 10 CFR 55.47(a)(1), were removed from the rule language and this information is instead covered in guidance documents, such as DRO-ISG-2023-01. However, the NRC agrees that the operating experience at a comparable facility should be recent, with guidance clarifying what constitutes "recent operating experience."

Accordingly, the NRC clarified in the rule language that waivers are only applicable to initial examinations and that operating experience must be recent for a waiver to be considered.

Comment Bin 3.6.2.1.L: A commenter said that the regulations of 10 CFR 53.780(b)(2)-(4) do not clearly define the timelines facility licensees are expected to meet regarding certain aspects of the operator licensing initial examination program (NEI2-0083, NEI2-0084). In 10 CFR 53.780(b)(2), the commenter recommended that the NRC delete "in advance of" and replace it with "prior to" and also include a timeframe in guidance documents (NEI2-0083).

The commenter also said that the word "sufficient" is vague and should be defined in guidance documents, and suggested that 10 CFR 53.780(b)(3) be rephrased to read, "The facility licensee must ensure that the Commission is notified of the expected date the examination is to be administered to provide the Commission with the opportunity to be present when the facility licensee administers the examination” (NEI2-0084).

NRC Response: The NRC agrees, in part, with the comments.

The use of “in advance of” in 10 CFR 53.780(b)(2) enables the facility licensee to determine its own timeline, as it is not feasible to determine one timeline for all facility licensees. A variable timeline is required because there are a variety of technologies and designs, each having a facility-specific examination program (i.e., the timeline would be based on individual examination programs that are tailored by the facility licensee to its design). The timeline would be based on the complexity of the examination (e.g., the length or format of the examination). Therefore, the time required for the NRC to review and approve the examination will vary. Consequently, a single timeline for all facility licensees cannot be provided; however, a timeline for submittal to the NRC should be included as part of the examination program that each facility licensee submits to the NRC under 10 CFR 53.780(a). Additionally, the NRC needs to be informed of the timeline to ensure that the timeline will support allocation of the resources required to review and approve the examination. Accordingly, the NRC did not change the rule language in response to this comment; the NRC did clarify the language in DRO-ISG-2023-01.

The NRC needs to know when examinations will be administered. The NRC needs to be informed ahead of the scheduled examination with sufficient time to allocate resources. Therefore, the regulatory requirement to inform the NRC ahead of the scheduled examination in sufficient time to allow the staff to be present is warranted. However, the NRC agrees that additional guidance regarding what this phrase means is warranted. Accordingly, the NRC did not change the rule language in response to this comment; the NRC did clarify the language in DRO-ISG-2023-01.

Comment Bin 3.6.2.1.M: A commenter asked if there is a difference between “complete requalification examination” and the “biennial requalification examination” in 10 CFR 53.780(c)(2)(ii)(C) and recommended that NRC clarify if it intends to require a complete examination “retake” if a candidate fails the requalification exam, or if there are cases where the candidate may only have to retake certain sections if failures were in particular areas. The commenter suggested revising the last sentence of the paragraph to read, “necessary remedial training has been completed, and the candidate has successfully passed the necessary reexamination” (NEI2-0088).

Another commenter wrote that 10 CFR 53.780(c)(2)(ii)(C) requires requalification for operators at a minimum every 24 months, while 10 CFR 53.795 states that an operator license would expire 6 years after the date of issuance. The commenter wrote that this is overly burdensome to limit an operator license for a time period less than one fuel cycle and asked the NRC to consider the timeframes in relation to some features of microreactors (WEST1-0012).

NRC Response: The NRC agrees, in part, with the comments.

There is no difference between a “complete requalification examination” and the “biennial requalification examination.” Per 10 CFR 53.780(c)(2)(ii)(C), the complete requalification examination is on a period of not to exceed 24 months, or biennially. Accordingly, the NRC updated the rule language for clarity in response to this comment.

Regarding whether a candidate would only need to retake certain portions of the biennial requalification examination, the NRC agrees that additional guidance on what would constitute an appropriate retake examination is warranted. No change to the rule language was made; however, the NRC updated DRO-ISG-2023-01 to provide this guidance in response to this comment.

The NRC disagrees with the statement that having a license expiration date of 6 years is overly burdensome. Renewal of the license provides the NRC periodic insight into the competence of an operator to operate the controls at a facility. This information enables the NRC to determine if the operator meets the medical and performance requirements to warrant continued licensing, if license modifications are necessary, or if the license should be allowed to expire. This is not contingent on the length of a given fuel cycle but instead is a periodic check by the NRC that the operator has operated the controls safely and is capable of continuing to do so. Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.N: A commenter said that 10 CFR 53.785(b) contains the language, “The license is limited to the facility for which it is issued...” The commenter said that the definition of “license” in 10 CFR 53.020 would indicate that the facility is one or more reactors in the same location and does not allow for being licensed to an identical design at another facility. The commenter recommended that NRC provide a means for operation of multiple remote facilities, from a central control facility and licensing to a specific reactor design in addition to a location as currently proposed (NEI2-0092). Another commenter wrote that they supported this comment (NEX-0030).

The commenter also discussed 10 CFR 53.785(c) which adds the language “or facilities” compared to the existing requirements in 10 CFR 55.53. The commenter asked NRC to clarify why it would not add this same language to 10 CFR 53.785(b). The commenter recommended that NRC either remove “or facilities” in 10 CFR 53.785(c) or add it to 10 CFR 53.785(b) (NEI2-0092).

NRC Response: The NRC agrees, in part, with the comments.

Per the AEA, a utilization facility is “any equipment or device … peculiarly adapted for making use of atomic energy” whereas a facility licensee is the entity that holds the license for that utilization facility. Also, per the AEA, an operator is “any individual who manipulates the controls of a utilization … facility”. A facility licensee can hold more than one facility license, and an operator could obtain a license that encompasses all comparable units for that facility licensee per the regulations as written. Additionally, there is nothing in the regulations that prohibit an operator from having a license at more than one facility so long as that operator is employed by the facility licensee. The current commercial operating fleet has examples of an operator holding a license for more than one utilization facility. For example, at a multi-unit site, an operator could be issued a license for more than one of the units (i.e., a license for more than one utilization facility by the same facility licensee). The NRC disagrees with the statement that the definition of license in 10 CFR 53.020 indicates that a facility is one or more reactors at the same location. The definition, as it relates to a facility, is a single LWA, CP, OL, ESP, COL, or ML. Each reactor would be its own facility, and the holder of the facility license, or facility licensee, could hold multiple facility licenses. This can be seen with the current reactor fleet as each unit, or reactor, has its own license, even if there are multiple reactors at the same location. In other words, if there are two reactors at a single location, there are two licensed facilities, but there may only be a single entity holding these licenses, referred to as a facility licensee. There is no requirement that the entity only hold licenses to facilities in a single location.

Although all operators that are currently licensed at more than one facility happen to be at co-located facilities, nothing in 10 CFR 53.785 would require that the utilization facilities be co-located. An operator could obtain a license that encompasses all comparable units for that facility licensee (i.e., it would be acceptable for an operator to be licensed at multiple facilities for a specific facility licensee) but not be tied to a specific location. Licensing an operator to a product (i.e., a specific reactor type or design) would not be pragmatic as there is the potential for there to be a variety of organizational structures, reporting structures, and conduct of operations that would preclude licensing operators at different facility licensees, including differing training programs and requalification requirements. Furthermore, there is the possibility of differences in the technical specifications and operating procedures of the same reactor type because of variations between different facility licensees.

The NRC agrees with the comment to expand facility in 10 CFR 53.785(b) to include more than one facility. Accordingly, the NRC has revised 10 CFR 53.785(b) in response to this comment.

Comment Bin 3.6.2.1.O: A commenter made several recommendations related to staffing requirements:

- In 10 CFR 53.800(a)(4), change "may be achieved through the use of SSCs that function through inherent characteristics or that have engineered protections against human failures" to "may be achieved through the use of SSCs that function through inherent characteristics or digital software/controls or that have engineered protections against human failures."
- In 10 CFR 53.805, change "permanent removal of fuel from the reactor vessel" to "permanent removal of fuel from the reactor vessel site."
- In 10 CFR 53.810(g), change the rule language from "conviction" to "arrest" as the timeline for waiting for a conviction may be too long, and change the time to either 7 or 14 days.
- In 10 CFR 53.815(f), delete the requirement if it refers to staff and not the simulator.

The commenter also wrote that 10 CFR 53.815(e)(iii) made "excellent points" and stated that 10 CFR 53.820 is too vague (TG10-0001).

NRC Response: The NRC disagrees with the comment.

Regarding adding the term "digital software/controls" to 10 CFR 53.800(a)(4), this would not meet the intent of the regulation, which is to ensure that there are highly robust mechanisms, such as inherent features of the design or specifically designed engineering protections, against human errors. This requirement is necessary to ensure that only those facilities meeting the requirement receive the reduced regulatory burden and oversight associated with the GLRO licensing process.

Regarding the proposed change from "permanent removal of fuel from the reactor vessel" to "removal of fuel from the reactor vessel site", the current language is consistent with the language in 10 CFR 53.1070, which is referenced by 10 CFR 53.805. The language in 10 CFR 53.1070 is consistent with the equivalent requirement in the NRC's existing regulations in 10 CFR 50.82. The NRC believes that "reactor vessel" is a more appropriate term to address the change of plant status when all fuel is removed from the primary reactor systems to some form of storage, including possible storage within the site of the commercial nuclear plant (e.g., spent fuel pool).

Regarding the comment on changing the term from "conviction" to "arrest" in 10 CFR 53.810(g), the NRC acknowledges the presumption of innocence until proven guilty via a conviction, hence the use of that term.

Regarding 10 CFR 53.815(f), 10 CFR 53.815(e) is the portion of the rule language for simulators. The overarching regulation of 10 CFR 53.815, which includes 10 CFR 53.815(f), covers training, examination, and proficiency requirements for individuals licensing under the GLRO process. The waiver regulation provides a mechanism for a previously licensed operator to waive the requirement for an initial examination if certain criteria, designed to demonstrate the operator's competence, are met. The NRC disagrees with removing this allowance. This waiver acknowledges that such operators have already demonstrated the capability of operating the plant safely and can have the requirement to take another examination waived.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.P: A commenter wrote that the NRC has taken a risk-informed approach in the development of GLROs but added that the requirements of 10 CFR 53.815 do not take full advantage of the enhanced safety benefits of self-reliant-mitigation facilities. The commenter explained that since no safety functions for a self-reliant-mitigation facility are assigned to operator actions, the license requirements imposed by 10 CFR 53.815(e) for plant simulators are overly burdensome for the training and qualification of GLROs. The commenter wrote that the requirements in 10 CFR 53.830 are sufficient to ensure that GLROs are competent and proficient to carry out their duties as specified in 10 CFR 53.805.

The commenter recommended that 10 CFR 53.815 be removed from the rule; an additional category of "Generally Licensed Reactor Operators" be added to 10 CFR 53.830(b); and a paragraph be added to 10 CFR 53.830(d) that identifies specific elements that must be included in the curriculum for GLROs including the topics listed in 89 FR 86940, as well as topics related to job performance requirements listed in 10 CFR 53.805 and 10 CFR 53.810. The commenter noted that this would allow for "continuous qualification" of the GLROs rather than a formal requalification process.

The commenter added it would be useful for the NRC to adopt GLROs and a similar set of graded operator licensing requirements in 10 CFR Part 55 (SHP-0005).

NRC Response: The NRC disagrees with the comment.

The comment states that the GLRO training program can be moved into 10 CFR 53.830 and that this would still allow for initial approval of that training program by the NRC. However, this statement is not accurate as 10 CFR 53.830 has no requirements for Commission approval of the SAT-based training programs. This is one of the reasons why the GLRO programs are separate. Commission approval of the GLRO training program is necessary to ensure uniform conditions for operator licensing as well as to ensure that those conditions are met prior to the license becoming effective.

Regarding the comment about changes to allow flexibility to propose a "continuous qualification" of GLROs, the current rule language in 10 CFR 53.815 requires that requalification and examination include in a training program developed using a SAT. The only uses of the term "periodicity" within 10 CFR 53.815 are as follows:

- 10 CFR 53.815(b)(3)(i): The facility licensee must periodically evaluate and revise the training program, and management must periodically review the training program for effectiveness

- 10 CFR 53.815(b)(3)(v): The requalification examination program must specify an appropriate periodicity

The rule language does not specify a periodicity for the requalification program itself. This could allow for continuous requalification; however, the NRC sees a need to verify GLROs' qualification periodically via an examination that demonstrates that the GLROs are maintaining the knowledge necessary to meet the requirements for their license. The NRC leaves it to the facility licensee to propose the appropriate periodicity for those examinations.

Including 10 CFR Part 53 provisions in 10 CFR Part 55 is out of scope of this rulemaking.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.Q: A commenter wrote that, as presently worded, 10 CFR 53.800(a)(5) appears to imply that the entirety of the multi-layered defense-in-depth scheme would need to be independent of human action, which is "excessive and likely impractical to achieve." Additionally, the commenter stated this is not needed as 10 CFR 53.250(c) clarifies that the entirety of the defense-in-depth scheme needs to not be based on a single feature or barrier. Given this, the commenter suggested revising 10 CFR 53.800(a)(5) to read, "[t]he plant design must, for each safety function, provide for at least one layer of defense-in-depth that is independent from credited human action" (JSE-0001).

NRC Response: The NRC agrees, in part, with the comment.

As stated in the proposed and final rules, the intent of the criterion described in 10 CFR 53.800(a)(5) is to require "adequate defense in depth achieved without reliance on human action." The NRC agrees that adequate defense in depth does not require that the entirety of the defense-in-depth scheme (for example, all layers of defense-in-depth) be independent of human action. The NRC does not wish to discourage possible contributors to defense-in-depth that might be provided by a GLRO at a self-reliant mitigation facility. Also, 10 CFR 53.250 does not require a specific defense-in-depth approach, and the NRC does not wish to unnecessarily restrict the types of defense-in-depth measures developed in response to 10 CFR 53.250 for self-reliant mitigation facilities. Therefore, the NRC updated the rule language to ensure that there are no important human actions needed to meet the requirements of 10 CFR 53.250.

Comment Bin 3.6.2.1.R: A commenter said that 10 CFR 53.805(a)(1) is a prescriptive requirement and GLRO training programs are already required to be developed using a SAT in accordance with 10 CFR 53.815 and 53.805(3). The commenter recommended that the NRC remove the requirement (NEI2-0095).

The commenter asked if the phrase "these requirements" in 10 CFR 53.805(a)(2) is referring to just (a)(1) or all of 10 CFR 53.805. The commenter recommended that the NRC update to more specific implementation of 10 CFR 53.800 requirements or words to that effect (NEI2-0096).

The commenter stated that the requirement in 10 CFR 53.805(a)(5) to report annually to the NRC the identity of all GLROs at the commercial plant should either be removed or rephrased to be more flexible and less burdensome. The commenter said that one option is to have this information available for inspection as opposed to an annual report (NEI2-0097).

Finally, the commenter said that the requirement in 10 CFR 53.805(a)(6) is already ensured by 10 CFR 53.1550 so this requirement should be removed (NEI2-0098).

NRC Response: The NRC agrees, in part, with the comments.

The NRC disagrees with removing the requirements in 10 CFR 53.805(a)(1). The requirements in 10 CFR 53.805(a)(1) are a list of requirements that must be met that are in addition to the requirements that must be met in 10 CFR 53.815. The requirements in 10 CFR 53.815 pertain to the requirements for GLRO training, examination, and proficiency programs whereas the requirements in 10 CFR 53.805(a)(1) and 10 CFR 53.805(a)(3) pertain to the general license requirements for facilities that have GLROs, the tasks that GLROs are expected to execute safely and competently, and the requirement for facilities to develop and maintain their training programs for GLROs. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC agrees with clarifying the language in 10 CFR 53.805(a)(2). Use of the term "these requirements" is vague and warrants clarification. Accordingly, the NRC modified the language in the rule to reflect what 10 CFR 53.805(a)(2) is referencing.

The NRC disagrees with the comment regarding the requirement to report annually to the NRC as stated in 10 CFR 53.805(a)(5). There is less oversight from the NRC at SRMFs because of the reduced safety significance of SRMFs and because of the minimal safety impact that GLROs have at these facilities; however, the NRC still needs to know who holds a GLRO license at these facilities. An annual reporting periodicity was selected to minimize the burden on the facilities but to still provide an accountability of GLROs without the NRC having to perform an onsite inspection. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC disagrees with the comment regarding the requirements in 10 CFR 53.805(a)(6). The requirements in 10 CFR 53.1550 pertain to guidelines for evaluating whether changes to licensing-basis information described in the FSAR would require the facility to obtain a license amendment to implement the change. This is different from 10 CFR 53.805(a)(6), which pertains to whether the design of the facility still meets the requirements to be classified as an SRMF. The former addresses implementing changes to the facility and the latter addresses the overall design of the facility and its adherence to the requirements that enable it to be classified as an SRMF. Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.S: A commenter requested that the NRC clarify the intent of "or facilities" in 10 CFR 53.810(c), or rephrase it to "is qualified", delete "at which the operator is employed", and reword the rule language to "The general license is limited to the facility for which it was issued" or rephrase it to "The general license is limited to the facility or facilities of which the operator is qualified." The commenter also stated that "arguably, facility is already defined to include 'facilities' meaning multiple reactors under one operating license for a plant" (NEI2-0100).

The commenter added that 10 CFR 53.810(d) states that the "Commission will suspend the general license on an individual basis for violations". The commenter asked if this means suspending the general license for the individual facility or the general license for an individual at the facility. The commenter recommended that NRC rephrase the rule language to state, “The Commission will suspend the general license of a generally licensed reactor operator on an individual basis for violations.” (NEI2-0101).

The commenter also requested clarification of when a general license is “issued” and asked whether it was on the date of an initial qualification or when an individual is employed into a position (NEI2-0099).

NRC Response: The NRC agrees, in part, with the comments.

The NRC disagrees with the request to change the rule language in 10 CFR 53.810(c). Section 107 of the AEA directs the Commission to license individuals as operators of facilities licensed under the AEA. The use of “or facilities” in 10 CFR 53.810(c) is pertinent as the regulation can authorize an individual to operate more than one facility. The AEA defines the term utilization facility, and the rule is written based on this definition. The NRC implements the licensing provisions of the AEA that govern utilization facilities by issuing an individual license for each licensed reactor and the comment does not provide any reason for departing from this practice. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC acknowledges that the term “facility licensee” could refer to an entity that holds multiple facility licenses. Therefore, an operator could be licensed to operate more than one facility while working for a single facility licensee. There are currently multi-facility sites, each with their own separate facility license, with a single facility licensee that follows this paradigm which happen to be, but are not required to be, co-located. Having a single facility licensee as the employer of the operators allows for a single training program, use of similar procedures and conduct of operations, and other administrative and programmatic efficiencies that would not be possible for an operator employed by multiple facility licenses. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC agrees that clarification is needed for the suspension of a license for violations. The general license allows a GLRO to manipulate the controls of a self-reliant-mitigation facility and, if the GLRO meets specified requirements, to direct the other GLROs. The rule provides that the NRC may suspend the license for an individual GLRO. Accordingly, the NRC clarified the language of 10 CFR 53.810(d).

The NRC disagrees that additional clarification to the rule language is needed regarding when the general license is “issued.” A rulemaking issues a general license, so the final 10 CFR Part 53 rule will issue the general license to any individuals that meet the criteria in 10 CFR 53.810(a). As stated in 10 CFR 53.810(a) the general license applies to an individual who is employed in a position requiring the license and has satisfied the requirements of the general license. In accordance with 10 CFR 53.805(a)(4), an individual not in compliance with the generally licensed operator training, examination, and proficiency programs is not qualified to be in a position that requires the license. Therefore, the individual must comply with the program, including satisfactorily completing the examination, prior to employment in such a position. Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.T: A commenter expressed support for 10 CFR 53.815(b)(3)(vi) and appreciation for the change that would have the NRC approve the examination process but not the exam itself (NEI2-0102).

NRC Response: The NRC agrees with the comment.

The comment supports the proposed rule and suggests no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.U: A commenter wrote that the staffing, training, personnel qualifications, and human factors requirements are more complex than existing requirements, and suggested replacing 10 CFR 53.725 through 10 CFR 53.800 with “simple elements of the current 10 CFR 50.120” (HPT19-0001, HPT33-0001)

NRC Response: The NRC disagrees with these comments.

The requirements in 10 CFR 53.725 through 10 CFR 53.745 address general requirements for staffing, training, personnel qualifications, and HFE. Requirements in 10 CFR 53.760 through 10 CFR 53.795 address the licensing of operators who manipulate the controls of interaction-dependent mitigation facilities. Requirements in 10 CFR 53.800 address the licensing of GLROs who manipulate the controls of self-reliant mitigation facilities. Note that the existing requirements for the licensing of operators, located within 10 CFR Part 55, are more prescriptive, technology-specific, and inflexible when compared to the corresponding risk-informed, technology-inclusive 10 CFR Part 53 rule language.

10 CFR 53.830 includes similar requirements to those in 10 CFR 50.120 for non-licensed plant personnel. 10 CFR 53.830 does not provide the provisions for licensing of operators, such as examinations to demonstrate mastery of the necessary material to operate the plant competently based on a risk-informed analysis of the operator role in safety.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.6.2.1.V: A commenter wrote that 10 CFR Part 53 does not consider the need for in-person, on-shift management of operations. Providing background, the commenter wrote that the nature of nuclear plants causes them to be exceptionally complex from a management perspective, and this is reflected in the causes of early major nuclear accidents. The commenter wrote that the SRO cannot perform this role as they need to focus on efforts involving the reactor and allied systems, and other plant operations would be conducted by specialized operators as appropriate.

The commenter wrote that the NRC should establish a new section in the rule that clearly states applicants must address on-shift management to ensure that a single individual has authority and responsibility to direct on-shift operations, and all on-shift operations personnel must report to this shift manager. The commenter’s suggestion included a recommendation that all on-shift activities involving the plant cannot occur without that individual's explicit knowledge.

The commenter added that this individual’s responsibilities and qualifications should not be subject to extensive regulatory requirements, where a site certificate involving knowledge of reactor operations and periodic training would be appropriate. Instead, the commenter suggested the NRC should be given the opportunity to provide a “no-objection” to the individual (HPT22-0001).

NRC Response: The NRC disagrees with the comment.

The NRC disagrees that the rule language should include a new section requiring applicants to address on-shift management to ensure that a single individual has authority and responsibility to direct on-shift operations and that all on-shift operations personnel must report to this shift manager. As stated in the proposed and final rule discussion related to 10 CFR Part 53, Subpart F, the requirements address staffing, training, personnel qualifications, and HFE in a manner that is risk-informed, technology-inclusive, performance-based, and flexible in nature. Adding a requirement for a single on-shift individual with specific authorities and responsibilities is overly restrictive.

The NRC considers the roles and responsibilities of operators and other plant staff as part of the HFE program review associated with 10 CFR 53.730.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.W: A commenter said that it appears that the training programs required under 10 CFR 53.830(c) are similar to those required under 10 CFR 50.120, and the commenter requested additional clarification on the intent and classifications of training programs required per this subpart. Specifically, the commenter asked:

1. if the category of “Supervisors” includes all supervisors from the technical disciplines or only supervisors overseeing operational aspects,

2. if operating personnel includes engineering expertise to on-shift operation personnel similar to 10 CFR 50.120,

3. if, similar to 10 CFR 50.120, 10 CFR Part 53 should not call out certified fuel handlers, and

4. if the term “auxiliary operators” in 10 CFR 53.830 and “non-licensed operators” in 10 CFR 53.020 are the same.

The commenter also asked NRC to clarify whether the category of “supervisors” includes technical program areas and maintenance supervisors or only operational shift supervisors as in 10 CFR 50.120, and to align definitions relating to non-licensed operator and auxiliary operator for consistency (NEI2-0107).

NRC Response: The NRC agrees, in part, with this comment.

The NRC agrees, in part, regarding clarifying whether the category of “Supervisors” in 10 CFR 53.830(c) is intended to include supervisors from the technical disciplines. The intent was to use a more technology-inclusive and flexible approach to categorizing disciplines that warranted a SAT-based training program. The regulation in 10 CFR 50.120 is based on the paradigm and conduct of operations for the current reactor technology designs and does not reflect changes in that paradigm as a result of efficiencies gained in the proposed advanced reactor designs. Therefore, the NRC developed a new categorization method that was intended to capture appropriate roles and disciplines requiring this training but did not intend to expand the scope beyond that currently required in 10 CFR Part 50.

The categories as defined in 10 CFR 53.830(c) were developed to align with the Nuclear Waste Policy Act of 1982, as amended. Section 306 directed the NRC to promulgate regulations for the training and qualification of civilian nuclear power plant operators, supervisors, technicians, and other appropriate operating personnel. The NRC updated the final rule FRN language to clarify the intent of the term “supervisors” for 10 CFR 53.830(c). However, the NRC does not believe this warrants additional clarification in the rule language itself.

The NRC agrees regarding operating personnel, including engineering expertise, to on-shift personnel and that the intent is similar to that in 10 CFR 50.120. The NRC developed the language in 10 CFR 53.830 to allow for greater flexibility in personnel categorization under different conduct of operations and organizational structures while ensuring that the appropriate disciplines are covered by a SAT-based training program.

The NRC disagrees regarding 10 CFR 50.120 not including certified fuel handlers while 10 CFR 53.830 does. The NRC developed the 10 CFR Part 53 rule language to cover all aspects of the facility lifecycle, including decommissioning, at which time there would no longer be a need for licensed operators but would instead transition to certified fuel handlers. Currently, these training programs are handled individually via changes to the facility’s technical specifications during decommissioning. The requirements were instead moved into regulations for consistency.

The NRC disagrees regarding non-licensed operators and auxiliary operators. The term auxiliary operator is defined in 10 CFR 53.725(c) and refers to any individual who operates components of a commercial nuclear plant who is not required to be licensed. However, this definition is only applicable in 10 CFR 53.725 through 10 CFR 53.830 and therefore is not referenced elsewhere, such as in 10 CFR 53.020. The term “non-licensed” is used in 10 CFR 53.020 in the context of a certified fuel handler and is intended to delineate that position from one that would require an operator license.

Accordingly, the NRC updated the final rule FRN language to clarify the intent of the term “supervisors” for 10 CFR 53.830(c).

Comment Bin 3.6.2.1.X: A commenter wrote that staffing, training, qualifications, and human factors requirements contained in the proposed rule are prescriptive and are fixated on reactor operators while not considering the automated nature of future advanced reactors. The commenter wrote that the NRC should take a simpler approach and state that licensee programs are required for reactor plant staffing, operator qualification and re-qualification, operator training, and simulators. The commenter added that the NRC should state that these programs must be developed from consensus industry codes and standards, and the applicable subsections in the rule should identify simple key requirements involving the programs. The commenter also stated that the NRC should accept licensee certifications of operators (HPT35-0001).

NRC Response: The NRC disagrees with the comment.

The NRC disagrees with the statement that the staffing, training, qualifications, and human factors requirements in the proposed rule are prescriptive. The staffing, training, licensing, and human factors requirements in 10 CFR Part 53 are designed to be risk-informed and technology-inclusive and appropriately provide requirements based on the requisite safety implications. For example, introduction of a GLRO simplifies and streamlines the licensing process for those operators at facilities that have shown that the operator is not relied upon for safety, as might be found in facilities with high levels of autonomous operations. The key aspect, however, is not how autonomous the facility is, but rather whether the operator is relied upon for safe operation of that facility under normal, abnormal, or emergency operations. The 10 CFR Part 53 proposed rule language already requires programs for staffing, operator training, simulators, and operator licensing.

Regarding the use of consensus codes and standards, NRC Forms 398 and 396, both referenced in this regulation, do refer to applicable industry codes and standards, which can be used to meet those requirements. Additionally, a SAT is a standardized approach that is well-understood in the training area. Other industry standards that can be used to meet the regulatory requirements may be endorsed through the appropriate process (e.g., an RG). Where necessary, the NRC has specified those minimum requirements in each area of staffing, training, licensing and human factors that must be met for both facilities and operators licensing under this part, to ensure that safety is met. Some of these requirements are prescriptive because that is what is needed to ensure that safety is addressed. Where appropriate, the NRC has designed the rule language to be risk-informed, scaling the requirements based on the associated risk while maintaining a technology-inclusive focus. This results in less prescriptive requirements as compared to 10 CFR Part 55, where the requirements for operators at facilities licensed under 10 CFR Parts 50 and 52 reside. As an example, 10 CFR Part 55 provides specific topics that must be covered in an examination, as well as the format (i.e., written or operating test) of that examination. No prescriptive list is in 10 CFR Part 53 rule language. This is intended to be technology-inclusive and to allow the facility to determine what operator knowledge is necessary based on the specific design and risk characteristics of that facility.

Regarding the NRC accepting licensee certification of operators, this would not be authorized under the AEA which requires the NRC to establish uniform conditions for the licensing of operators. Allowing facilities to establish their own processes for certifying operators would be contrary to the AEA.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.Y: A commenter wrote that the staffing approach is performance-based and has the potential to allow for reduced staffing levels if safety objectives are met through other means (NYS2-0012).

NRC Response: The NRC agrees with the comment. The comment supports the proposed rule and suggests no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.Z: A commenter wrote that they disagreed with the proposed GLRO class of operators and added that the NRC should maintain a similar type of license for this class of operators as is done with other licensed nuclear operators. The commenter stated that a GLRO would not be required to hold a license with the NRC. The commenter also added that GLROs should be subject to similar medical evaluations and standards to other commercial nuclear licensed operators (NYS2-0013).

NRC Response: The NRC disagrees with the comment.

GLROs are licensed to perform duties under the provisions of a general license embedded in the general licensing process covered in 10 CFR 53.805 through 10 CFR 53.820, specifically 10 CFR 53.810. Therefore, GLROs are required to hold a license with the NRC, but that license would not be specifically issued via an application and license letter from the NRC.

Facilities licensed under 10 CFR 53.800 as SRMFs are required to report annually to the NRC the names of the GLROs at their facility in accordance with 10 CFR 53.805(a)(5). The GLROs would not need to have a comparable medical requirement to licensed operators at other commercial nuclear facilities because GLROs are not expected to have a role in the fulfillment of safety functions at an SRMF; licensed operators at other commercial nuclear facilities have roles that include the fulfillment of safety functions, thereby requiring more stringent medical requirements. By satisfying the criteria in 10 CFR 53.800, an SRMF establishes that GLROs will have minimal safety impact on the SRMF. The minimal safety impact warrants less oversight by the NRC.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.AA: A commenter wrote that 10 CFR 53.740 bases its staffing requirements on licensee specific staffing plans. The commenter wrote that these provisions are ambiguous and will “negatively impact state and public stakeholders and their ability to understand the current licensing basis (CLB) or participate in the 10 CFR 2.206 process.” The commenter added that the NRC should provide a more clear and structured process to allow for involvement of State regulators and stakeholders (NYS2-0007).

NRC Response: The NRC disagrees with the comment.

The NRC acknowledges that 10 CFR Part 53 is much less prescriptive than the traditional regulatory framework implemented by regulations such as 10 CFR Parts 50, 52, and 55. The 10 CFR Part 53 framework needs to be less prescriptive and more risk-informed and performance-based to accommodate a wide variety of possible reactor technologies and designs, consistent with the statutory direction in NEIMA. The variety of reactor technologies and designs will likewise lead to significant differences in approved staffing plans under 10 CFR 53.740(b) and other licensing basis information. Although the specific licensing basis information, including approved staffing plans, is expected to vary from facility to facility, the organization of the information will be similar and will be publicly available in each facility’s licensing basis to facilitate the involvement of State regulators and stakeholders.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.1.BB: A commenter recommended that the NRC eliminate most of the specifically licensed operator requirements in the proposed rule and instead reference existing regulations in 10 CFR Part 55. To accomplish this, the commenter recommended that the NRC adopt the edits to Subpart F that were included in Commissioner Caputo's vote on the proposed rulemaking.

The commenter wrote that this would allow companies with facilities licensed under 10 CFR Part 50 or 10 CFR Part 52 to continue using their established programs if they elect to license a new facility under 10 CFR Part 53. Otherwise, the commenter stated that companies would need to implement changes to existing documents and other processes. For new operating companies intending to seek a license under 10 CFR Part 53, the commenter stated there would be less of an administrative burden associated with the duplicated requirements since these companies would not be expected to have existing licensed operator infrastructure; however, by continuing to adopt the existing 10 CFR Part 55 licensed operator regulations, new operating companies would benefit from decades of experience, guidance, and other documentation (SHP-0004).

NRC Response: The NRC disagrees with the comment.

The current regulations for the licensing of operators in 10 CFR Part 55 are prescriptive and based on safety considerations for reactors designed under 10 CFR Parts 50 and 52; they do not provide for efficiencies that could be gained based on advanced reactor designs.

The requirements for specifically licensed operators under 10 CFR Part 53 are not identical to those in 10 CFR Part 55. For example, an allowance is made under 10 CFR Part 53 for facilities to administer and grade the initial licensing examination. This allowance is a gain in efficiency over 10 CFR Part 55, which requires the NRC to administer and grade all initial licensing examinations, adding regulatory burden and resource requirements in scheduling the examinations. Other efficiencies include the ability to determine the minimum number of reactivity manipulations required, a more streamlined training and examination program, more flexibility in the type of test instruments used in the examination program, and flexibilities in maintenance or re-establishment of proficiency. All of these efficiency gains would be lost if 10 CFR Part 53 referred to the current 10 CFR Part 55 requirements, leading to significant costs over the life of the facility.

Regarding the commenter's concern about needing to make changes between one facility licensed under 10 CFR Part 50 or 52 (and therefore licensing operators under 10 CFR Part 55) and another facility licensed under 10 CFR Part 53, operator licensing under 10 CFR Part 53 is designed to accommodate a program developed under 10 CFR Part 55. In other words, if the facility licensee wants to maintain the prescriptive requirements under 10 CFR Part 55 (such as having the NRC administer and grade examinations, using NUREG-1021 for development of examinations, requiring at least five reactivity control manipulations, etc.), these can be maintained under 10 CFR Part 53. Programs approved under 10 CFR Part 55, such as a Commission-approved training program, would also meet the requirements for Commission approval under 10 CFR Part 53. Regarding examinations, the NUREG-1021 process under 10 CFR Part 55 would be considered a Commission-approved examination program under 10 CFR Part 53. The programs would not be required to be changed unless the facility licensee wished to gain the efficiencies inherent within Part 53. This would allow the facility to benefit from the experience, guidance, and other documentation based on the 10 CFR Part 55 operator licensing process.

The NRC sees benefit in providing flexibility to allow facilities to determine the appropriate programmatic requirements for their respective reactor design using risk insights without requiring all facilities to follow the requirements of 10 CFR Part 55.

Accordingly, the NRC did not change the rule language in response to this comment

3.6.2.2. RFC: Allowing GLROs to manipulate facility controls

Comment Bin 3.6.2.2.A: A commenter expressed support for NRC's proposed requirements to allow the manipulation of the controls of certain facilities by GLROs in lieu of specifically licensed ROs and SROs. The commenter said that if a plant meets criteria specified in 10 CFR 53.800(a)(1)-(5), then there are no required operator actions or credible human errors that would impact the safe operation of the plant.

The commenter also said that guidance should be provided on what meets defense-in-depth criteria under 10 CFR 53.800(a)(5) and recommended that NRC should require a time frame of seven days with no operator intervention needed as the first layer of defense in depth as the advanced reactors are less complex, have improved HSI, and significantly more time for accident sequences to progress without risk of core damage. The commenter stated that without timing in guidance, few plants will meet an unbounded criteria. The commenter also said that the criteria for being a self-reliant mitigation facility are not time bound with respect to human interaction, and that historically mission times for systems were 7 days or less with some out to 14 days.

The commenter added that if defense in depth has a clear time-based limit defined either by the NRC or by the licensee, such that actions taken after that would be additional positive actions to keep the plant in a safe condition, then more plants could take advantage of the GLRO. The commenter supported the concept of a time requirement for defense-in-depth criteria and proposed a time of 72 hours (NEI2-0197, NEI2-0198, NEI2-0245).

Another commenter wrote that they support the introduction of GLROs and added that they envision an operating paradigm where a non-licensed individual may command nominal "states" or "modes" for reactor operation. The commenter added this would be possible as non-licensed individuals would not require the same level of training and expertise as licensed operators given they would not be directly manipulating controls or power levels, would not be required to use information about the operating state of the reactor to make decisions, and would not execute safety-affecting actions (RAD-0011).

NRC Response: The NRC agrees, in part, with the comments.

The intent of the criteria defining the "self-reliant mitigation facility" class is to ensure that human actions are not relied upon for safety for this class of facility. Any use of a time limit for those actions would be dependent upon the specific design of the facility and therefore would not be technology-inclusive. The intent of 10 CFR 53.800(a)(5) is to ensure that the facility design can achieve a defined end state per 10 CFR 53.450(e)(3) with no credited human actions. After this point, any additional human action would be beyond the intent of the design criteria of 10 CFR 53.800. A prescriptive, arbitrary time limit that does not show that this defined end state is reached without reliance on human action would not meet the intent of this criteria. The NRC did change the rule language to ensure that there are no important human actions needed to meet the requirements of 10 CFR 53.250 in response to Comment Bin 3.6.2.1.Q.

Regarding the comment about an operating paradigm where non-licensed individuals may command nominal "states" or "modes" for reactor operation, that may be permissible provided that those operators are not operating apparatus or mechanisms that would meet the definition of controls as defined in 10 CFR 53.725(c) and provided that any actions that may impact reactivity are performed only when plant conditions are monitored by a licensed operator as required under 10 CFR 53.740(e).

Accordingly, the NRC did not change the rule language in response to these comments.

3.6.2.3. RFC: Criteria for GLRO staffing at self-reliant-mitigation facilities

Comment Bin 3.6.2.3.A: A commenter wrote that 10 CFR 53.730(b)(7)(ii) allows GLROs for SRMFs the ability to immediately initiate a reactor shutdown from their location; however, the commenter wrote this is not the case under 10 CFR 53.805(a)(1)(v) for interaction-dependent mitigation facilities, which would be staffed by SROs and ROs. The commenter wrote that the proposed rule does not prescribe a location where SROs and ROs must be located, and, therefore, they could potentially be located offsite. The commenter added that since HFE requirements in 10 CFR 53.730(a) focus on the fulfilment of safety functions, it is possible that, if the reactivity/heat production safety function were adequately addressed without need for human action, it may be possible to exclude the ability to immediately initiate a plant shutdown from the scope of HFE design work. The commenter wrote that, as a result, a similar requirement should be added to 10 CFR 53.730(b) to ensure the ability for a licensed operator to immediately initiate a reactor shutdown (JSE-0002).

NRC Response: The NRC agrees with the comment.

Accordingly, the NRC has revised the rule language in 10 CFR 53.730(b) to require that licensed operators have the capability of initiating an immediate reactor shutdown at their location for both interaction-dependent and self-reliant mitigation facilities.

Comment Bin 3.6.2.3.B: With regard to 10 CFR 53.800, a commenter asked if the rule language implies that all events require some kind of human action unless the system is fully automated and asked what is considered “acceptable event mitigation” (RD-0025).

NRC Response: The NRC acknowledges the comment.

The rule language does not imply that all events for a facility require some kind of human action unless that facility is fully automated. A facility may be designed to rely upon features such as inherent characteristics like heat transfer through a medium or automated systems to achieve the desired safety outcomes without reliance on human action. While operation of a facility may require human actions, a self-reliant mitigation facility cannot rely on those human actions to mitigate events or meet safety functions and must meet the requirements of 10 CFR 53.800(a)(5). Whether these criteria are met through automation, inherent design characteristics, or another method is left to an applicant to determine.

Regarding what is considered “acceptable event mitigation” for a self-reliant mitigation facility, this is achieved in part when analysis of the facility’s design-basis accidents demonstrates that the dose limits of 10 CFR 53.210 would not be exceeded without reliance on human action. Additionally, acceptable event mitigation is described by the requirements of 10 CFR 53.800(a)(1), (2), and (4) as it relates to LBEs other than DBAs.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.3.C: A commenter said that 10 CFR 53.800(a) appears to have a lot of “give and take” to show all requirements will be met. The commenter said that paragraph (a)(4) is the only paragraph that describes how compliance may be achieved and suggested this paragraph should be moved to guidance (NEI2-0094).

Regarding 10 CFR 53.800(a), a commenter asked what is the acceptable level of diversity and redundancy in any and all safety systems, emergency actions, and on-site and off-site resources, and how it is determined given that PRA has limited capabilities and scenarios are incomplete (RD-0027).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees that the 10 CFR Part 53 regulatory framework allows applicants flexibility in determining how to meet various requirements. However, the NRC disagrees that 10 CFR 53.800(a)(4) should be moved to guidance because it is used as a criterion for defining a new class of facility. Because 10 CFR Part 53 was developed to be technology-inclusive and is expected to be used for a wide variety of designs, an applicant’s evaluation of the adequacy of their design’s defense in depth, including whether a PRA or other systematic risk evaluation may have been used to inform that evaluation may differ significantly from one application to another. As such, NRC determinations of the acceptability of an applicant’s defense-in-depth evaluation will likewise need to be made on an application-specific basis.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.6.2.3.D: A commenter said that 10 CFR 53.815(e) appears to be a copy and paste of 10 CFR 53.780(e) and suggested that the NRC consolidate requirements applicable to both interaction dependent and self-reliant facilities into a separate section (NEI2-0104).

NRC Response: The NRC disagrees with the comment.

There are subtle differences between the two sections to account for the differences between simulator usage for specifically licensed operators under 10 CFR 53.780(e) and GLROs under 10 CFR 53.815(e). For example, 10 CFR 53.780(e) addresses simulators that will be used to administer examinations, train operators, and comply with experience requirements. Although 10 CFR 53.815(e) also addresses simulators used for training and examinations, it addresses maintaining proficiency, as well. Specifically licensed operators cannot use the simulator to maintain proficiency whereas generally licensed reactor operators can. Another difference is when results of uncorrected performance test failures are made available for NRC review. In 10 CFR 53.780(e), the results are made available to the NRC for review prior to or concurrent with each initial examination or requalification examination. In contrast, in 10 CFR 53.815(e)(2)(iv), the results are made available to the NRC for review at the time of an NRC inspection. Finally, 10 CFR 53.780(e)(4) requires compliance with paragraphs (e)(2) and (e)(3) of the same section in order for the NRC to accept the facility for initial examinations, requalification examinations, and performing control manipulations. This same requirement does not exist under 10 CFR 53.815(e).

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.3.E: A commenter wrote that there does not appear to be significant reduction in the administrative burden for GLROs compared to SROs and ROs, and unless there is more clarity it is unclear why additional effort would be expended to make a change (NEI2-0244).

NRC Response: The NRC disagrees with the comment.

There are multiple reductions in burden, both administrative and otherwise, for GLROs as compared to specifically licensed SROs and ROs. For example, there is no explicit medical requirement for GLROs as there is for SROs and ROs, thus saving the burden of having a medical review officer, getting physicals, tracking compliance, and completing and submitting the associated forms. Another example is that GLROs do not need to fill out an initial application or renewals. Relatedly, there is no need for the facility to have a tracking mechanism for when the licenses expire to ensure that renewal is timely pursued. Although the facility does need to provide a list of GLROs to the NRC each year, it is not required to notify the NRC when a GLRO no longer requires a license due to taking another position or leaving the facility. In addition, examinations for GLROs do not require prior NRC review and approval for administration as examinations for SROs and ROs do. This decreases the burden on the facility and provides greater flexibility in the scheduling of examinations. Potential reductions and their associated cost benefits were quantified as part of the regulatory analysis for this rule. The regulatory analysis for the proposed rule quantified approximately two million dollars in savings for a facility with GLROs as opposed to SROs/ROs.

Accordingly, the NRC did not change the rule language in response to this comment.

3.6.2.4. <u>RFC: Medical requirements for GLROs</u>

Comment Bin 3.6.2.4.A: A commenter said that it is reasonable to not require medical requirements through regulation. The commenter also said that the GLROs should be subject to the same requirements as the remaining plant personnel, who are not subject to the additional medical requirements, and the general fitness-for-duty (FFD) requirements should be sufficient to address the FFD of a GLRO (NEI2-0199).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that GLROs should not be subjected to additional medical requirements, and 10 CFR Part 53 does not impose medical requirements on GLROs. However, the NRC disagrees that 10 CFR Part 26 requirements alone are sufficient for GLROs, especially since there are no additional medical requirements imposed on GLROs in 10 CFR Part 53.

Even though GLROs do not have a role in the fulfillment of safety functions at SRMFs, GLROs manipulate the controls at SRMFs. Therefore, GLROs must not only meet the same FFD requirements that other plant personnel are required to meet under 10 CFR Part 26, but they must also meet additional FFD requirements as outlined in 10 CFR 53.810(d) and (f) to ensure that they are able to safely and competently perform licensed duties.

Accordingly, the NRC did not change the rule language in response to this comment.

3.6.2.5. RFC: Onshift engineering experience

Comment Bin 3.6.2.5.A: A commenter wrote that the nuclear industry and new designs have progressed to the point that the Shift Technical Advisor position could be eliminated, and the rule should offer a path to do so through training programs and human system interface design.

The commenter expressed agreement with broadening engineering expertise but disagreed with the phrasing that suggests or requires that expertise be continuously on-shift. The commenter said that recent light-water reactor precedent suggests that it is not required due to reduced reliance on operator actions, results of task analysis and validation activities, and industry upgrades to qualifications of operators. The commenter suggested that engineering expertise as a support function be available to assist operations remotely.

The commenter also disagreed with the proposed requirement that engineering expertise can only be acquired by a qualifying four-year degree. The commenter said that many components of the training upgrades that were implemented due to the Three Mile Island action plan provide a better foundation for critical thinking in a nuclear power plant and added that the NRC should not require a four-year degree (NEI2-0200).

NRC Response: The NRC disagrees with the comment.

The NRC disagrees that 10 CFR 53.730(f)(1) requires engineering expertise to be continuously on-shift. The requirement is that engineering expertise must be available to the on-shift operators.

The staffing plan requirement in 10 CFR 53.730(f) is a performance-based staffing requirement which allows, in part, an applicant to propose how it will meet the requirement for engineering expertise to be available to the on-shift personnel. The approach results in a staffing plan that is appropriate for the facility’s design, concept of operations, and workload levels for licensed operators. DRO-ISG-2023-02 contains guidance for the staff to use in the review of how an application satisfies the requirement for engineering expertise. This includes information about reviewing the location of and the response time for a person fulfilling this position. The NRC does not intend this requirement to mean that the engineering expertise must be fulfilled by a dedicated member of the on-shift crew like that of the Shift Technical Advisor for 10 CFR Part 50 or 52 facilities. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC acknowledges that there is precedent for the elimination of the Shift Technical Advisor position as explained in SECY 21-0039, “Elimination of the STA for the NuScale Design.” However, the requirement for engineering expertise in 10 CFR 53.730(f)(1) is not equivalent to the Shift Technical Advisor position at large-light-water reactors. As explained in NUREG-0737, the original purpose of the Shift Technical Advisor, in the aftermath of the accident at Three Mile Island Unit 2, was to improve the ability of the on-shift operating crew to recognize, diagnose, and effectively respond to plant transients and abnormal conditions. With an increased reliance on automation and passive safety features, the staff expects that reactors licensed under 10 CFR Part 53 will have very few (if any) risk-significant operator actions during plant transients and abnormal events. The purpose of the engineering expertise requirement is for a qualified person to provide on-shift operators technical support if a situation arises that is not covered by operator training or operating procedures. Accordingly, the NRC added clarifying information to section 1.4 of DRO-ISG-2023-02 in response to this comment.

The NRC disagrees with the commenter's recommendation to remove the four-year degree requirement for the engineering expertise role. The engineering expertise requirement is based on Commission policy located in "Education for Senior Reactor Operators and Shift Supervisors at Nuclear Power Plants" (published in the *Federal Register* (54 FR 33639) on August 15, 1989), in which the Commission acknowledged the potential for situations to arise that are not covered through training or operating procedures and stated that there is "a need for some individuals on each nuclear power plant operating shift who have an innate understanding of the systems-level performance of a nuclear power plant" and "knowledge of scientific and engineering fundamentals and the basic scientific principles that govern the behavior of electrical, mechanical and other engineering systems." The policy statement explains that this kind of knowledge is acquired from an academic degree program in a technical discipline and that individuals with technical degrees can utilize their in-depth knowledge when called upon to assess the causes of a novel incident and determine the appropriate response. Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.2.5.B: A commenter said that guidance should provide clarity on the meaning of "be available to the on-shift personnel" in 10 CFR 53.730(f)(1). The commenter also suggested that NRC provide a clarifying statement that allows or requires flexibility for what time frame "engineering expertise" is required, and whether that time frame is based on accident progression timelines specific to the design (NEI2-0075). Another commenter expressed support for this comment (NEX-0028).

NRC Response: The NRC agrees with the comments.

As stated in the proposed and final rules, 10 CFR Part 53 includes provisions to address staffing, training, personnel qualifications, and HFE in a manner that is risk-informed, technology-inclusive, performance-based, and flexible in nature. The staffing plan requirement in 10 CFR 53.730(f) is a performance-based staffing requirement which, in part, allows an applicant to propose how it will meet the requirement for engineering expertise to be available to the on-shift personnel. The approach results in a staffing plan that is appropriate for the facility's design, concept of operations, and workload levels for licensed operators.

The NRC will review staffing plan submittals using the guidance in DRO-ISG-2023-02, which contains a performance-based process for determining an adequate number of control operators. In reviewing DRO-ISG-2023-02, the NRC also agrees that additional clarity is needed in this guidance regarding the response time.

Accordingly, the NRC revised the review criteria for staffing plan submittals in section 1.3 of DRO-ISG-2023-02 in response to these comments to explain that, for the engineering expertise role, response time means:

- If located off-site, this is the time it takes personnel fulfilling the engineering expertise requirement to answer a request for technical assistance; or

- If located on site, this is the time it takes personnel fulfilling the engineering expertise requirement to arrive at the location of the on-shift operating personnel to provide technical assistance.

3.6.2.6. RFC: Use of simulation facilities as HFE testbeds

Comment Bin 3.6.2.6.A: The proposed 10 CFR Part 53 rulemaking solicited feedback on how to address the use of simulation facilities as HFE testbeds and whether this should be established in regulations or addressed in guidance. In response to this request for comment, a commenter stated that the use of simulation facilities as HFE testbeds should be addressed in guidance instead of regulation as methods change and improve over time (NEI2-0201).

NRC Response: The NRC agrees with the comment.

The NRC had envisioned that the use of simulation facilities as HFE testbeds should be addressed in guidance. The NRC plans to develop future guidance regarding the use of simulation facilities as HFE testbeds.

Accordingly, the NRC did not change the rule language in response to this comment.

3.6.3. Programmatic requirements (§§ 53.845-53.910)

3.6.3.1. Graded approach to emergency preparedness (§§ 53.855) and security programs (§§ 53.860(a)) and protection against DBT of radiological sabotage, including RFCs on scenarios that might arise, need for additional rule language or guidance, and EPZ sizing

Comment Bin 3.6.3.1.A: A commenter wrote that 10 CFR 53.855 does not appear to require any actual funded emergency response organization. In 10 CFR 53.860(a)(2)(ii), the commenter recommended changing “permanent removal of fuel from the reactor vessel” to “permanent removal of fuel from the reactor vessel site” (TG11-0001).

NRC Response: The NRC believes the comment intended to reference offsite emergency response organizations when referring to emergency response organizations. The NRC agrees that 10 CFR 53.855 does not require NRC licensees to fund offsite emergency response organizations. Funding of offsite emergency preparedness is outside the NRC’s regulatory purview. Any such activities would result from an arrangement between the licensee and State and local authorities. Communities that have one or more commercial interests that pose risk to the public (e.g., fires, gas leaks) have developed emergency plans to maintain the safety of the public. Comprehensive Preparedness Guide 101, “Developing and Maintaining Emergency Operations Plans,” issued November 2010, provides the tools and guidance to develop all-hazards emergency response plans with funding typically provided from Federal Emergency Management Agency (FEMA) Stafford Act funding, local taxes, or both.

Regarding the suggested change to proposed 10 CFR 53.860(a)(2)(ii), the NRC has removed proposed 10 CFR 53.860(a)(2)(i) and (ii) from the final rule. See the NRC’s response to Comment Bin 3.6.3.3.C.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.3.1.B: A commenter stated that emergency response to significant catastrophic events is far beyond the capabilities, procedures, understanding, and abilities of any one owner, operator, or State and should recognize the need for coordinated and comprehensive action at the national level. The commenter wrote that proposed emergency response regulations are not sufficient because “defenses, barriers, protocols” can become overwhelmed. The commenter argued that in an emergency, the real issue is to define who holds decision-making power and what resources can be brought to control the situation. The commenter wrote that this calls for integrated technical responses with transparent decision-making, communication, and command structure. The commenter said that risk-informed decision-making can help in defining and analyzing relative risk and promoting effective actions. The commenter recommended revising emergency planning requirements so that there is a coherent national response plan that involves all government bodies and national resources. The commenter referenced several emergency planning requirements in the proposed rule without proposing specific changes to the requirements. The commenter recommended that the response plan should have a situation room and central national emergency facility staffed by the NRC and other key governmental bodies like the Department of Defense, Department of Homeland Security, and FEMA (RD-0015).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that a significant nuclear reactor event could quickly become a national event exceeding the capabilities of a licensee. However, the NRC disagrees that emergency planning requirements should be revised to include a coherent national response plan involving government bodies, national resources, a situation room, and a central national emergency facility staffed by the NRC and other key governmental bodies like the Department of Defense, Department of Homeland Security, and FEMA.

The commenter’s concerns are addressed in the Federal Government’s National Preparedness System (NPS). The NPS was created to develop a scalable Federal emergency response that provides a means to make available additional resources in support of State and local emergency response if they become overwhelmed. The NPS is supported by the national response framework (NRF) established by Presidential Policy Directive 8, “National Preparedness,” dated March 30, 2011. The NRF is designed to be scalable and manage the consequences of incidents at the lowest possible, State, Tribal, or local level response. The NRF is supported by Federal Interagency Operational Plans (FIOPs). FIOPs describe how the Federal Government aligns resources and delivers core capabilities. FIOPs are supported by incident annexes, one of which is the nuclear/radiological incidents annex (NRIA). The “Nuclear Radiological Incident Annex to the Response and Recovery Federal Interagency Operational Plan,” issued May 2023, describes the policies, situations, concepts of operations, and responsibilities of key Federal radiological resources and assets governing the early, immediate, and late phases of response for incidents involving the release of radioactive materials. FIOPs describe the Federal response and support as incidents change in size, scope, and complexity.

For incidents involving fixed nuclear/radiological facilities, the NRIA describes State and local governments as having primary responsibility for protecting life, property, and the environment for the areas surrounding the nuclear/radiological incident site. State, Tribal, and local governments may then request assistance from FEMA, other Federal agencies, and/or State governments with which they have existing arrangements or relationships.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.3.1.C: Two commenters wrote that the NRC should provide additional guidance as needed on applying graded emergency planning and security approaches, and that this would balance regulatory flexibility in the rule language while providing applicants clarity. The commenters added that new or updated guidance should account for varying reactor technologies, deployment models, and security risks while maintaining a predictable and transparent regulatory framework. Additionally, security events, up to the DBT, should be considered relative to protective actions for risk insights and defense in depth (SCWG-0004, BI1-0023). Another commenter echoed these concerns, writing that the NRC should establish clear rule language and guidance on addressing interactions between the graded approaches for emergency planning and security programs (USNIC2-0032).

One of the commenters added that revisions should be made to guidance to clarify that the spectrum of events should be categorized to potential offsite impacts and evaluated against protective actions as appropriate. Additionally, the commenter wrote that the NRC should clarify that the existence of sequences that have the potential for offsite consequences is not a direct indicator that a reduced-size EPZ is not appropriate (SCWG-0004).

One of the commenters recommended rule language and guidance revisions with the following approach: 1) for an EPZ sizing analysis, the potential consequences from security events, including those involving the DBT, are adequately bounded if the licensee meets the regulatory requirements to protect against the DBT found in 10 CFR Part 73; and 2) when a licensee does not need to protect against the DBT of radiological sabotage, then the potential consequences from security events up to and including the DBT should be assessed as part of the EPZ sizing analysis. The commenter said that the determination of the EPZ boundary location would consider the offsite doses resulting from analyzed security events and whether predetermined, prompt protective measures are necessary (NEI2-0202, NEI2-0203). Another commenter expressed support for this comment (NEX-0016).

In response to the NRC's request for comment on the treatment of security-related events in emergency planning, a commenter wrote that they supported a version of the second scenario that reflects a risk-informed and performance-based EPZ size determination. The commenter added that security events will need a consequence analysis consistent with the target set determination guidance given in the draft RG 5.81, "Target Set Identification and Development for Nuclear Power Reactors," Revision 2, and the values for offsite doses can be compared to values used for the EPZ size determination to determine if they are bounded by that analysis. Finally, the commenter said that if values are not bounded by the EPZ determination, then considerations for the DBT-initiated events should be considered in emergency planning (IDNL-0008).

Another commenter wrote that they oppose any provision that would allow nuclear power plants to be exempt from the requirement to protect against the DBT of radiological sabotage. The commenter wrote that it is unlikely that any reactor will meet the requirements in 10 CFR 53.860(a)(2)(i), but the commenter expressed concern that the NRC will "succumb to political pressure" and accept non-credible analyses. The commenter added that it is also critical that radiological sabotage scenarios be considered in the EPZ size determination, as radiological release scenarios that would warrant maintaining or expanding the current 10-mile EPZ may be possible as the result of sabotage events even though they may be screened out of the accident spectrum used for the EPZ determination (UCS-0012).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees with the comment concerning establishing clear rule language and guidance on addressing interactions between the graded approaches for emergency planning and security programs. As described in the proposed rule section VI, “Specific Requests for Comments” (10 CFR Part 53, Subpart F—Emergency Preparedness and Security Programs, 89 FR 86985), the NRC is planning to issue a draft revision of RG 1.242, “Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities,” issued November 2023 (ML23226A036) for public comment. The NRC plans to issue this draft revision after the publication of the 10 CFR Part 53 final rule. The planned revision to RG 1.242 will add guidance for 10 CFR Part 53 applicants and licensees to address interactions between graded approaches for emergency planning and security programs. The NRC’s guidance already suggests that licensees categorize the spectrum of events to potential offsite impacts and evaluate the events against protective actions as appropriate. The NRC will consider if additional guidance is necessary.

The NRC disagrees with the comment concerning EPZ sizing analysis. The NRC disagrees with the strict statement that the potential consequences from security events, including those involving the DBT, are adequately bounded if the licensee meets the regulatory requirements to protect against the DBT found in 10 CFR Part 73. An applicant will need to document an evaluation demonstrating that the security events are bounded. The NRC agrees that meeting the DBT requirements found in 10 CFR Part 73 can inform and support an evaluation. The NRC agrees with the comment that the determination of the EPZ boundary location would consider the offsite doses resulting from analyzed security events and whether predetermined, prompt protective measures are necessary.

The NRC agrees that the existence of sequences with the potential for offsite consequences is not a direct indicator that a reduced-size EPZ is not appropriate. The requirements described in 10 CFR 50.33(g)(2) require applicants complying with 10 CFR 50.160 to submit as part of the application the analysis used to determine whether the criteria in 10 CFR 50.33(g)(2)(i)(A) and (B) are met and, if met, the size of the plume exposure pathway EPZ. The criteria in 10 CFR 50.33(g)(2)(i)(A) and (B) are that the plume exposure pathway EPZ is the area within which public dose is projected to exceed 10 millisieverts (mSv) (1 rem) TEDE over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology; and predetermined, prompt protective measures are necessary.

The NRC disagrees with the opposition to any provision that would allow nuclear power plants to be exempt from the requirement to protect against the DBT of radiological sabotage. The NRC has deleted 10 CFR 53.860(a)(2)(i) from the rule language (see the NRC’s response and rule language revisions in response to Comment Bin 3.6.3.3.C). Instead, in this final rule the NRC has provided a graded approach that allows licensees to be exempt from certain physical security requirements in 10 CFR 73.100 (see the NRC’s response and rule language revisions in response to Comment Bin 5.1.B). Under 10 CFR 73.100(a)(1)(i), a licensee is exempt from requirements for defense against the DBT only if it demonstrates that it has no achievable target sets and does not rely on any active measures (e.g., operator action, mitigative action, detection, assessment, armed response) to prevent a significant release of radionuclides.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.6.3.1.D: A commenter wrote that the NRC needs to provide further guidance on what the site-specific analysis identified in 10 CFR 53.4330(a)(2)(i) and (ii) would entail and how an applicant would fulfill this requirement. The commenter asked the following questions (AN5-0005):

- Can a current licensee of a large-LWR meet this requirement?
- Has that analysis been done to ensure regulations are equivalent across the fleet, no matter the licensing vehicle that is chosen?
- Why not apply the same requirements as the current research and test reactor fleet (i.e., 10 CFR 73.60(f))?
- What is the correlation between 2 megawatt thermal and the 25 rem dose limit?
- What is the defense in depth applied to those types of reactors?
- Can a lower dose rate be applied to allow for reduced security requirements that would be more in line with current research and test reactor security requirements (i.e., 5 rem vs 10 rem vs 15 rem vs 20 rem)?
- What is the basis for using 25 rem to allow alternative security requirements?

NRC Response: The NRC disagrees with this comment.

While 10 CFR 53.4330 was not part of the 10 CFR Part 53 proposed rule as published (89 FR 86918), it was included as part of the Part 53 draft proposed rule in SECY-23-0021, Enclosure 1, and was the Framework B equivalent to 10 CFR 53.860 in the proposed rule as published.

Regarding the questions, which the NRC understands to apply to 10 CFR 53.860(a)(2)(i) and (ii), the NRC has removed these requirements from the final rule in response to Comment Bin 3.6.3.3.C and therefore will not be providing additional guidance on these requirements.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.3.1.E: In response to the agency's request for comment on a graded approach to emergency preparedness and security programs, two commenters provided several pieces of feedback and recommendations. The commenters wrote that the requirements in 10 CFR 50.160(c)(2) are not sufficiently technology-inclusive to meet the mandate of NEIMA as it does not provide sufficient flexibility for reactors that may be mobile or redeployable. The commenters wrote that the use of "initial" in 10 CFR 50.160 may be overly limiting for reactors that could operate in more than one location. The commenters wrote that the NRC has historically considered fuel loading as the point of commercial operation, which does not align with advanced reactor deployment models. The commenters argued that for transportable microreactors, commercial operation should be defined as the generation of electricity, process heat, or other usable energy at the intended deployment site, not at the point of initial fueling.

The commenters continued that security events are not part of the design basis licensing, and significant security events should be considered relative to protective actions for risk insights and defense in depth. The commenters added that the NRC already approved bounding events in the "Regulatory Improvements for Production and Utilization Facilities Transitioning to

Decommissioning; Proposed Rule" (87 FR 12254; March 3, 2022) that exceed a 1 rem threshold with a site boundary emergency planning zone.

The commenters recommended the following changes (BI1-0008, SCWG-0003):

- Modify 10 CFR 50.160 and 10 CFR 53.855 to be technology-inclusive and enable mobile reactors.
- Revise existing guidance to clarify how uncertainty should be considered for risk-informed decision-making.
- Provide further clarity that 1 rem is not a strict threshold, and the spectrum of events, along with protective actions, should be considered to determine appropriate emergency preparedness.

NRC Response: The NRC agrees, in part, with the comments.

The NRC disagrees with modifying 10 CFR 50.160 and 10 CFR 53.855 to enable mobile reactors. The requirements in 10 CFR 50.160 and 10 CFR 53.855 are already technology-inclusive. In addition, consistent with the ADVANCE Act and EOs issued in 2025, the NRC has initiated development of an additional rulemaking to expedite licensing of qualified microreactors and other potentially low-risk, low-consequence reactors.

The NRC disagrees with revising existing guidance related to risk-informed decision-making. The NRC has a long-standing history of using risk-informed decision-making as demonstrated in NUREG-0396, "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants," issued December 1978 (ML051390356). NUREG-0396 describes a planning basis as a very large range of possible accidents starting with a zero point of requiring no planning at all because significant offsite radiological accident consequences are unlikely to occur, to planning for the worst physically possible accident regardless of its extremely low likelihood. As an alternative to attempting to define a specific accident sequence (i.e., a risk-based approach), the NRC decided to identify the bounds of the parameters for which planning is recommended (i.e., a risk-informed approach) based upon a knowledge of the potential consequences, timing, and release characteristics of a spectrum of accidents.

The NRC agrees that the existence of sequences that have the potential for offsite consequences is not a direct indicator that a reduced-size EPZ is not appropriate and a reduced-size EPZ is based on risk insights and the potential for protective actions to mitigate consequences, not based on a strict dose threshold. However, the NRC disagrees with the need to add additional clarity. The requirements described in 10 CFR 50.33(g)(2) require applicants complying with 10 CFR 50.160 to submit as part of the application the analysis used to determine whether the criteria in 10 CFR 50.33(g)(2)(i)(A) and (B) are met and, if met, the size of the plume exposure pathway EPZ. The criteria in 10 CFR 50.33(g)(2)(i)(A) and (B) include: whether projected public dose would exceed 10 mSv (1 rem) TEDE over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology; and whether predetermined, prompt protective measures would be necessary. Each of these criteria is considered holistically; none of them would be a "strict limit."

The NRC disagrees that the NRC has approved bounding events in the "Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning" proposed rule. That proposed rule was only a proposal on which the public was asked to comment. The NRC has not issued a final rule in that proceeding, so the proposal is still pending.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.6.3.1.F: A commenter wrote that scalable EPZs included in the proposed rule will lead to reduced offsite emergency planning requirements for certain advanced reactors, based on their risk profile and safety features. Specifically, the commenter argued this will result in no mechanisms to ensure that off-site personnel will have sufficient knowledge and training to support activities on site when needed. The commenter added that the NRC has indicated that typical emergency response functions from offsite response organizations will fulfill many of the licensing requirements for new types of reactors, but there can be issues using historical, non-radiological emergency protective actions as precursors to predict response readiness. Given a response agency's responsibilities and authority changes depending on the location and scenario, there remains a need to maintain working relationships between licensees and off-site response organizations. The commenter added that the NRC should not assume that responders and decision makers will be prepared to enact protective actions without significant prior coordination and training of staff.

The commenter added that it is unclear how the proposed approach would maintain adequate protection for health and safety if an EPZ does not extend beyond the site boundary and questioned whether FEMA could provide adequate protection, writing that the FEMA Radiological Emergency Preparedness Program Manual does not address program requirements for advanced reactors.

The commenter stated that the NRC needs to provide clear guidance on coordination between police, fire, state public health and environmental response agencies, and FEMA with regard to EPZ boundaries that do not extend beyond the site boundary. The commenter added that the NRC should ensure that local authorities are provided with sufficient site information to be able to effectively perform their required duties (NYS2-0021).

Another commenter wrote that the “need for emergency planning and a trained, exercised emergency response organization is being quietly ignored” and that there is no mention of training for responders or how to pay for such training. The commenter added that mobile response equipment might be needed and this is not discussed. Finally, the commenter added that it appears very high doses are required before “anyone is obligated to take action” (TG17-0003).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees that scalable EPZs allowed in 10 CFR 50.33(g)(2) will lead to appropriately reduced offsite emergency planning requirements for certain advanced reactors, based on their risk profile and safety features. The NRC disagrees this will result in no mechanisms to ensure that off-site personnel will have sufficient knowledge and training to support activities on site when needed. The NRC disagrees that neither FEMA nor local responders are prepared to handle radiological emergencies.

The Federal Government’s responses to various emergencies, including radiological emergencies, are described in the NRF (one of the five National Planning Frameworks constituting the NPS required by Presidential Policy Directive 8, “National Preparedness,” dated

March 30, 2011) (see the NRC's response to Comment Bin 3.6.3.1.B). FEMA's website at https://www.fema.gov/emergency-managers/national-preparedness contains more information on these topics. Additionally, applicants and licensees are subject to training and coordination requirements of either 10 CFR 50.47(b)(2), (14), (15) and Appendix E to Part 50, or 10 CFR 50.160(b)(1)(iii)(B)-(C) and 10 CFR 50.160(b)(1)(iv)(A)(*5*). The former set of regulations requires emergency declaration and notification capabilities, the conduct of periodic exercises and drills, evaluation of major portions of emergency response capabilities, development and maintenance of key skills, and the capability to identify and correct deficiencies in implementing the licensee's emergency plan. The latter set of regulations requires the capability to make protective action recommendations for offsite response organizations and communicate with response organizations that have emergency response responsibilities identified in the emergency plan, and the provision of site familiarization training for response organizations expected to respond to the site during an emergency.

The NRC disagrees that the NRC needs to provide clear guidance on coordination between police, fire, State public health and environmental response agencies, and FEMA with regard to EPZ boundaries that do not extend beyond the site boundary. The NRC does not have the authority to direct offsite response organization actions. Furthermore, NRC regulations do not impact FEMA responsibilities and authorities with regard to assisting State and local emergency planning.

The NRC agrees that local authorities should be provided with sufficient site information to be able to effectively perform their required duties. This is covered in the training and coordination requirements cited above.

The NRC understands that the comment concerning the need for emergency planning and a trained, exercised emergency response organization is in reference to offsite emergency responders. The NRC agrees that 10 CFR 53.855 does not require funding of offsite emergency response organizations (see the NRC's response to Comment Bin 3.6.3.1.A).

The NRC agrees that mobile response equipment might be needed. However, the NRC does not have the authority to determine what actions offsite response organizations should take or what equipment they should use or need.

The NRC disagrees that very high doses are required before "anyone is obligated to take action." Actions taken in response to radiological doses are based on the EPA PAG values. The EPA PAG values are guidance and only intended to assist public officials with their radiological emergency response planning activities. The EPA PAG values are established to ensure the risk of the amount of radiological exposure avoided is equal to or greater than the risk of the protective action taken.

Accordingly, the NRC did not revise the rule language in response to these comments.

Comment Bin 3.6.3.1.G: A commenter wrote that the proposed rule would benefit from a more performance-based focus with clear performance metrics beyond public dose consequence. The commenter said that this would be similar to the recently promulgated "Non-Power Production or Utilization Facility License Renewal; Final Rule" (89 FR 106234; December 30, 2024) (USNIC2-0009).

NRC Response: The NRC disagrees with the comment.

The overall construct of 10 CFR Part 53 is already performance-based with performance metrics generally either defined in Subpart B (e.g., the safety criteria in 10 CFR 53.210) or required to be proposed by applicants for NRC review and approval (e.g., the safety criteria in 10 CFR 53.220(b)). The other subparts in 10 CFR Part 53 refer to the performance metrics and provide a great deal of flexibility on how combinations of design features, human actions, and programmatic controls are used to satisfy the criteria. Other elements of performance-based approaches such as performance monitoring are specifically addressed for the operations phase of the plant life cycle in Subpart F to 10 CFR Part 53.

Accordingly, the NRC did not revise the rule language in response to this comment.

Comment Bin 3.6.3.1.H: A commenter wrote that referencing emergency preparedness requirements in 10 CFR Part 50 is intended to provide clarity, but there are multiple available EP approaches in 10 CFR Part 50. In addition, the emergency preparedness requirements in 10 CFR Part 50 and 10 CFR Part 52 are deterministic and applied as the last layer of defense in depth which may not be appropriate for a performance-based framework. The commenter wrote that an integrated performance-based and risk-informed approach should consider emergency preparedness protective actions relative to the spectrum of events to determine whether safety requirements are met (BI1-0032).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that the emergency preparedness requirements in 10 CFR Part 50 provide clarity on regulatory requirements. The NRC agrees that multiple approaches are identified in 10 CFR Parts 50 and 52. The NRC agrees that emergency preparedness is the last layer of defense-in-depth.

However, the NRC disagrees that emergency preparedness protective actions related to the spectrum of events should be considered in the determination of whether safety requirements are met. Only the State or local decisionmaker has the authority to determine and implement protective actions to protect the health and safety of the public. Without knowing whether a specific protective action would be implemented, it is not possible to know the protective action's effect on meeting a specific design requirement.

Accordingly, the NRC did not change the rule language in response to this comment.

3.6.3.2. <u>Other comments on emergency preparedness programs (§ 53.855)</u>

No comments are associated with this issue.

3.6.3.3. <u>Other comments on security programs (§ 53.860(b))</u>

Comment Bin 3.6.3.3.A: A commenter recommended that, when finalizing the security requirements in 10 CFR 53.860, 10 CFR Part 73, and associated guidance, the NRC should consider the topics and recommendations contained in NEI Proposal Paper, "Regulation of Rapid High-Volume Deployable Reactors in Remote Applications (RHDRA) and Other

Advanced Reactors," dated July 2024, and NRC Staff White Paper, "Nth-of-a-Kind Micro-Reactor Licensing and Deployment Considerations," issued September 2024 (ML24268A310) (NEI2-0110).

NRC Response: The NRC agrees, in part, with this comment.

The NRC has revised 10 CFR 53.860 in response to Comment Bin 3.6.3.3.C. In addition, consistent with the ADVANCE Act and EOs issued in 2025, the NRC has initiated development of an additional rulemaking to expedite licensing of qualified microreactors and other potentially low risk, low consequence reactors. This activity, along with other NRC guidance development activities, is intended to address topics such as those discussed in the documents referenced in the comment.

Accordingly, the NRC did not change the rule language in response to this comment beyond those changes described in response to Comment Bin 3.6.3.3.C.

Comment Bin 3.6.3.3.B: A commenter wrote that they are unsure how outside law enforcement would be able to promptly respond to an incident at an isolated SMR, and that these types of responses would be done on a "gratis basis" (TG17-0005).

NRC Response: The NRC acknowledges the comment.

As required by 10 CFR 73.100(b)(4)(iv)(A)(*1-5*), a licensee must meet specific requirements in order to rely entirely or partially on law enforcement or other offsite armed response. These requirements provide reasonable assurance that commercial power reactors, including SMRs, will have an adequate response available.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.3.3.C: A commenter said, with respect to the consequence analysis, the NRC should modify the requirements and guidance to allow an applicant or licensee to consider security-related design features in the consequence analysis required by 10 CFR 53.860(a)(2) when a sufficient technical basis for such consideration can be provided. As an example, the commenter said that an applicant or licensee could install features providing reasonable assurance of a reactor shutdown if a given event is detected, thus lowering the potential consequences from a security event to levels below that specified in 10 CFR 53.210(b). The commenter stated that for some security designs, the requirements and guidance for conducting the consequence analysis are too conservative and restrictive (NEI2-0109).

Another commenter wrote that the intention of the requirement in 10 CFR 53.860(a)(2) is unclear as it appears to require a bounding analysis representing a specific result of a design-basis threat attack but also requires the identification of target sets. The commenter said that the language does not allow for the full crediting of a reactor design and assumes the loss of design features that may be beyond adversary capabilities. The commenter added that 10 CFR 53.860(a)(2)(ii) specifically excludes mitigative and recovery actions by operators, but RG 5.81 has specific requirements for the crediting of operator actions in target sets. The commenter argued RG 5.81 would better inform the crediting of operator actions than the statement provided within the rule language and suggested that the NRC remove the language and address the crediting of operator and recovery actions through guidance. The commenter recommended revising 10 CFR 53.860(a)(2)(ii) to read as follows (IDNL-0007):

> The licensee must demonstrate compliance with the provisions set forth in either §§ 73.55 or 73.100 of this chapter, unless the licensee demonstrates compliance with the following criterion:
>
> (i) The radiological consequences from any design-basis threat-initiated event [Strikethrough: involving the loss of engineered systems for decay heat removal and possible breaches in physical structures surrounding the reactor, spent fuel, and other inventories of radioactive materials] result in offsite doses below the values in § 53.210.
>
> (ii) The applicant must perform a site specific analysis, including identification of target sets, to demonstrate that the criterion in § 53.860(a)(2)(i) is satisfied. [Strikethrough: The analysis must assume that licensee mitigation and recovery actions, including any operator actions, are unavailable or ineffective.] The licensee must maintain the analysis until the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070.

Regarding 10 CFR 53.860, a commenter asked what analysis had been done to provide reasonable assurance that “this event” would not occur. The commenter wrote that if you do not protect against an event, then the assumed outcome is that it will happen. The commenter wrote that further guidance is needed on the regulations that would be applicable to a license that satisfies the criterion in 10 CFR 53.860(a)(2)(i) (AN5-0004).

NRC Response: The NRC agrees, in part, with the comments.

The NRC has removed the proposed requirements in 10 CFR 53.860(a)(2)(i) and (ii), which would have required an unmitigated consequence analysis using the offsite dose reference values from 10 CFR 53.210 to demonstrate that the radiological sabotage DBT does not apply. Instead, the NRC relocated this analysis requirement to 10 CFR 73.100 and introduced a graded approach based on a general performance objective and the achievability of target sets. This approach allows licensees to implement a physical security program appropriate and sufficient to prevent a release of radionuclides from a security event based on the dose reference values in 10 CFR 53.210, with the option to credit active measures, such as reactor shutdown. In response to Comment Bin 5.1.B, the NRC added a performance objective to 10 CFR 73.100 aligned with the dose reference values in 10 CFR 53.210. Additionally, RG 5.81 (formerly DG-5071) and RG 5.97 (formerly DG-5076) have been revised to reflect and provide guidance on these regulatory changes.

Accordingly, the NRC changed the rule language and guidance as stated above in response to these comments.

3.6.3.4. <u>Integrity assessment programs (§ 53.870), including RFC</u>

Comment Bin 3.6.3.4.A: A commenter said that the overall requirements in 10 CFR Part 53 addressing design and inspection provide a sound basis for seeking to identify potential degradation phenomena, ensure that materials used in the SSCs are qualified for use in the operating environments, provide margins against failure, and require assessments of operating experience. The commenter listed the relevant requirements, including 10 CFR 53.220, 53.250, 53.440, 53.450, 53.710, 53.715, 53.865, and 53.880, and said that these requirements provide for a robust approach to ensuring integrity of SSCs (NEI2-0204).

The commenter said that the Integrity Assessment Program under 10 CFR 53.870 remains duplicative of these other 10 CFR Part 53 requirements (NEI2-0006, NEI2-0020, NEI2-0112, NEI2-0204) and suggested that the NRC remove 10 CFR 53.870 (NEI2-0006, NEI2-0112, NEI2-0204). Another commenter expressed support for this comment (NEX-0023).

A commenter wrote that the proposed integrity assessment program risks duplicating other programs such as the Reliability and Integrity Management (RIM) Expert Panel (RIMEP), LMP Integrated Decision Panel, and the Surveillance Frequency Control Program Integrated Decision Panel, and suggested removing the proposed integrity assessment program (SCWG-0005).

Another commenter wrote that existing regulations in 10 CFR Part 50 do not include any integrity assessment program, and that the ASME Boiler and Pressure Vessel Code already provides for acceptable comprehensive approaches for reducing risks associated with ongoing degradation issues involving operational reactors, and the proposed rule overrides this program while providing no discernable acceptance criteria. The commenter added that the requirements are decoupled from risk because the “assumption is made that significant danger to the public must flow from the specific mechanisms identified” and “no existing measures exist to alleviate the claimed problem.” The commenter argued that this contradicts the requirements of NEIMA.

The commenter wrote that the NRC should remove the integrity assessment program requirements in 10 CFR 53.870, and instead the rule should state that an inservice inspection effort in accordance with ASME code is required for SR components, and the use of ASME code is required for all reactors. The commenter suggested the following revised rule language for 10 CFR 53.870 (HPT4-0001, HPT4-0002):

> In-service Inspection Programs.
>
> Each holder of an OL or COL under this part must develop, implement, and maintain an program to monitor, evaluate, and manage the ongoing fitness for operation of key components—
>
> (a) The program involves surveillances, tests, and inspections conducted, for specific safety-related SSCs employed in conjunction with protecting the public from hazardous radiation (section 210) with the program in accordance with the ASME boiler and pressure vessel code the use of other consensus codes and standards require specific approval by the NRC.

The commenter wrote that there is nothing in existing requirements under 10 CFR 50.34 analogous to integrity programs, and the NRC is attempting to impose burdensome new requirements that contradict NEIMA. The commenter recommended replacing the integrity assessment program requirement in 10 CFR 53.1239 with inservice inspections and recommended revised rule language (HPT4-0004). The commenter further recommended revising 10 CFR 53.1369 to remove the integrity assessment program (HPT4-0005).

NRC Response: The NRC disagrees with the comments.

As explained in the proposed and final rules, including requirements in 10 CFR Part 53 related to designing and monitoring for possible degradation mechanisms reflects important lessons learned from the history of LWRs and the likely introduction of new design features and materials in future commercial nuclear plants. The NRC recognizes that some consensus codes and standards such as ASME Section XI, Division 2, “Reliability and Integrity Management (RIM)” could be useful in fulfilling the requirements for integrity assessment programs in 10 CFR 53.870. The NRC disagrees that use of the ASME code should be required for all reactors in lieu of an integrity assessment program. The NRC seeks to provide greater flexibility in 10 CFR Part 53 by not requiring the use of certain portions of the ASME code, as is currently done in 10 CFR Part 50, and instead allowing the applicant or licensee to define what is necessary to maintain the integrity of facility SSCs.

In addition, consensus codes and standards other than ASME Section XI, Division 2, covering inservice inspections do not directly address the identification and monitoring of all degradation mechanisms and so gaps could be introduced. One example of such a gap that resulted in the need for supplemental programs for operating LWRs was the issue of intergranular stress corrosion cracking of materials used in the primary coolant systems. To the degree that an applicant or licensee identifies efficiencies in combining programs or to satisfy 10 CFR 53.870 (integrity assessment) and 10 CFR 53.880 (inservice inspection and inservice testing), 10 CFR 53.845 allows licensees to combine, separate, and otherwise organize programs and related documents as appropriate for the technologies and organizations associated with the commercial nuclear plant. As noted in the response to Comment Bin 3.6.1.G, applicants and licensees are likewise able to organize the associated expert panels to minimize duplication of efforts and improve efficiencies.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.6.3.4.B: A commenter wrote that they supported the inclusion of language regarding degradation mechanisms, but added that the “degradation mechanisms of aging, fatigue, embrittlement, chemical interactions, operating temperatures, effects of irradiation, corrosion, and other environmental factors, and the collective and cumulative synergistic effects of such factors that may affect the performance of SR and NSRSS SSCs” should also be included in the final rule. The commenter also requested that the NRC continue to identify and incorporate lessons learned from the commercial industry to better equip the safe operation of advanced reactors (NYS2-0016).

NRC Response: The NRC agrees, in part, with the comment.

The comment largely favors the inclusion of an integrity assessment program as included in the proposed and final rules. The NRC does not take issue with the expanded list of possible degradation mechanisms or the need to consider combined or synergistic effects of the various degradation mechanisms. However, the NRC believes that the description of degradation mechanisms included in the rule in 10 CFR 53.870(c), including the broad “other environmental factors,” provides adequate requirements for integrity assessments under the design and program sections in 10 CFR Part 53. As explained in the NRC’s response to Comment Bin 3.6.3.4.C, the development of additional guidance related to 10 CFR 53.870 will provide an additional opportunity to emphasize a systematic approach to the identification of and monitoring for degradation mechanisms and the need to consider synergistic effects.

Accordingly, the NRC did not change the rule language in response to the comment.

Comment Bin 3.6.3.4.C: A commenter wrote that 10 CFR 53.870 is not needed given the Reliability and Integrity Management (RIM) provisions of ASME Section XI, Division 2, as endorsed in RG 1.246 along with the Maintenance Rule requirements in 10 CFR 53.715. The commenter wrote that if 10 CFR 53.870 remains as is, then guidance will need to be developed to support implementation of the required program (NEI3-0021).

NRC Response: The NRC agrees, in part, with the comment.

The NRC will work with standards development organizations, industry organizations, and other stakeholders to endorse consensus codes or standards or other documents and will, as necessary, independently develop guidance to address this and other requirements in 10 CFR Part 53. The NRC acknowledges in the response to Comment Bin 8.10.B that updates to various RGs or development of companion guidance will be needed to help in the use of numerous codes and standards under 10 CFR Part 53. The NRC will issue revisions or 10 CFR Part 53-related companions to these guidance documents for public comment and finalize and issue the guidance documents following publication of the final 10 CFR Part 53 rule. The NRC appreciates commenters' suggestions for prioritization of such guidance.

The NRC disagrees with the suggestion that the NRC's endorsement of ASME Section XI, Division 2, through RG 1.246 obviates the need for an integrity assessment program. Whereas ASME Section XI, Division 2, could be useful in fulfilling the requirements for integrity assessment programs in 10 CFR 53.870, the NRC does not require its use or the use of any specific consensus code or standard in 10 CFR Part 53. Other consensus codes and standards covering inservice inspections do not directly address the identification and monitoring of all degradation mechanisms and so gaps could be introduced if a requirement such as 10 CFR 53.870 was not included in the framework.

Accordingly, the NRC did not change the rule language in response to this comment.

3.6.3.5. <u>Other comments on programmatic requirements (e.g., fire protection, inservice inspection, quality assurance)</u>

Comment Bin 3.6.3.5.A: A commenter wrote that guidance for the radiation protection requirements in 10 CFR 53.850 should be updated to note the applicability of appropriate Division 8 RGs (NEI2-0108). Another commenter expressed support for this comment (NEX-0021).

Another commenter recommended revising the language in 10 CFR 53.850(c) from "operational controls for solid radioactive waste processing," to "operational controls for solid, liquid, and gaseous waste processing" (TG10-0002).

NRC Response: The NRC agrees, in part, with the comments.

Regarding the updating of guidance related to 10 CFR 53.850, the NRC acknowledges in the response to Comment Bin 8.10.C that updates to various RGs or development of companion guidance will be needed to help in the implementation of radiation protection programs under

10 CFR Part 53. The NRC will issue revisions or 10 CFR Part 53-related companions to these guidance documents for public comment and finalize and issue the guidance documents following publication of the final 10 CFR Part 53 rule. The NRC appreciates commenters' suggestions for prioritization of such guidance.

The NRC disagrees with the suggestion of changing 10 CFR 53.850(c) (Process Control Program for solid radioactive waste) to address solid, liquid, and gaseous waste because liquid and gaseous waste processing is addressed under 10 CFR 53.850(b).

Accordingly, the NRC did not change the rule language in response to the comment.

Comment Bin 3.6.3.5.B: A commenter said that 10 CFR 53.880 is too detailed and descriptive and could be moved to guidance and deleted from the rule language. If the NRC decides to keep the requirements, the commenter suggested that it be revised to read, "(a) Each holder of an OL or COL under this part must develop, implement, and maintain a program for in-service inspection (ISI) and in-service testing (IST) prior to receiving an OL or COL. The ISI/IST program must be documented in a written manual and managed by qualified personnel." (NEI2-0116, NEI2-0118). The commenter alternatively suggested that if NRC does not remove "plant manager" from 10 CFR 53.880(a) and (b), it should be replaced with more generic language such as "director, responsible officer, or designated person" (NEI2-0117).

The commenter also said that the language "minimize risk" in 10 CFR 53.880(a) is ambiguous and impossible to implement. The commenter said that minimal risk to the public may require inspection of equipment in a high radiation area immediately, but minimal risk to plant workers would require all work to be completed with the plant shut down with sufficient time for radionuclide decay. The commenter recommended NRC remove from 10 CFR 53.880(a) "Risk insights must also be used to determine when to conduct the inspections and tests (e.g., full power, shutdown, refueling) to minimize risk to the plant workers and the public" and only rely on the requirements of 10 CFR 53.715 (NEI2-0119). Additionally, the commenter suggested that NRC revise the requirement for baseline inspections in 10 CFR 53.880(b) to be less prescriptive and more performance based (NEI2-0120).

Another commenter wrote that an ISI/IST requiring use of consensus industry codes and standards should not be optional, and there is no legal basis for the language "otherwise found to be acceptable." The commenter stated that this is because if an identified code or standard did not include NRC staff involvement, then the code and standard is not a consensus code and standard and the NRC has the right to reject it. The commenter wrote that their focus on SR SSCs is because the bulk of the risk lies with these items as opposed to other general plant safety systems that may involve ISI/IST activities. The commenter added that, as currently configured, the ISI/IST requirements conflict with the risk-informed aspects of NEIMA. In particular, the language "all inspections and tests required by of the codes and standards used in the design" is open-ended and ill-defined and should be deleted.

The commenter continued that future ISI/IST efforts may evolve over time as technology advances, and a "no objection" approach should be sufficient considering that the ISI/IST forms one leg of the defense-in-depth philosophy. The commenter added that the reference for designing ISI/IST is better suited for 10 CFR 53.440. Finally, the commenter wrote that the ISI/IST effort is highly technical and more appropriate for a technical manager instead of a plant manager. The commenter proposed the following revised rule language for 10 CFR 53.880 (HPT18-0001, HPT18-0002):

53.880 In-service inspection and in-service testing.

(a) Each holder of an OL or COL under this part must develop, implement, and maintain a program for in-service inspection (ISI) and in-service testing (IST) of safety-related and allied SSC's prior to receiving an OL or COL. The ISI/IST programs must employ generally accepted key consensus industry codes and standards. These standards as well as the general scope and key items subject to inspections and tests must be identified in the safety analysis report, with specifics contained in a program manual. The ISI/IST program must be documented in a controlled manual and managed by technically qualified personnel, with ultimate program approval resting with the facility's executive manager, the program is subject to Appendix B quality assurance measures.

(b) In conjunction with construction and initial reactor start-up efforts, baseline inspections and testing must be performed using the techniques intended for future inspections and testing. The results of these inspections and testing must be used in support of establishing as benchmarks for evaluating the results of future inspections and testing.

The design efforts should include providing for sufficient room to accommodate the personnel, ISI/IST equipment, and shielding necessary to perform the inspections and testing thereby aiding efforts to achieve acceptably low personnel radiation exposure.

ISI/IST acceptance criteria for determining whether corrective action is needed must be derived from the original codes/standards, engineering specifications, and design documents cited in the design of the item in question. The results of the inspections and testing must be provided to the Technical Manager who is responsible for determining and justifying what, if any, corrective action is needed and when the actions should be taken. The ISI/IST results and corrective actions must be documented and retained for the life of the plant.

Material changes to the ISI/IST program to accommodate on-going technology advancements must be identified, in a timely fashion, to the NRC prior to implementation in order to obtain a "no objection" letter from the NRC.

Another commenter wrote that a major shortcoming in the NRC’s policies is that the Commission has not told the agency what amount of risk is acceptable, and this is important as it “would not prevent the kind of insight that would identify one type of risk as greater, (or less than), another” and “it also does not allow a risk analyst to ignore any risk (at or less than that specified).” The commenter wrote that this is not an untested idea and rather was encouraged by the NRC 30 years ago. The commenter added it is important to have acceptance criteria, which is pointed out in 10 CFR 53.880(b) (TG11-0002).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees that the term “plant manager” in 10 CFR 53.880 is too specific for the requirement because it may have different meanings depending on the specific application. Accordingly, the NRC has revised the final rule language to replace that term with more generalized phrasing.

The NRC otherwise disagrees that all the requirements in 10 CFR 53.880 are too detailed and descriptive and should be moved to guidance and that the requirement in 10 CFR 53.880(a) to use risk insights should be removed. As discussed in the proposed and final rules, 10 CFR 53.880 establishes requirements for ISI and IST, which are historically important activities conducted in accordance with ASME codes and regulations in 10 CFR 50.55a. The additional use of risk insights in 10 CFR 53.880(a) for minimizing risk to plant workers and the public is consistent with the risk-informed and performance-based nature of the design process under 10 CFR Part 53.

The NRC disagrees with the comment regarding consensus codes and standards. The NTTAA directs all Federal agencies and departments to use technical standards that are adopted or developed by voluntary consensus standards bodies and also addresses consultation and participation with such bodies. OMB Circular A-119 establishes policies on the Federal use and development of voluntary consensus standards as it relates to the NTTAA and does not require United States Government involvement in the development of a voluntary consensus standard for such a standard to be considered as such. Further, the NTTAA also includes an exception to allow the adoption of technical standards that are not developed or adopted by voluntary consensus standards bodies.

The NRC disagrees that the requirements in 10 CFR 53.880 conflict with the risk-informed aspects of the Nuclear Energy Innovation and Modernization Act because the requirements in 10 CFR 53.880 allow for flexibility in determining how a technology-inclusive, risk-informed, and performance-based ISI and IST program could be established. The NRC disagrees with moving the requirements for an ISI/IST program to 10 CFR 53.440 because 10 CFR 53.440 primarily focuses on requirements for the design of commercial nuclear plant.

The NRC disagrees that the Commission has not provided guidance and perspectives on acceptable levels of risk. The stated objective of the Commission's policy statement, titled, "Safety Goals for the Operations of Nuclear Power Plants," is to establish goals that broadly define an acceptable level of radiological risk that might be imposed on the public as a result of nuclear power plant operation.

Accordingly, the NRC did not change the rule language in response to these comments other than the revision related to the term "plant manager."

Comment Bin 3.6.3.5.C: A commenter wrote that the goal for quality assurance should be to reduce costs while maintaining safety, and one way to do this is a performance-based approach. The commenter referenced a program by the Electric Power Research Institute as a way to do this, but on a larger scale. The commenter also said additional redundancy is a way to deal with QA costs while maintaining safety. The commenter wrote that areas like QA need to be updated using performance data as part of the NRC's modernization process (MU1-0007).

NRC Response: The NRC agrees, in part, with the comment. The NRC believes the sentiments expressed in the comment are already accommodated by the 10 CFR Part 53 regulatory framework, including updates thereof based on performance data accrued through operational experience.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.3.5.D: A commenter wrote that the requirements in 10 CFR 53.865 should be deleted. The commenter wrote that including Appendix B to 10 CFR Part 50 in the rule already requires a QA program, and there is no legal basis for requiring that the NRC must endorse consensus codes and standards or that consensus codes and standards must be used to develop the QA program. The commenter added that there are no discernable acceptance standards for guiding the conduct of the quality assurance program, and as such applicants would be "subject to the whims of the NRC staff." The commenter wrote that NEIMA requires the NRC staff to cooperate with the nuclear industry in developing consensus codes and standards, and that subsequently requiring of codes and standards is "double jeopardy" as the NRC has previously approved the document by virtue of being part of the consensus (HPT21-0001).

NRC Response: The NRC agrees, in part, with the comment.

The NRC disagrees with the suggestion that 10 CFR 53.865 be deleted, and the section is maintained in the final rule. Experience with the construction and operation of plants licensed under 10 CFR Parts 50 and 52 demonstrated the importance of quality assurance programs and associated regulations that provided the basis for the requirements in 10 CFR Part 53.

The NRC agrees that there is no current requirement that the NRC must endorse consensus codes and standards or that consensus codes and standards must be used to develop the quality assurance program. An applicant or licensee could choose to develop a quality assurance program manual that does refer to all or parts of generally accepted consensus codes and standards.

Accordingly, the NRC has revised the rule language to delete the requirement to develop QA program manuals and guide the QA program in accordance with generally accepted consensus codes and standards that have been endorsed or otherwise found acceptable by the NRC.

Comment Bin 3.6.3.5.E: One commenter said that 10 CFR 53.875(a)(2) provides examples of specific features to be included within a fire protection plan, which implies minimum criteria. The commenter recommended that NRC remove all examples of specific features to be included within a fire protection plan (NEI2-0114).

The commenter also expressed appreciation for the language in 10 CFR 53.875(b) that states, "Each holder of an OL or COL under this part must develop a performance-based or deterministic fire protection program," but wrote that RG 1.189 and RG 1.205, " Risk-Informed, Performance-Based Fire Protection for Existing Light-Water Nuclear Power Plants," issued May 2021 (ML21048A448) should be updated to facilitate implementation of this regulation (NEI2-0113).

Finally, the commenter said that 10 CFR 53.875(b)(2) replicates the Appendix A to 10 CFR Part 50 General Design Criteria 3 for Fire Protection. The commenter stated that the scope of 10 CFR 53.875(b)(2) implies all SR and NSRSS SSCs must meet the requirements, which is inconsistent with RG 1.189. The commenter recommended that NRC remove 10 CFR 53.875(b)(2) or delete "and NSRSS" from the rule language (NEI2-0115).

A commenter wrote that the proposed rule language maintains the core principles for fire protection found in 10 CFR Part 50 and 10 CFR Part 52 but provides additional risk-informed options. However, the commenter said that the "Fire PRA" approach raises issues, similar to broader concerns over the PRA requirements regarding transparency, quality control, and regulatory predictability (NYS2-0019).

A commenter stated that the fire protection requirements in 10 CFR 53.875 involve design elements and belong in 10 CFR 53.440. The commenter wrote that fire protection design elements should include requiring the applicant identify the consensus industry codes and standards used in conjunction with design of the fire detection, suppression, and mitigation features. The commenter said that modern power plants rely on automatic fire detection and suppression measures, and requiring plant personnel to manually suppress anything but a small fire would put them at risk. The commenter added that if a local fire department is not available to support timely arrival, then the facility should supply a professional and trained full-time firefighting brigade. The commenter wrote that 10 CFR 53.875 should be revised as follows (HPT17-0001, HPT17-0002):

> Fire Response Plan.
>
> (a)(1) Each holder of an OL or COL under this part must have a program document to identify how the facility is to respond to a fire, including: (2) identification of evacuation routes; (3) identification of personnel alarm notification methods; (4) identification of responsible party for alerting the fire department; (5) responsibility to declare the event is over; (6) responsibility for insuring the operability of fire alarm, detection, suppression, and mitigation equipment; (7) responsibility for periodically testing the fire protection equipment; (8) responsibility for maintaining display of evacuation routes within the plant; (9) responsibility for conducting periodic drills, including those involving the local fire department; (10) responsibility for maintaining the response plan manual; (11) responsibility for maintaining prominent identification of the location of fire mains, hydrants, hose stations, and allied equipment to support the fire department; (12) responsibility to maintain liaison with the local fire department; (13) general fire detection and mitigation measures and locations. Specifics of the fire protection equipment should be on a need-to-know basis from a security standpoint, but available within the control room.
>
> (b) The plan must include performance measures to periodically demonstrate the effectiveness of the plan, including proving the availability and operability of fire detection, suppression, and mitigation equipment. The plan is subject to quality control measures under Appendix B.

NRC Response: The NRC agrees, in part, with the comments.

The NRC disagrees with removing all examples of specific features to be included within a fire protection plan. As explained in the proposed and final rules, the rule language in 10 CFR 53.875(a) supporting operations is similar to 10 CFR 50.48. The use of consistent rule language is intentional and will facilitate guidance development and application of lessons learned from many years of developing and improving fire protection programs for plants licensed under 10 CFR Parts 50 and 52.

Regarding the statement that RG 1.189 and RG 1.205 should be updated to facilitate implementation of 10 CFR 53.875, the NRC agrees that updates to existing RGs to reflect methodologies acceptable under 10 CFR Part 53 facilitate implementation of the rule. The NRC continues to identify and develop additional guidance needed to support 10 CFR Part 53 and appreciates commenters' suggestions for inclusion of the specific guidance documents mentioned.

Regarding the scope of the fire protection program in 10 CFR 53.875 (and related design requirements in 10 CFR 53.440(e)), the NRC made a conforming change to 10 CFR 53.875 in response to Comment Bin 3.3.2.1.B regarding the treatment of NSRSS SSCs in the fire protection program. However, no additional changes to the rule language were made in response to this comment.

With regard to generalized concerns about the use of PRA methodologies, as noted elsewhere in this document, PRA offers licensing flexibilities that can accommodate a variety of reactor designs; however, while the regulations are flexible, the NRC approval will be reflected in the plant's specific and detailed licensing basis, which will provide adequate transparency, predictability, and quality control.

Regarding the statement that a more prescriptive list of items should be included in the fire protection program, the NRC believes many of the items are more appropriate for implementing procedures and would logically result from the requirements as written in the proposed and final rule language.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.6.3.5.F: A commenter wrote that they supported the inclusion of the requirements for a facility safety program in the rule and added that the NRC should retain the requirement as it is an important tool to provide States and the public information on safety oversight (NYS2-0018).

NRC Response: The NRC disagrees with the comment.

For the reasons expressed in SRM-SECY-23-0021, the Commission specifically disapproved including the proposed requirements for the facility safety program in 10 CFR Part 53. The concept of a facility safety program that was included in the draft proposed rule (SECY-23-0021) was intended to provide a new, risk-informed approach to addressing changes to plant risk driven by new information regarding external hazards. The Commission determined this was not needed because the NRC will continue to address new information on external hazards through its ongoing oversight and other provisions in 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.6.3.5.G: A commenter wrote that the rule should require a quality control program with the support of specific but flexible guidance. The commenter wrote that the NRC should include guidance in accordance with the ISO Standard 9000 series, specifically ISO 19433, because it is widely accepted internationally and informed by industry stakeholders. The commenter added that the standard is flexible, providing some requirements, recommendations, and possibilities and considerations (RH-0001, RH-0002).

Another commenter wrote that they supported direction from the Commission in using Appendix B to 10 CFR Part 50 with the rule. The commenter added that a broader set of standards should be evaluated for adequacy of meeting Appendix B to 10 CFR Part 50 requirements to ensure new reactor equipment and components can meet demand (USNIC2-0010).

NRC Response: The NRC agrees with the comments.

The proposed and final rule language reference Appendix B to 10 CFR Part 50. As explained in the proposed rule, references to generally accepted consensus codes and standards endorsed or otherwise found acceptable by the NRC in 10 CFR 53.865 would have allowed for the use of international codes and standards not previously used in NRC licensing but recognized that the use of any consensus code or standard would ultimately need to be found acceptable by the NRC, either through generic efforts to endorse a code or standard or on an application-specific basis during an individual licensing review.

However, in response to Comment Bin 3.6.3.5.D, the NRC agreed, in part, with another comment that noted that there is no current requirement that the NRC must endorse consensus codes and standards or that consensus codes and standards must be used to develop the quality assurance program. In response to that comment, the NRC has revised the final rule language to delete the requirement to develop QA program manuals and guide the QA program in accordance with generally accepted consensus codes and standards that have been endorsed or otherwise found acceptable by the NRC.

Accordingly, the NRC did not make further changes to the rule language in response to these comments.

3.7. Subpart G: Decommissioning Requirements (§§ 53.1000-53.1080)

3.7.1. Comments on Subpart G requirements not related to RFC

Comment Bin 3.7.1.A: A commenter stated that the NRC report, “Best Practices for Establishment and Operation of Local Community Advisory Boards Associated with Decommissioning Activities at Nuclear Power Plants,” required by section 108 of NEIMA and delivered to Congress on July 1, 2020 (ML20113E857) demonstrated that the community advisory board (CAB) is a useful tool which can support all nuclear power and fuel cycle facilities through decommissioning. The commenter advocated for the use of CABs to support all aspects of nuclear power and fuel cycle facilities, from initial planning and siting through decommissioning. The commenter discussed that the 2020 CAB report is limited in scope in context of decommissioning, but that NEIMA sections 103(a)(1), (a)(3), (b)(4)(A)(iii), (b)(4)(B)(iii), and (b)(4)(B)(iv) include high-level policy goals for the NRC to find and implement program changes resulting in “predictable, efficient, and timely” licensing processes.

The commenter added that CAB formation prior to decommissioning is likely to improve its overall effectiveness in working with the community and licensee, including to develop a charter, consider membership, develop a selection process for CAB members, provide training or other background information, and identify and address community needs during decommissioning. The commenter further lists seven processes related to licensing within 10 CFR Part 53: ESP, LWA, standard design approval (SDA), standard design certification (SDC), CP, OL, and ML, that the commenter believes could involve a CAB (UT1-0002).

NRC Response: The NRC agrees with the comment.

Insofar as it is noted in the 2020 CAB report referenced in the comment, the NRC encourages the formation of CABs to foster communication and information exchange between the licensee and the members of the community. The comment suggests no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to the comment.

Comment Bin 3.7.1.B: A commenter stated that the NRC conducts monitoring to ensure sufficient decommissioning trust funds at nuclear power plants, and that SECY-18-0078, “Summary of Staff Review and Findings of the 2017 Decommissioning Fund Status Reports From Operating Power Reactor Licensees and Power Reactor Licensees in Decommissioning,” issued August 2018 (ML18096B523) provides periodic cost estimate data describing the present amount of money in the trust fund and an estimate to complete radiological decommissioning for each nuclear plant. The commenter discussed that the cost estimates presented in SECY-18-0078 only cover costs for decommissioning radioactive portions of the plant, but that the cost to decommission a nuclear plant includes costs for both radiologically and non-radiologically affected items. The commenter expressed concern that NRC estimates based only on radiological costs may underestimate the total decommissioning funding required.

The commenter presented the case studies of the Shoreham nuclear plant on Long Island, New York, and Indian Point to discuss the consequences of insufficient decommissioning funding. The commenter stated that empty buildings exist at the Shoreham site to this day and that Long Island residents are subject to a multi-billion-dollar debt because of insufficient decommissioning funds. For Unit One at Indian Point, the commenter stated that no new money from ratepayers entered the decommissioning fund once the unit went into SAFSTOR decommissioning mode and that the net income from earnings on the fund was limited to a 2 percent rate of return. The commenter added that it would take many years to accrue sufficient decommissioning funds, despite a transfer of ownership from Consolidated Edison to Entergy.

The commenter further discussed that the three units at Indian Point were later transferred to Holtec Decommissioning International, who placed all units into DECON decommissioning mode and submitted a post-shutdown decommissioning activities report (PSDAR) with multiple cost estimates to the NRC. The commenter stated that the NRC did not review the PSDAR cost estimates in detail and instead relied on summary tables that could potentially be invalid due to incorrect, incomplete, or faulty analysis, putting the local community at financial risk. The commenter suggested that a different approach to decommissioning funding is needed and that financial assurance methods including surety bonds be part of the licensing process prior to approving any transfer of licenses. The commenter recommended that all utilities, including merchant and long-term local utilities, make lasting commitments to their service areas to protect the public from financial risk and that the NRC reconsider the need to submit PSDARs if the NRC does not plan to conduct detailed reviews or address public questions (MU1-0006).

Relatedly, another commenter discussed that the U.S. energy portfolio must adequately prepare for the time when advanced nuclear reactors must be decommissioned. The commenter expressed agreement with the NRC’s proposed approach to integrate 10 CFR Part 50 decommissioning standards into 10 CFR Part 53, including license termination plans specific to reactor types and site environments. The commenter added that it would be important for each site to develop cost estimates and justify sufficient decommissioning funding and requested that the NRC consider developing guidance on the cost of decommissioning for a variety of reactor technologies (RH-0003).

NRC Response: The NRC agrees, in part, with the comments.

The NRC acknowledges the comment's concern that NRC estimates based only on radiological costs may underestimate the total amount of funding required to radiologically and non-radiologically decommission a site. 10 CFR 53.020, like 10 CFR 50.2, specifically defines "*Decommission or decommissioning*"; this definition is focused on the reduction of the residual radioactivity at a site. The provisions in 10 CFR Part 53 related to the scope of decommissioning cost estimates in Subpart G are equivalent to those found in 10 CFR Part 50 and are appropriate given the NRC's mission.

The NRC acknowledges the specific comments regarding decommissioning funding for Shoreham and Indian Point; however, these comments are outside of the scope of this rulemaking. The NRC staff review decommissioning funding estimates and monitor the amount of decommissioning funds for plants in decommissioning to ensure that sufficient funds, consistent with NRC regulations, are available for decommissioning.

The comment recommending that all utilities, including merchant and long-term local utilities, make lasting commitments to their service areas to protect the public from financial risk is outside the scope of this rulemaking, as it is a comment directed at actions that NRC licensees should undertake.

Regarding the comment that the NRC reconsider the need to submit PSDARs if the NRC does not plan to conduct detailed reviews, formal approval of the PSDAR is not necessary to provide adequate protection of the public health and safety during the decommissioning process. Requiring approval of the PSDAR would effectively reinstate the Decommissioning Plan review requirements removed from the regulations by the "Decommissioning of Nuclear Power Reactors; Final Rule" (61 FR 39278; July 29, 1996), which established the current PSDAR process.

One of the main drivers for the 1996 decommissioning final rule, beyond the recognition that decommissioning power reactors inherently pose less risk to public health and safety than operating reactors, was to provide more flexibility in dealing with premature closures and the decommissioning process in general while establishing "a level of NRC oversight commensurate with the level of safety concerns expected during decommissioning activities" (61 FR 39279). One of the primary methods for increasing this flexibility was removal of the NRC's approval of a Decommissioning Plan in favor of a licensee's submittal of the PSDAR to streamline the decommissioning process.

The NRC acknowledges the comment that it consider developing guidance on the cost of decommissioning for a variety of reactor technologies. The NRC intends to develop guidance on this topic in the future.

The NRC is conducting a wholesale review of its regulations, including those related to decommissioning, in response to EO 14300, "Ordering the Reform of the Nuclear Regulatory Commission," dated May 23, 2025.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.7.1.C: A commenter expressed concern that the proposed rule is not inclusive of "small advanced" reactors. The commenter discussed an example scenario in which a staff of three employees remotely operate a "small advanced" reactor plant at 100% power without NRC regulatory control over operator licensing or the communication pathways between the reactor and the supporting office. The commenter questioned whether the NRC would plan to inspect any part of such an operation or whether the NRC has considered: the amounts and types of insurance need to protect the local public, and requirements for appropriately ending reactor operations and for handling remaining fuel (TG20-0001).

Two commenters discussed that the proposed rule maintains the same decommissioning regulations for microreactors as for large-LWRs and does not adequately address transportation of microreactors to the manufacturer for decommissioning or refurbishment. The commenters stated that Subpart G should consider two decommissioning funding plans for a reactor site; one plan by the microreactor manufacturer for reactor removal and eventual decommissioning, and a second plan by the OL or COL holder for removal of radioactive material left onsite after removal of the microreactor. The commenters added that decommissioning regulations should allow for a microreactor to be transported to a facility for decommissioning (WEST1-0011, NEI2-0255).

A commenter asked how a "trailer truck sized" SMR holding [ir]radiated fuel could be removed from the site at the end of its life cycle (TG17-0006).

NRC Response: The NRC agrees, in part, with the comments.

The NRC acknowledges the comments' concern that the proposed rule was not inclusive of "small advanced" reactors or microreactors and that the proposed rule maintained the same decommissioning regulations as large-LWRs and was inadequate to address microreactors. A key objective of the 10 CFR Part 53 rulemaking was to develop a technology-inclusive alternative to the existing licensing processes in 10 CFR Parts 50 and 52. However, the NRC acknowledges that the final rule may not completely address every regulatory issue for every potential future advanced reactor but is considering some of the decommissioning funding issues for SMRs under the EO 14300, "Ordering the Reform of the Nuclear Regulatory Commission," dated May 23, 2025, activities.

Consistent with the ADVANCE Act and EOs issued in 2025, the NRC has initiated development of an additional rulemaking to expedite licensing of qualified microreactors and other potentially low risk, low consequence reactors. This activity, along with other NRC guidance development activities, are intended to address questions such as those raised by the comments (the amounts and types of insurance need to protect the local public, and requirements for appropriately ending reactor operations and for handling remaining fuel).

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.7.1.D: A commenter requested that NRC consider the benefits of the ISO quality management system as an alternative to a more deterministic risk management approach and the importance of creating a flexible yet robust decommissioning provision in proposed Subpart G to 10 CFR Part 53 (RH-0001).

NRC Response: The NRC acknowledges this comment.

The NRC acknowledges the request that the NRC consider the benefits of the ISO quality management system as an alternative to a more deterministic risk management approach as well as the importance of creating a flexible yet robust decommissioning provision in proposed Subpart G to 10 CFR Part 53. The NRC maintains awareness of all international decommissioning standards and incorporates that information into the NRC's regulations and guidance documents, as applicable.

Accordingly, the NRC did not change the rule language in response to this comment.

3.7.2. RFC: Decommissioning draft final rule

Comment Bin 3.7.2.A: Two commenters said that the regulations for transitioning to decommissioning set forth in SECY-24-0011, "Final Rule: Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning," issued January 2024 (ML23258A205) should be incorporated into the 10 CFR Part 53 rulemaking, taking into account the differences in reactor and fuel designs (NEI2-0205, USNIC2-0033). One commenter suggested that the primary objective of a 10 CFR Part 53 rule should be to eliminate the need for licensees to request license amendments and exemptions from regulations (NEI2-0205).

Relatedly, another commenter stated that the NRC should incorporate the entirety of the draft final decommissioning rulemaking into 10 CFR Part 53. The commenter discussed that the decommissioning rulemaking was under development from 2014 to 2022 but added that the Commission has taken no action on the proposed final rule provided in January 2024 via SECY-24-0011. The commenter expressed that the decommissioning rulemaking should be complete before 10 CFR Part 53 is promulgated and recommended that the NRC incorporate the decommissioning provisions into the current proposed rulemaking to accomplish this. The commenter added that any substantive changes to a final decommissioning rule can be addressed as the 10 CFR Part 53 rulemaking is finalized or in a subsequent rulemaking to ensure consistency across NRC regulations (LMNT-0003).

A commenter discussed that the decommissioning rulemaking includes much needed changes to current regulations and should be incorporated into the 10 CFR Part 53 rule to reflect the latest regulatory thinking without unnecessary delays or regulatory uncertainty for advanced reactor developers. The commenter expressed agreement with the NRC's approach to make current decommissioning requirements more technology-inclusive and to develop site-specific decommissioning cost estimates (SCWG-0006).

NRC Response: The NRC agrees with the comments.

In the future, the NRC plans to make conforming changes to 10 CFR Part 53, Subpart G, consistent with the Commission's direction on the draft final decommissioning rule contained in SECY-24-0011 once the Commission has issued that direction.

Accordingly, the NRC did not change the rule language in response to these comments.

3.7.3. RFC: Financial assurance requirements (§ 53.1060(b))

Comment Bin 3.7.3.A: In response to the NRC's request for comment related to proposed 10 CFR 53.1060(b), a few commenters supported the NRC's proposed approach but suggested that it may be more appropriate to require financial assurance within 30 days of initial fuel loading rather than within 30 days of issuance of the notice of intended operation. One of the commenters noted that a conforming change to 10 CFR Part 52 would achieve the desired consistency, and another commenter noted that these requirements are an example of how allowing transferability between 10 CFR Part 50 or 10 CFR Part 52 and 10 CFR Part 53 licenses would streamline regulatory processes (NEI2-0206, SCWG-0007).

Additionally, a commenter said that 10 CFR 53.1060 would require COL holders to submit a decommissioning report updating the decommissioning cost estimate and providing a copy of its financial assurance instrument two years and one year before the date for initiating physical removal of the physical mechanisms to prevent criticality. The commenter stated that this may not be practical considering the sequence in which manufactured reactors will be produced by manufacturers, purchased by a COL holder, and then deployed to a site, potentially in a brief time from the date of purchase (NEI2-0206).

NRC Response: The NRC agrees, in part, with the comments.

The NRC acknowledges the commenters' concerns that some of the timelines in the proposed rule may not be practical for certain business models for manufactured reactors, which the NRC interprets to include microreactors. A key objective of the 10 CFR Part 53 rulemaking was to develop a technology-inclusive alternative to the existing licensing processes in 10 CFR Parts 50 and 52. However, the NRC acknowledges that the final rule may not completely address every regulatory issue for every potential future advanced reactor. To address issues such as those raised in the comments, the NRC has initiated development of an additional rulemaking to expedite licensing of qualified microreactors and other potentially low risk, low consequence reactors, consistent with the ADVANCE Act and EOs issued in 2025. This activity, along with other NRC guidance development activities, is intended to address questions such as those raised by the comments.

The NRC agrees in part that allowing transferability between 10 CFR Part 50 or 10 CFR Part 52 and 10 CFR Part 53 licenses would streamline regulatory processes. The NRC agrees that licensing basis information should be transferable when appropriate, however, the NRC disagrees that it should codify a process for "cross-part" licensing between 10 CFR Parts 50, 52, and 53. See the response to Comment Bin 3.8.1.A on cross-part licensing.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.7.3.B: A commenter discussed that proposed 10 CFR Part 53 provides an adaptable framework for financial assurance, including decommissioning funds and liability insurance, which could allow for tailored financial assurance approaches for advanced reactor designs while ensuring adequate decommissioning funds. However, in consideration of the enhanced safety margins provided by advanced reactors, the commenter requested that the NRC revisit the liability limits established under the Price-Anderson Act and the NRC's implementing regulations at 10 CFR Part 140. The commenter discussed that overall liability protection provided by the Price-Anderson framework may not be necessary for advanced reactor facilities, as enhanced safety margins could translate into lower insurance premiums for owner-licensees, increased private insurance coverage for owner-licensees, and decreased costs to taxpayers for insurance support while incentivizing increased safety. The commenter additionally recommended that the NRC ensure owners establish sufficient funds for spent fuel management and storage, as well as adequate resources for decommissioning to avoid adverse consequences to vulnerable host communities (NYS2-0011).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that 10 CFR Part 53 provides an adaptable framework for financial assurance. Regarding requirements for financial protection under the Price-Anderson Act and NRC regulations in 10 CFR Part 140, the NRC considers such suggestions to be beyond the scope of this rulemaking. Regarding ensuring that sufficient funds are available for spent fuel management and storage, such requirements exist in 10 CFR Part 53 (see, for example, 10 CFR 53.1405 on continuation of requirements for an operating license).

Accordingly, the NRC did not change the rule language in response to this comment.

3.8. Subpart H: Licenses, Certifications, and Approvals (§§ 53.1100-53.1470)

3.8.1. Comments on licenses, certifications, and approvals under Subpart H (e.g., contents of applications for ESP, SDA, SDC, ML, CP, OL, and COL; limited work authorizations)

Comment Bin 3.8.1.A: Many commenters wrote that they supported the transferability of 10 CFR Part 50 licenses and 10 CFR Part 52 licenses to 10 CFR Part 53 as this would improve efficiency (BI1-0029, BI1-0013, ENT-0003, SHP-0003, NIA2-0005, NGO-0004, DOM-0005, NEX-0011, DOM-0001, USNIC2-0015, ENW-0002, CP-0009, SCWG-0007, CP-0002). Several commenters emphasized that transferability is critical as many applicants have already begun engaging the NRC under existing frameworks (SHP-0003, NIA2-0011, NIA2-0005, NGO-0004, DOM-0005, USNIC2-0015, CP-0005, BI1-0029).

Two commenters recommended removing “under this part”, or adding “or Parts 50 or 52” in 10 CFR 53.1124(a)-(h), 53.1221, 53.1312, 53.1330(b), 53.1384(b), 53.1425, 53.1443(d), 53.1470, 53.1525, and 53.1530 in order to ensure transferability from 10 CFR Parts 50 and 52 to 10 CFR Part 53, as well as from 10 CFR Part 53 to 10 CFR Parts 50 Part 52 (NEI2-0004, NEI2-0137, NEI2-0122, BI1-0033). One of the commenters echoed these concerns, and wrote that early-stage approvals such as ESPs, CPs, SDAs, and design certification (DCs) received under 10 CFR Parts 50 and 52 should be allowed to seek late-stage approvals under 10 CFR Part 53. The commenter noted that ESPs would rely on the same licensing and technical basis. The commenter suggested that guidance could be provided to clarify limitations and any additional requirements to support license transfers or licenses for identical designs at multiple sites for LMP applications under 10 CFR Part 50 or 52 using principal design criteria equivalent to the functional design criteria in 10 CFR Part 53 (NEI2-0004, NEI2-0137, NEI2-0122). The other commenter suggested that evaluations such as SARs, environmental impact statements (EISs), or environmental assessments (EAs) conducted under another part should be referenceable under 10 CFR Part 53 (BI1-0033).

The commenter added that they appreciated the ability to reference existing OLs or COLs to support a standard design certification or approval, and the ability for CPs, OLs and COLs to support licenses for identical designs at multiple sites and wrote that similar references would be appropriate for 10 CFR Part 50 or 52 licensees using LMP (NEI2-0122, NEI2-0137). The commenter wrote that, while it would be unlikely to happen, the NRC should modify rule language to allow an applicant to transfer from 10 CFR Part 53 to 10 CFR Part 50 or 52. To support this, the commenter recommended removing “under this part” from 10 CFR 53.1161, 53.1218, 53.1221, 53.1251, 53.1279, and 53.1288(a)(3) (NEI2-0122).

Given “nearly all” existing applicants are engaging with the NRC on 10 CFR Parts 50 and 52, two commenters wrote that applicants may not use 10 CFR Part 53 without a clear pathway to move from existing frameworks (NGO-0004, NIA2-0005). One commenter wrote that applicants may continue to use existing frameworks given they are established and predictable and enabling pathways to use 10 CFR Part 53 would allow applicants to gain experience with the framework while reducing regulatory risk (NIA2-0011).

A commenter wrote that applicants should be permitted to use preliminary regulatory approvals under 10 CFR Parts 50 and Part 52 to support licensing decisions under 10 CFR Part 53. The commenter wrote that this transferability should be based on applicant compliance with any additional requirements in 10 CFR Part 53 that were not present in 10 CFR Parts 50 and 52 but should maintain the regulatory finality of what was approved under 10 CFR Part 50 and 10 CFR Part 52. The commenter wrote that this transferability is precluded due to the rule language in 10 CFR 53.1124. The commenter added that they envisioned applicants under existing frameworks using features of 10 CFR Part 53 such as GLROs, security requirements, fitness for duty, Access Authorization and more (NEI2-0004).

A commenter expressed concern that the words “under this part” in 10 CFR 53.610(b) preclude a 10 CFR Part 50 CP holder or a 10 CFR Part 52 ESP holder from transitioning to a 10 CFR Part 53 OL or COL, which the commenter said is unnecessary and precludes legitimate licensing pathways with no technical basis. The commenter suggested deleting those words from paragraph 10 CFR 53.610(b) (NEI2-0065). A commenter wrote that flexibility between frameworks was important to them as the holder of an ESP and emphasized the ability to maintain finality approved under existing frameworks (ENT-0003). Another commenter argued that ESPs issued under 10 CFR Part 52 or 10 CFR Part 53 should be valid for any other licensing pathway (BI1-0019).

The commenter also wrote that licensees should be able to convert final regulatory approvals under 10 CFR Part 50 and 10 CFR Part 52 to an equivalent decision under 10 CFR Part 53. The commenter added that this would be more difficult but should be possible if applicants can “demonstrate that the prescriptive safety case developed to meet the regulatory requirements” in 10 CFR Part 50 and 10 CFR Part 52 would also meet the performance-based safety requirements in 10 CFR Part 53 (NIA2-0011).

A commenter suggested that the NRC update the preamble for the final rule indicating that transitioning from 10 CFR Part 50 and 10 CFR Part 52 to 10 CFR Part 53 would not reopen settled safety issues (NEI2-0004).

A commenter added that the NRC should remove 10 CFR 53.610 as this would improve supply chain efficiency and allow for alternative quality assurance programs that would ensure that quality assurance requirements are transferable between 10 CFR Part 50 and 10 CFR Part 52 and 10 CFR Part 53 (BI1-0013).

NRC Response: The NRC agrees, in part, with these comments.

The NRC disagrees with the comments to codify a process for “cross-part” licensing between 10 CFR Parts 50, 52, and 53, but notes that other, less complex pathways exist for applicants and licensees under 10 CFR Parts 50 and 52 to seek flexibilities similar to those allowed under 10 CFR Part 53 for the various regulatory areas mentioned in the comments without the need for rulemaking. Some of these alternative pathways were outlined in SECY-23-0021 in relation to the staff's draft proposed 10 CFR Part 53, Framework B.

From a legal and regulatory perspective, it would be almost impossible to codify such a framework in a clear and coherent manner given the fundamentally different safety constructs of 10 CFR Parts 50 and 52 as compared to 10 CFR Part 53. It would require not only revisions to 10 CFR Part 53, but also revisions to other parts of the NRC's regulations (e.g., 10 CFR Parts 2, 51, and 52). Such a licensing construct would likely benefit only a small number of applicants that would be in a position to take advantage of such a framework. The benefits of developing such a regulatory construct would be unlikely to outweigh the costs (in terms of dollars, time, and clarity in the regulations).

However, the NRC agrees that guidance could help to clarify limitations and provide additional guidelines to support license transfers for LMP applications under 10 CFR Part 50 or 52 to 10 CFR Part 53. The NRC notes that a subset of current 10 CFR Part 50 or 52 applicants may utilize the NRC's Advanced Reactor Content of Application and Technology-Inclusive Content of Application guidance documents. Those guidance documents, like 10 CFR Part 53, were designed to accommodate applications based on LMP. For those applicants, the NRC recognizes the possibility that a simpler approach to moving from 10 CFR Part 50 or 52 into 10 CFR Part 53 may exist, based on the common licensing methodology underlying both approaches. Technical information from either a 10 CFR Part 50 or Part 52 application can be reused by an applicant for a 10 CFR Part 53 application, and the transition would be especially straightforward for an applicant using the LMP methodology. The NRC will consider providing guidance on this topic as part of its efforts to develop additional guidance on 10 CFR Part 53 following completion of this rulemaking.

The NRC disagrees with the comment that the NRC should remove 10 CFR 53.610 to ensure that quality assurance requirements are transferable between 10 CFR Part 50 and 10 CFR Part 52 and 10 CFR Part 53. The NRC regulatory frameworks in 10 CFR Parts 50, 52, and 53 all rely on the same quality assurance requirements, namely, those in 10 CFR Part 50, Appendix B.

Accordingly, the NRC did not revise the rule language in response to these comments.

Comment Bin 3.8.1.B: Two commenters wrote that 10 CFR 53.1449(c)(3) requires 225-day notification, if ITAAC have not been closed for a COL, and 10 CFR 53.1452(a) requires both notification of plans to operate 270 days prior to initial fuel load and for the NRC to publish notification in the *Federal Register* 180 days prior to initial fuel load. The commenters wrote that these timelines are not fit for microreactors who will be looking to operate within 180 days of identification of a need for power. The commenters requested that the NRC consider whether the proposed timelines should be graded based on the reactor being licensed (WEST1-0013, WEST1-0014, NEI2-0136, NEI2-0257).

One of the commenters said that the timelines for specific actions provided in 10 CFR 53.1449(a) and (c)(3) and in 10 CFR 53.1452(a) are not reasonable for small plants whose construction schedules may be shorter than large plants. The commenter said that some of the timelines could create administrative burdens if the pace of construction compresses the time between specific actions and the scheduled initial fuel load date. The commenter recommended that NRC consider revisions to report timelines that would be linked to the licensee's construction and ITAAC completion schedules which would be informed by SECY-24-

0008 and the commenter's proposal paper on Rapid, High-Volume Deployment of Microreactors (NEI2-0136).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees that the current ITAAC timelines may not be a good fit for applicants looking to operate microreactors within 180 days of identification of a need for power. However, the current timelines were established in accordance with the AEA section 185.b requirement that the Commission, "prior to operation" find that the acceptance criteria in the COL are met and the AEA section 189.a(1)(B) requirement to publish a notice of intended operation and opportunity for hearing on ITAAC in the COL at least 180 days before the scheduled date for initial fuel load by the COL holder (hereafter "notice of intended operation"). Absent changes to the AEA, the NRC is not in a position to shorten the requirement to publish a notice of intended operation at least 180 days before the scheduled date for initial fuel load by the COL holder. Also, the NRC is required to make available to the public the notifications to be submitted under 10 CFR 53.1449(c)(1) and (c)(2), no later than the FRN of intended operation under 10 CFR 53.1452(a). These notifications need to be available to provide information to interested persons to support their ability to address the AEA section 189.a(1)(B) threshold for requesting a hearing with respect to both completed and as-yet uncompleted ITAAC.

The NRC is requiring that the 10 CFR 53.1449(c)(2) notification be made 225 days before the date scheduled for initial loading of fuel to ensure that the NRC has sufficient time to process the licensee notifications and make them publicly available before the 10 CFR 53.1452(a) notice of intended operation is published in the Federal Register. The NRC's goal is to publish that notice 210 days before the date scheduled for fuel loading, but in all cases the 10 CFR 53.1452(a) notice would be published no later than 180 days before the scheduled fuel load, as required by section 189.a(1)(B) of the AEA. Also, the NRC is requiring the 10 CFR 53.1452(a) notification of scheduled initial fuel load be submitted at least 270 days before the scheduled date to ensure the NRC is adequately prepared to timely process ITAAC notifications and publish the notice of intended operation.

While a key objective of the 10 CFR Part 53 rulemaking was to develop a technology-inclusive alternative to the existing licensing processes in 10 CFR Parts 50 and 52, the NRC acknowledges that the final rule may not completely address every regulatory issue for every potential future advanced reactor. Nevertheless, consistent with the ADVANCE Act and EOs issued in 2025, the NRC has initiated development of an additional rulemaking to expedite licensing of qualified microreactors and other potentially low risk, low consequence reactors that could address the concern raised in the comment.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.8.1.C: Two commenters said that section 301 of the ADVANCE Act directs changes removing certain limitations on foreign ownership of some types of licensed facilities and recommended that the NRC update 10 CFR 53.1118 to be consistent with this (NEI2-0138, WEST1-0015, NEI2-0258).

NRC Response: The NRC agrees with the comments.

In response to the ADVANCE Act, section 301, and these public comments, the NRC has revised the rule language in 10 CFR 53.1118.

Accordingly, the NRC changed the rule language in response to these comments.

Comment Bin 3.8.1.D: A commenter wrote that 10 CFR 53.1124 should be revised to emphasize that an LWA can be submitted concurrently with applications for ESPs, CPs, and COLs as this helps streamline the process and reduces redundancy. The commenter proposed the following text (MR-0003):

> Relationship between sections.
>
> (a) Limited work authorization. An application for a limited work authorization (LWA) under this part may be submitted as part of an application for an early site permit, construction permit (CP), or combined license (COL) under this part as required in 53.1130(a)(2).

NRC Response: The NRC agrees with the comment but notes that the suggested rule text already exists in 10 CFR 53.1124(a).

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.E: A commenter recommended clarifying 10 CFR 53.1124(b) so that CP or COL applicants may reference an ESP, and proposed the following rule text (MR-0004):

> Early site permit.
>
> (1) A holder of an early site permit may request an LWA.
>
> (2) An application for a CP or COL under this part may, but need not, reference an early site permit.

NRC Response: The NRC agrees with the comment.

The NRC notes that the suggested rule text already exists in 10 CFR 53.1124(b).

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.F: A commenter wrote that 10 CFR 53.1120 does not make sense and asked if it was necessary. In 10 CFR 53.1124(e)(1), the commenter asked what would occur if a manufactured reactor needed to be returned after it arrived at a site as a result of damage in transit. Finally, the commenter wrote that they did not understand the text in 10 CFR 53.1124(f) (TG12-0002).

NRC Response: The NRC acknowledges the comment.

The NRC considered the questions contained in the comment. Regarding the first question, the requirements in 10 CFR 53.1120 are necessary. They are equivalent to the requirements found in current NRC regulations in 10 CFR 50.11 and are necessary to characterize the licensing authority of the NRC as being limited to regulation of civilian uses of radioactive materials.

Regarding the commenter's second question, if a manufacturer reactor needed to be returned after it arrives at a site as a result of damage in transit, the holder of the manufacturing license for that reactor would need to maintain possession of it and work with the entity that transported the manufactured reactor from the factory to the site to have it returned to the factory for repairs. With regard to the commenter's statement that they did not understand 10 CFR 53.1124(f), that provision is noting that the original applicant for the referenced design certification must provide the CP applicant with the details of the design for use in the CP application, otherwise, the NRC would not accept the CP application referencing that design.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.G: A commenter asked about the requirements in 10 CFR 53.1241 and the uncertainties associated with analyses, methods, and equipment discussed in this requirement and how such uncertainties could be derived without any data. The commenter asked what is being done about scaling and uncertainties of analyses in the absence of prototype testing (RD-0026).

NRC Response: The NRC acknowledges the comment.

The NRC understands the comment to be asking how uncertainties are to be addressed in analyses and methods used in the design of plant equipment in the absence of prototype testing. The requirement in 10 CFR 53.1241 for an applicant to describe how the performance of each design feature has been demonstrated stems from 10 CFR 53.440(a)(1), which requires that analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof must demonstrate that each design feature required by 10 CFR 53.400 meets the defined functional design criteria required by 10 CFR 53.410 and 53.420. This requirement closely aligns with the language in existing NRC requirements in 10 CFR 50.43(e) which the NRC has relied on for its review of many past nuclear power reactor applications. It is the responsibility of the applicant to justify the method(s) they are using to demonstrate the performance of their design features, including the need to address uncertainties in areas where they are relying on analyses. The NRC will review those justifications for acceptability during review of the subject application for a commercial nuclear reactor. The comment did not suggest changes to the rule language.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.H: A commenter wrote that the proposed rule lacks explicit requirements for a comprehensive environmental impact assessment and recommended adding the following text to 10 CFR 52.1239 (MR-0005):

> Environmental Impact. The FSAR must include a comprehensive environmental impact assessment detailing the potential effects on local ecosystems, water sources, and the surrounding environment.

NRC Response: The NRC disagrees with the comment.

10 CFR 51.20 specifies those licensing and regulatory actions requiring the NRC to produce an EIS. Specific types of licensing action that require an EIS are listed under 10 CFR 51.20(b). A

comprehensive environmental evaluation is conducted by the NRC, under the NRC's NEPA implementing regulations and not by an applicant as part of the FSAR. The applicant must provide an environmental report that is a separate document from the FSAR as stated in 10 CFR 51.45(a) or as required by another 10 CFR Part 51 regulation (e.g., 10 CFR 51.54 and 51.55). An appropriate environmental evaluation will occur once a license application is submitted to actually construct, operate, and eventually decommission a nuclear power plant under 10 CFR Part 53. That is when the issues mentioned in the comment (e.g., potential impacts on local ecosystems, water sources, and the surrounding environment, if appropriate for the site being considered) would be assessed by the applicant and the NRC. As stated in several locations in Subpart H of 10 CFR Part 53 (e.g., within 10 CFR 53.1100, 53.1112, 53.1130, 53.1146, 53.1241, 53.1282, 53.1312, 53.1372, 53.1419, and 53.1470), the applicant must provide an environmental report in accordance with 10 CFR Part 51 (e.g., 10 CFR 51.49, 51.50, 51.53, 51.54, and 51.55).

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.I: A commenter wrote that 10 CFR 53.1239(a)(16) and 10 CFR 53.1279(a)(5) were "very good" (TG13-0003).

NRC Response: The NRC agrees with this comment.

The comment supports the proposed rule and suggests no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.J: A commenter wrote that the NRC should add requirements for managing waste to 10 CFR 53.1239, and proposed the following language (MR-0007):

> (27) Waste Management. The application must include a detailed waste management plan describing how radioactive waste will be managed, stored, and disposed of throughout the reactor's lifecycle.

NRC Response: The NRC disagrees with the comment.

Other parts of the NRC's regulations govern radioactive waste, such as 10 CFR Part 72, "Licensing requirements for the independent storage of spent nuclear fuel and high-level radioactive waste, and reactor-related greater than Class C waste."

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.K: A commenter wrote that the NRC should revise 10 CFR 53.1109(g)(2)(i)(A), as accident likelihood should not be a part of the dose calculation; rather, the dose calculation would be a result of the accident actually occurring (TG4-0001). The commenter also recommended changing the rule language from "from the facility considering accident likelihood and source term" to "from the facility considering source term" as the accident "is already occurring at this time."

Additionally, the commenter wrote that the text, “The exact configuration of the plume exposure pathway EPZ surrounding the facility shall be determined in relation to the local emergency response needs,” in 10 CFR 53.1109 excuses licensees from providing an emergency response and should be rewritten so that the “response is provided to the plume” (TG12-0001).

NRC Response: The NRC disagrees with this comment.

The rule language in 10 CFR 53.1109(g)(2)(i)(A) defines a plume exposure pathway emergency planning zone (EPZ), in part, as the area within which “public dose, as defined in 10 CFR 20.1003, is projected to exceed 10 mSv (1 rem) TEDE over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology.” The term “accident likelihood” refers to the criteria used in the selection of the spectrum of accidents that inform the EPZ size determination. Accident likelihood is not used in the dose evaluation of the chosen spectrum of accidents.

The 10 CFR 53.1109(g)(2)(i)(A) rule language is consistent with the existing requirement in 10 CFR 50.33(g)(2)(i)(A), which was adopted as part of the final rule on “Emergency Preparedness for Small Modular Reactors and Other New Technologies” (88 FR 80050; November 16, 2023). That rulemaking involved extensive stakeholder interactions and an extended public comment period. Consideration of accident likelihood in combination with event sequences, source term, and timing is used to arrive at the spectrum of accidents to develop the basis for the applicant’s site-specific plume exposure pathway EPZ. Source terms are used to determine dose consequences. Timing of the accident sequence facilitates determining if prompt protective measures are warranted. Meteorology input is essential in determining the weather conditions that impact dose consequences due to atmospheric transport and dispersion of the radioactive plume. The NRC has added additional discussion to the final rule FRN to provide further guidance on the plume exposure pathway EPZ size determination in response to these comments.

The NRC disagrees with the comment that 10 CFR 53.1109 excuses licensees from providing an emergency response. 10 CFR 53.1109 describes the requirements for establishing the size of an EPZ inside of which predetermined prompt protective measures are warranted, not whether an emergency response is provided.

Accordingly, the NRC did not change the rule language in response to this comment but did revise the final rule FRN as described above.

Comment Bin 3.8.1.L: A commenter asked if LWAs are necessary and whether they cause double work for the NRC (TG13-0001).

NRC Response: The NRC disagrees with this comment.

The LWA process does not cause double work for the NRC because the issues that are reviewed in an LWA application do not need to be re-reviewed in a subsequent CP or COL application.

LWAs have been an option under NRC licensing regulations for many decades. An LWA is a partial CP that allows the applicant to perform the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of the foundation, including placement of concrete, any of which are for a structure, system, or component of the facility for which either a CP or COL is otherwise required. In addition, LWAs can support an earlier start to the construction process than would otherwise occur if the applicant had to wait until it was prepared to submit an entire CP or COL application. The LWA process has been used successfully by many applicants over the years, and the NRC sees no reason to remove the flexibility it allows in the timing of construction activities.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.M: Regarding 10 CFR 53.1146, a commenter wrote that they do not understand why emergency plans include a requirement to describe the proposed inspections, tests, and analyses that a licensee must perform, given emergency plans are for when equipment "does not work properly" (TG13-0002).

NRC Response: The NRC understands the commenter to be asking about how the reference to inspections, test, and analyses in 10 CFR 53.1146 relates to emergency planning requirements for an ESP application. Inspections, tests, analyses, and acceptance criteria (ITAAC) are a key component of the current licensing processes under 10 CFR Part 52, many of which have been carried over into 10 CFR Part 53. The emergency preparedness ITAAC are used to identify those aspects of the emergency plan that cannot be completely addressed until the facility is constructed, such as emergency action level schemes and the overall demonstration of the licensee's ability to implement their plan during a full-scale exercise required to be performed prior to fuel load. ITAAC are used to ensure, through subsequent inspection, exercise, or both, the necessary reasonable assurance for emergency preparedness programs and facilities associated with the yet-unbuilt reactor. The NRC will not be able to make the required finding without the inclusion of proposed ITAAC in an ESP application that includes complete and integrated emergency plans. The commenter did not suggest any changes to the rule language.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.N: In 10 CFR 53.1279(c)(1), a commenter recommended changing "shipping to the site" to "shipping to or from the site" in case a reactor damaged in transportation must be returned.

In 10 CFR 53.1279(d)(1), the commenter wrote that "consistent with the design...at the place of operation" is "good."

In 10 CFR 53.1288(a)(2), the commenter asked if "including those that have already been transported" should continue to be included in the rule text since areas to be modified may no longer be accessible (TG13-0004).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that the wording in 10 CFR 53.1279(d)(1) is appropriate. The NRC disagrees that the rule language in 10 CFR 53.1279(c)(1) needs to be changed to cover "shipping to or from the site," as this level of detail can be covered in associated guidance. Moreover, because the requirements governing the shipment of a damaged reactor may depend on the condition of the reactor and may involve requirements in other regulations, expanding the rule at this time to include shipping from the site may not be appropriate. The NRC is responding to the ADVANCE Act and EOs issued in 2025 by developing an additional rulemaking to expedite licensing qualified microreactors and other potentially low risk, low consequence reactors. This activity, along with other NRC guidance development activities, are intended to address questions such as those raised by the comments.

The comment asked whether revisions should be made to the language in 10 CFR 53.1288(a)(2) related to modifications to the design of a manufactured reactor imposed by the Commission under 10 CFR 53.1288(a)(1). The Commission would only impose such modifications for one of two reasons. The first reason would be if the Commission determined that the modification was necessary to bring the design or manufacture of the reactor into compliance with NRC requirements that were in effect at the time the ML was issued. The second reason would be to provide reasonable assurance of adequate protection to public health and safety or common defense and security. Therefore, it would be necessary to apply such modifications, as described in 10 CFR 53.1288(a)(2), to all the subject manufactured reactors, including those that have already been transported to the site where the reactor was to be operated.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.O: Referencing 10 CFR 53.1372(b) and 10 CFR 53.1419(a)(2), a commenter asked what are “availability controls” (TG14-0001).

NRC Response: The NRC acknowledges this comment.

Availability controls are controls on plant operations to ensure that the configurations and special treatments for SR SSCs and NSRSS SSCs provide the capabilities, availability, and reliability consistent with meeting the safety criteria under 10 CFR 53.220 and the analyses of LBEs other than DBAs under 10 CFR 53.450(e). The comment did not suggest any changes to the rule language.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.P: Referencing 10 CFR 53.1470, a commenter asked what the criteria is for determining “sufficiently detailed and complete” in order to qualify for “without reopening or repeating the review” given no design will ever be completely “identical” (RD-0028).

NRC Response: The NRC acknowledges this comment.

The NRC understands the commenter to be asking about phrases that come from the definition of standard design in 10 CFR 53.020, such as “sufficiently detailed and compete” and “without reopening or repeating the review,” in the context of 10 CFR 53.1470. However, in 10 CFR Part 53, the definition of “standard design” supports the use of the term in provisions related to standard design approvals and standard design certifications. Whereas, in 10 CFR 53.1470, the NRC provides optional requirements related to the submittal and NRC review of CP, OL, and COL applications to construct and operate commercial nuclear plants of identical design at multiple sites, similar to requirements found in Appendix N in both 10 CFR Parts 50 and 52.

In 10 CFR 53.1470, the term “common design” is used to describe that portion of the facility design that is common to all applications being submitted together under this provision. In Section VI, “Specific Requests for Comment,” of the 10 CFR Part 53 proposed rule, the NRC asked for comments on whether there are opportunities to allow added flexibility for applicants under the provisions in 10 CFR 53.1470, including consideration of whether applications for which the “common design” is not completely identical could be evaluated under this provision and, if so, what the process would be for determining the appropriateness of a common review. See Section 3.8.4 of this document for comments pertaining to this request and the NRC response to those comments.

Accordingly, the NRC did not change the rule language in response to this question.

Comment Bin 3.8.1.Q: In 10 CFR 53.1416, a commenter asked what constitutes “identical” and how it is determined, and if there is any degree of variation possible (RD-0029).

NRC Response: The NRC acknowledges this comment.

In 10 CFR 53.1470, the NRC provides optional requirements related to the submittal and NRC review of CP, OL, and COL applications to construct and operate commercial nuclear plants of identical design (the “common design”) at multiple sites, similar to requirements found in appendix N in both 10 CFR Parts 50 and 52. Paragraph (c) of 10 CFR 53.1470 requires that each application identify the common design, and that the FSAR either incorporate by reference or include the common design. This requirement ensures that there will be a single physical FSAR document that may be utilized by the NRC and viewed by members of the public. For this reason, whatever portions of the facility constitute the “common design” must be identical. The meaning of “identical” in this context is the plain language meaning of the term (i.e., “the same” or “similar in every detail”).

Relatedly, in Section VI, “Specific Requests for Comment,” of the 10 CFR Part 53 proposed rule, the NRC asked for comments on whether there are opportunities to allow added flexibility for applicants under the provisions in 10 CFR 53.1470, including consideration of whether applications for which the “common design” is not completely identical could be evaluated under this provision and, if so, what the process would be for determining the appropriateness of a common review. See Comment Bin 3.8.4.A of this document for comments pertaining to this request and the NRC’s response to those comments. This comment suggests no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.R: A commenter wrote that 10 CFR 53.1209, 53.1239, 53.1309(a)(2), 53.1369(b), and 53.1416(a)(2) are based on the PRA-based approach addressed in the LMP and do not permit use of other risk-informed approaches or more traditional approaches that may be more appropriate for very simple designs (NEI2-0126, NEI2-0133, NEI2-0134, NEI2-0135).

For 10 CFR 53.1209, a commenter stated that design certifications have traditionally been for a single unit and suggested that multi-unit considerations be left to CPs, OLs, and COLs. The commenter wrote that 10 CFR 53.1209 and 10 CFR 53.1239 should be revised to permit the use of other risk-informed approaches, and that 10 CFR 53.1239[(a)](16) should be removed (NEI2-0126).

For 10 CFR 53.1309(a)(2), the commenter wrote that the level of detail required is not consistent with a preliminary SAR, and in 10 CFR 53.1309(a)(2)(ii) it is not clear what aspects of the design staff would accept as preliminary. The commenter suggested that 10 CFR 53.1309 be revised to introduce the “preliminary” nature of the design adequate for a CP review, consistent with 10 CFR 50.34.

The commenter also suggested that issuance of a CP as described in 10 CFR 53.1333 should be consistent with 10 CFR 50.35. The commenter said that 10 CFR 53.1309 should be revised to permit use of other risk-informed and more traditional approaches; revisions to 10 CFR 53.1309 should also address conforming changes on planned research, and programmatic controls; and references to 10 CFR 53.1279[1239(a)](24) should be removed (NEI2-0133).

For 10 CFR 53.1369, the commenter wrote that requirements for integrity assessment programs under 10 CFR 53.1369(d) should be removed, 10 CFR 53.1369(g) is duplicative of 10 CFR 53.1239[(a)](27), 10 CFR 53.1369(c) is duplicative of 10 CFR 53.1239[(a)](25), 10 CFR 53.1369(d) is duplicative of 10 CFR 53.1239[(a)](13), 10 CFR 53.1369(e) and (n) is duplicative of 10 CFR 53.1239[(a)](14), 10 CFR 53.1369(l) is duplicative of 10 CFR 53.1239[(a)](22), and 10 CFR 53.1369(aa) is duplicative of 10 CFR 53.1239[(a)](26). The commenter wrote that 10 CFR 53.1369(b) should be revised to permit use of other risk-informed and more traditional approaches (NEI2-0134).

For 10 CFR 53.1416(a)(2), the commenter wrote that requirements for integrity assessment programs under 10 CFR 53.1416(a)(4) should be removed, 10 CFR 53.1416(a)(3) is duplicative of 10 CFR 53.1239[(a)](25), 10 CFR 53.1416(a)(7) is duplicative of 10 CFR 53.1239[(a)](27), 10 CFR 53.1416(a)(14) is duplicative of 10 CFR 53.1239[(a)](14), 10 CFR 53.1416(a)(12) is duplicative of 10 CFR 53.1239[(a)](22), and 10 CFR 53.1416(a)(25) is duplicative of 10 CFR 53.1239[(a)](26). The commenter wrote that 10 CFR 53.1416(a)(2) should be revised to permit use of other risk-informed and more traditional approaches (NEI2-0135).

NRC Response: The NRC agrees, in part, with these comments.

Regarding the statement that certain provisions in Subpart H of 10 CFR Part 53 are based on the PRA-based approach addressed in the LMP and do not permit use of other risk-informed approaches or more traditional approaches that may be more appropriate for very simple designs, see the NRC’s response to Comment Bin 3.3.2.2.E.

The NRC disagrees that design certifications have traditionally been for a single unit and that multi-unit considerations be left to CPs, OLs, and COLs. The most recent design certified by the NRC for the NuScale design in Appendix G to 10 CFR Part 52 is a multi-unit design. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC disagrees that additional rule text is needed in 10 CFR 53.1309 to further detail NRC expectations for the level of detail in CP applications. The NRC will provide regulatory guidance on the level of detail for CP applications under 10 CFR Part 53. The comment referred to 10 CFR 50.34 as a model for the level of detail desired. However, that regulation supports the prescriptive, deterministic nature of the regulatory framework under 10 CFR Part 50, and many of its provisions are not appropriate for the technology-inclusive, risk-informed, and performance-based regulatory framework under 10 CFR Part 53.

The NRC agrees that issuance of a CP as described in 10 CFR Part 53 should be consistent with 10 CFR 50.35 but disagrees that changes to the rule are needed to achieve this. The provisions in 10 CFR 53.1333(a) and (b) combined with those in 10 CFR 53.1336 form the equivalent of the technically relevant portions of 10 CFR 50.35 related to issuance of a CP.

The NRC agrees that the reference in 10 CFR 53.1309 to 10 CFR 53.1239(a)(24) for interface requirements should be removed in so far as it is not relevant for a CP application. Accordingly, the NRC has revised the rule language in response to this comment. Specifically, the NRC has deleted the reference to 10 CFR 53.1239(a)(24) in 10 CFR 53.1309(a)(2).

The NRC disagrees that requirements for integrity assessment programs under 10 CFR 53.1369(d) and 10 CFR 53.1416(a)(4) should be removed for the reasons stated in response to Comment Bin 3.6.3.4.A. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC agrees, in part, that certain provisions in 10 CFR 53.1369 and 10 CFR 53.1416 are duplicative. The NRC has also reviewed other sections in Subpart H for duplication of requirements.

Accordingly, the NRC has revised the rule language in response to this comment. Specifically, in 10 CFR 53.1279, the NRC has deleted references to 10 CFR 53.1239(a)(22) (QA) and (a)(24) (interface requirements) because other paragraphs within 10 CFR 53.1279 cover these requirements. Also, in 10 CFR 53.1309, the NRC deleted the reference to 10 CFR 53.1239(a)(22) (QA) and 53.1239(a)(25) (technical qualifications) because other paragraphs within 53.1309 covers these requirements.

The NRC also deleted the reference to 10 CFR 53.1239(a)(24) (interface requirements) because this requirement is not applicable to CP applicants, as the commenter pointed out. In 10 CFR 53.1369, the NRC has deleted references to 10 CFR 53.1239(a)(27) (10 CFR 53.1369(g) covers Role of Personnel), 10 CFR 53.1239(a)(13) (10 CFR 53.1369(d) covers the Integrity Assessment Program), 10 CFR 53.1239(a)(24) (not applicable to OLs), and 10 CFR 53.1369(c) on Technical Qualifications (duplicative of 53.1239(a)(25)).

In addition, in 10 CFR 53.1416, the NRC has deleted reference to 10 CFR 53.1239(a)(13), (a)(22), (a)(25), (a)(26), and (a)(27) because they are duplicative of other requirements in 10 CFR 53.1416 or are not applicable at the COL stage. The NRC has also deleted the reference to 10 CFR 53.1239(a)(14) in partial agreement with Comment Bin 3.3.2.1.E.

Comment Bin 3.8.1.S: Regarding 10 CFR 53.1103, a commenter wrote that there is no guidance on how applications and licenses could be combined or how this could be achieved. The commenter asked what kinds of licenses and which elements are combinable. The commenter wrote that the aim should be for one license to cover the entire facility design, construction and operation, and by inclusion multiple units. The commenter wrote that design certification and issuance of construction and operating permits and licenses should “preferably be as practiced and enforced in the airline industry and internationally agreed as far as possible via ‘type certification’ rather than using ‘design authorization/licensing’ and Improvements” (RD-0006).

NRC Response: The NRC agrees, in part, with this comment.

The NRC understands the comment to be asking how applications and licenses can be combined under 10 CFR 53.1103. The provisions in 10 CFR 53.1103 address combining applications and are equivalent to existing requirements in 10 CFR 50.31, 50.52, and 52.8. The provisions in 10 CFR 53.1103(a) provide that an application may be combined with applications for different licenses in other parts of 10 CFR Chapter I and 10 CFR 53.1103(b) would continue the Commission's practice of combining multiple authorizations for a facility under 10 CFR Parts 30, 40, 50, 53, and 70 into one license based on the Commission's authority under section 161h of the AEA to combine NRC licenses.

The NRC agrees that it is possible for one license to cover the facility design, construction, and operation, and, possibly, multiple units. The NRC disagrees that it should restructure the design certification and issuance of CPs and operating licenses (or COLs) to "preferably be as practiced and enforced in the airline industry and internationally agreed as far as possible via 'type certification.'" The licensing framework for U.S. commercial nuclear power reactors stems from the requirements of the AEA and is reflected in NRC regulations. Those regulations, found in 10 CFR Parts 50 and 52, and now also in 10 CFR Part 53, provide tremendous flexibility for applicants to choose a licensing pathway that best fits their needs.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.T: A commenter said that a limit on information requests similar to 10 CFR 52.39(f) should be included in 10 CFR 53.1188 to ensure similar rigor in evaluating information requests before they are issued (NEI2-0123).

NRC Response: The NRC agrees, in part, with this comment.

The NRC agrees that a limit on information requests similar to 10 CFR 52.39(f) should be included in 10 CFR Part 53 to ensure rigor in evaluating information requests before they are issued. However, the NRC disagrees that 10 CFR 53.1188 should be modified to include such a provision because a provision covering this requirement, similar to 10 CFR 52.39(f), already exists in 10 CFR 53.1580. Note for clarity that the 10 CFR Part 53 definition of "license" in 10 CFR 53.020 already includes ESPs, and thus ESPs are also included in 10 CFR 53.1580.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.U: A commenter discussed inconsistencies in application filing requirements both within 10 CFR Part 53 and between 10 CFR Parts 52 and 53. First, the commenter said that 10 CFR 53.1203 is essentially identical to 10 CFR 52.135 except for paragraphs (b) and (c). Next, the commenter said that 10 CFR 53.1100(a)(1) also contains requirements that are similar to those in 10 CFR 52.135(b), and the fees requirements in 10 CFR 52.1100(e) are captured under 10 CFR 52.135(c). The commenter said that there is further inconsistency in Subpart H in that paragraphs addressing filing of applications appear in 10 CFR 53.1143 for ESPs, 10 CFR 53.1203 for SDAs, 10 CFR 53.1233 for DCs, and 10 CFR 53.1273 for MLs, but does not appear for CPs, OLs, or CLs. The commenter stated that these inconsistencies contribute to a lack of clarity on filing requirements. To resolve these issues, the commenter said that the NRC should move all filing requirements into 10 CFR 53.1100, removing them from the other sections in Subpart H. The commenter also stated that an alternative is to keep the current section structure but include the section on filing of applications for every application type and make the language consistent (NEI2-0124).

NRC Response: The NRC agrees with this comment.

Accordingly, the NRC has revised the rule language in response to this comment. Specifically, the NRC has moved the filing requirements from proposed 10 CFR 53.1143, 53.1203, 53.1233, and 53.1273 to 10 CFR 53.1100(a) and made the appropriate conforming changes where references to those proposed rule sections appeared.

Comment Bin 3.8.1.V: A commenter said that 10 CFR 53.1209(a) includes “general expectations” on submitting “major portions” of a design for an SDA. The commenter said that the implementation of the requirements in this section, given the PRA-based requirements in the balance of 10 CFR 53.1209, warrant further explanation and guidance. The commenter recommended limiting the requirement in 10 CFR 53.1209(a) to design criteria and removing requirements to the PRA. The commenter also suggested that NRC develop regulatory guidance and examples, potentially including tabletop exercises, to clarify implementation of the expectations for approving major portions of an SDA (NEI2-0125).

NRC Response: The NRC agrees, in part, with this comment.

The NRC disagrees with limiting the requirement in 10 CFR 53.1209(a) to design criteria and removing requirements related to the PRA. However, consistent with the NRC’s response to comments suggesting that 10 CFR Part 53 allow for risk evaluations other than PRA (see Comment Bin 3.3.2.2.E), the requirement in 10 CFR 53.1239(a)(18) that is applicable to SDAs is being revised to require a description of the PRA, other SREs, or combination thereof required by 10 CFR 53.450(a) and associated results. The NRC agrees that developing additional regulatory guidance related to major portions of an SDA could be useful and is willing to work with stakeholders further to determine the need for and appropriate prioritization of such guidance.

Accordingly, the NRC has revised the rule language in response to comments in Comment Bin 3.3.2.2.E but did not revise the rule further in response to this comment.

Comment Bin 3.8.1.W: A commenter said that 10 CFR 53.1221 is essentially identical to 10 CFR 52.145. However, the commenter stated that 10 CFR 52.145 does not include a provision akin to 10 CFR 53.1221(d), which states in part, “The Commission will require, before granting a construction permit, combined license, operating license, or manufacturing license which references a standard design approval, that information supporting required design and analysis application content be completed and available for audit if the information is necessary for the Commission to make its safety determination." The commenter said that similar language also appears in other 10 CFR Part 53 paragraphs such as 10 CFR 53.1239, 10 CFR 53.1221, 10 CFR 53.1254(a), 10 CFR 53.1263(c), 10 CFR 53.1416(a), and 10 CFR 53.1263(c). Additionally, the commenter said that language in 10 CFR 53.1221(d) and 10 CFR 53.1263(c) makes clear that for CPs, OLs, COLs, or MLs referencing an SDA or DC, the Commission will require this information. The commenter said that this language is included for the other application types, whether or not they reference an SDA or DC. To resolve inconsistencies, the commenter recommended that the NRC revise Subpart H to include the noted language in a consistent manner. Additionally, the commenter said that the requirement is used inconsistently in Subpart H, and it should be resolved so that, if incorporated, the language appears in the same paragraph for each application type (NEI2-0127).

NRC Response: The NRC agrees, in part, with this comment.

The NRC agrees with the suggestion to revise Subpart H to include the noted language in a more consistent manner. The NRC disagrees with the suggestion that the language appear in the same paragraph for each application type. The cited rule text appears in different locations within Subpart H of 10 CFR Part 53 because it serves different purposes depending on its location. In cases where the cited text appears within a paragraph related to the required content of an application (i.e., 10 CFR 53.1239 and 10 CFR 53.1416), including an application for renewal (i.e., 10 CFR 53.1254(a)), the subject requirement indicates that the Commission will require certain information be complete and available for audit if such information is necessary for the NRC to make its safety determination on that application.

In other cases where the cited text appears with a paragraph related to the finality of a particular NRC certification or approval (i.e., 10 CFR 53.1221(d) and 10 CFR 53.1263(c)), the subject requirement indicates that the Commission will require certain information be complete and available for audit if such information is necessary for the NRC to verify the information in the application referencing the subject certification or approval and make its safety determination on that application, including the determination that the application is consistent with the certification or approval information being referenced.

Accordingly, the NRC has revised the rule language in response to this comment. Specifically, the NRC is rewording 10 CFR 53.1221(d), 10 CFR 53.1254(a), and 10 CFR 53.1416(a) to be consistent with the wording of similar provisions in 10 CFR 53.1239 and 10 CFR 53.1263(c).

Comment Bin 3.8.1.X: Two commenters said that 10 CFR 53.1251(a) and 10 CFR 53.1260 both state that a DC should be valid for no more than 15 years, but in SRM-COMDAW-24-0001, "Revising the Duration of Design Certifications, Memorandum to Commissioner Wright," issued November 2024 (ML24319A227), the Commission approved extending the duration of a DC to 40 years. The commenters suggested that 10 CFR Part 53 be revised to be consistent with this direction, and DCs should be able to be issued to be valid for 40 years (NEI2-0128, WEST1-0016).

The commenters also said that 10 CFR 53.1291 states that an ML is valid for no more than 15 years, but in SRM-SECY-22-0052, "Proposed Rule: Alignment of Licensing Processes and Lessons Learned From New Reactor Licensing," issued November 2024 (ML24326A003), the Commission approved extending the duration of MLs to 40 years. The commenters suggested that 10 CFR Part 53 be consistent with the 40-year duration (NEI2-0130, WEST1-0016, NEI2-0184, NEI2-0186).

NRC Response: The NRC agrees with these comments.

Accordingly, the NRC has revised the rule language to extend the duration of design certifications and manufacturing licenses from 15 to 40 years in response to these comments.

Comment Bin 3.8.1.Y: A commenter wrote that the requirements in 10 CFR 53.1279 are based on the PRA-based approach addressed in the LMP and do not permit use of other risk-informed approaches that may be more appropriate for very simple designs. The commenter said that 10 CFR 53.1279 should be revised to permit use of other risk-informed approaches, and that NRC should remove reference to 10 CFR 53.1239(16) (NEI2-0129).

NRC Response: The NRC agrees, in part, with this comment.

Regarding the comment that 10 CFR 53.1279 should be updated to allow flexibility in the use of PRA, see the NRC's response to Comment Bin 3.3.2.2.E. In response to those comments, the NRC has revised 10 CFR 53.1239(a)(18) (which is referenced in 10 CFR 53.1279) to be consistent with changes made to 10 CFR 53.450(a) allowing the use of a PRA, other SREs, or combination thereof.

The NRC interprets the comment that the NRC should remove the reference in 10 CFR 53.1279 to 10 CFR 53.1239(16) to be a suggestion to remove the reference to 10 CFR 53.1239(a)(16). The NRC disagrees with this portion of the comment. If the ML application is not for a design that is for a "multi-unit commercial nuclear plant," then this requirement would not apply. If it is, then the requirement is just as applicable to an ML application as it is to a DC application, since both are an approval of the facility design.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.Z: A commenter said that proposed 10 CFR Part 53 does not appear to give holders of an ML authority to make changes to the ML similar to the requirements in 10 CFR 52.171(b)(1) and suggested that NRC add a provision to the rule language allowing this (NEI2-0131).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that 10 CFR Part 53 should give holders of an ML the authority to make changes to the ML and has expanded the provisions in 10 CFR 53.1530 to give ML holders more flexibility in this regard. However, the NRC notes that a provision equivalent to 10 CFR 52.171(b)(1) was already included in proposed 10 CFR 53.1530(a), and that provision is being revised in the final rule in response to other public comments (see Comment Bin 3.9.3.B) to provide a more flexible change process.

Accordingly, the NRC did not make additional changes to the rule in response to this comment.

Comment Bin 3.8.1.AA: A commenter wrote that the life cycle for the deployment and design of MLs involves a number of regulations touching on management and transportation of new and used fuel, construction and operating licenses on specific sites, and decommissioning that have not been harmonized with 10 CFR Part 53. The commenter said that the NRC should provide the scope and proposed schedule for resolution of regulations affected by and invoked in 10 CFR Part 53, particularly those related to MLs (NYS2-0022).

NRC Response: The NRC disagrees with the comment.

The NRC disagrees that regulations invoked in the 10 CFR Part 53 provisions affecting MLs have not been harmonized with 10 CFR Part 53. The NRC included necessary conforming changes, including changes to 10 CFR Parts 30, 40, 50, 70, 73, and 74 in this rulemaking.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.BB: A commenter wrote that they are concerned that in the future, 10 CFR Part 53 will be reconciled with 10 CFR Parts 50 and 52 causing "problematic aspects" of 10 CFR Part 53 to be mandated, which could cause regulatory instability (NRC-2019-0446-0005).

NRC Response: The NRC disagrees with this comment. The NRC has no plans for a future rulemaking to "reconcile" 10 CFR Part 53 with 10 CFR Parts 50 and 52 for the purpose of mandating that aspects of 10 CFR Part 53 requirements be imposed on applicants and licensees under 10 CFR Parts 50 and 52.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.CC: A commenter said that 10 CFR 53.1306 should include references to 10 CFR 53.1660 through 10 CFR 53.1700 which set out the requirements and procedures related to financial qualifications and related reporting requirements (NEI2-0132).

NRC Response: The NRC agrees, in part, with this comment.

The NRC agrees that additional information about financial qualification requirements in 10 CFR 53.1306 will help to increase clarity. In this regard, the NRC has revised 10 CFR 53.1306 in response to other comments regarding financial qualification requirements (see the NRC's response to Comment Bin 3.10.2.C).

The NRC disagrees that 10 CFR 53.1306 should include references to 10 CFR 53.1660 through 10 CFR 53.1700. The provisions in 10 CFR 53.1306 provide the requirements related to the content of CP applications, including information demonstrating that the applicant appears to be financially qualified. The provisions in 10 CFR 53.1660 through 10 CFR 53.1700 provide the substantive requirement that an applicant must appear to be financially qualified as well as reporting requirements and creditor regulations. The NRC does not believe it is necessary to provide references to these requirements in 10 CFR 53.1306 or any of the other content of application provisions requiring information related to financial qualifications.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.1.DD: A commenter said that the PRA discussion in 10 CFR 53.1309 is helpful but should provide more information. For example, the commenter said that guidance should be clear that only a Full Power Internal Events PRA is required at the CP stage, consistent with RG 1.253 (NEI2-0024).

NRC Response: The NRC disagrees with the comment. It would be inconsistent to have the level of detail suggested by the comment in the rule language for 10 CFR Part 53 applicants when it is in guidance for applicants under 10 CFR Parts 50 and 52.

Accordingly, the NRC did not change the rule language in response to this comment.

3.8.2. Comments on fuel loading requirements in Subpart H (§§ 53.1279-53.1287, and 53.1452)

No comments are associated with this issue.

3.8.3. Other comments on Subpart H requirements not related to RFC

Comment Bin 3.8.3.A: A commenter said that for Subpart H, the approach of referencing the detailed technical requirements for the various application types to those in the technical requirements for a design certification has been a major improvement. However, the commenter said that the length and complexity of Subpart H may lead to a reduction in regulatory clarity and introduce the potential for similar requirements having unintended differences. The commenter recommended that NRC streamline the requirements in Subpart H (NEI2-0121).

NRC Response: The NRC agrees, in part, with the comment.

The NRC has revised and streamlined Subpart H to some degree based on specific comments provided on this subpart but has not undertaken an independent reassessment of opportunities for further streamlining in light of the importance of having the requirements for each licensing instrument clearly stated.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.3.B: A commenter suggested that the NRC introduce a new provision into 10 CFR 53.500 to formalize preapplication processes. The commenter provided suggested language including encouragement of early engagement between the Commission and applicants (BI1-0017).

NRC Response: The NRC disagrees with the comment.

Regulatory requirements are not an appropriate vehicle for providing encouragement of early engagement between the NRC and an entity planning to submit an application. While early engagement with the NRC leading up to the submittal of an application may allow the NRC to gain a better understanding of an application and foster a more efficient review, such preapplication activities are, by definition, outside the scope of NRC-regulated activities, which commence when the application is filed.

Accordingly, the NRC did not change the rule language in response to this comment.

3.8.4. <u>RFC: Licenses to construct and operate commercial nuclear plants of identical design at multiple sites (§ 53.1470)</u>

Comment Bin 3.8.4.A: Two commenters wrote that they support efforts to identify opportunities for added flexibility in the 10 CFR 53.1470 process. The commenters stated that flexibility in this process is important given: 1) NRC's and the industry's ongoing work related to nth-of-a-kind microreactors and other advanced reactors that may be rapidly deployed in high volumes in remote applications (RHDRA); and 2) certain provisions in the ADVANCE Act aimed at improving the efficiency of the NRC's new reactor licensing process (NEI2-0207, USNIC2-0034).

One of the commenters said that, in a previous RHDRA proposal paper, they identified the Appendix N process as a potential tool to reduce schedule and cost risks associated with licensing review for each site-specific RHDRA applications. In particular, the paper identified the need for a rapid efficient and repeatable licensing process that can achieve 6-month deployment times by:

> completing all, or as much as possible, of the safety and environmental reviews and public engagement processes at one-time, prior to the identification of a specific site, and
>
> performing a simplified site license application review that focuses on verifying that the site characteristics, which are based on pre-existing generic data as much as possible, conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews.

The commenter wrote that some individual applicants may seek to deploy numerous microreactors and RHDRA to a given area in a relatively short time, the requirements in 10 CFR 53.1470 could be useful in fulfilling this objective. The commenter also cautioned that some of these efficiencies could be useful for any new reactor application and is not limited solely to microreactors.

The commenter suggested that 10 CFR 53.1470 be modified to allow for the possibility of staggered license applications. The commenter wrote that this section is based on the Appendix N process in 10 CFR Parts 50 and 52, which was developed with large-risk LWRs in mind. Given this, the commenter specifically highlighted that the text "[e]ach application must list each of the other applications to be treated together under this section" should be modified to allow for the staggered or sequential submittal of applications that will rely on a common design, perhaps over a specified time frame such as 12 or 18 months.

Additionally, the commenter wrote that the Commission's "Policy Statement on the Regulation of Advanced Reactors," issued October 2008 (ML082750370) suggests it intends for the "common design" in Appendix N to 10 CFR Part 52 to be applied in a flexible manner. Specifically, the commenter suggested that this should include the possibility of sequential or staggered license applications, as well as potential variances or exemptions from design certifications (or other NRC generic approvals) and revisions to specific applications (NEI2-0207).

Another commenter recommended revising 10 CFR 53.1470 to provide flexibility in the review process for "common designs" that are not fully identical in order to support the efficient licensing and deployment of advanced reactors. The commenter recommended allowing staggered submissions which they said would balance regulatory efficiency with industry flexibility and ensure that lessons learned from earlier reviews can be incorporated into subsequent applications, improving regulatory outcomes while reducing redundant NRC efforts.

Specifically, the commenter recommended allowing applications for "common designs" that are not completely identical to be reviewed under this provision. This could include minor variations related to site-specific conditions or operational optimizations. The commenter suggested revising the rule language as follows:

> Applications for commercial nuclear plants with a 'common design' that are not fully identical may be reviewed under this provision, provided the applicant demonstrates that deviations are minor, site-specific, or do not significantly increase the risk or safety performance of the design, or reduce safety margins below accepted levels. The NRC shall evaluate such applications against performance-based thresholds specified in subpart [X].

The commenter also recommended allowing applicants to submit applications on a staggered basis while maintaining the option for simultaneous submissions. The commenter suggested revising the rule language as follows (BI1-0009):

> Applicants may submit applications under this provision on a staggered basis. The applicant should list all intended applications in the initial submission and that the applicant provides a roadmap detailing the intended submission sequence and integration of NRC feedback from earlier reviews to the extent practical.

Regarding 10 CFR 53.1470, another commenter wrote that metrics for single and multi-unit sites should be the same as risk is measured and quantified by probability. The commenter wrote that the language pinpointing "identical design" should be removed and suggested replacing it with "incremental changes in already-licensed 'standard design' that lead to enhance safety and performance will not lead to extensive additional, repeated or already submitted licensing requirements, or negatively impact existing approved or licensed builds" (RD-0013).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees with modifying 10 CFR 53.1470 to allow for the possibility of staggered license applications. One comment noted that the Commission's 2008 Policy Statement suggests it intends for the "common design" in Appendix N to 10 CFR Part 52 to be applied in a flexible manner. The NRC expects to apply this Policy Statement in a similar manner to applications submitted under 10 CFR 53.1470. Accordingly, the NRC has revised the rule language in response to this comment. Specifically, the NRC has revised the last sentence in 10 CFR 53.1470(b) to allow each application under this section to either list each of the other applications to be treated together under the section or specify that such other applications will be submitted to the NRC within 12 months of submittal of the first application.

The NRC disagrees that rule language changes should provide flexibility in the review process for "common designs" that are not fully identical. The provisions under 10 CFR 53.1470 require that the design of facility described in separate applications be identical in order for the Commission to treat those applications under Subpart D of 10 CFR Part 2, which provides adjudicatory efficiencies for reviewing multiple, “identical,” designs. The potential benefits of the staff conducting its safety reviews using this “design-centered” approach, in which multiple applicants would apply for licenses for plants of identical design at different sites, include consolidation of issues common to such applications before a single Atomic Safety and Licensing Board. The FSAR for each application must either incorporate by reference or include the final safety analysis of the common design, including, if applicable, the FSAR for the referenced standard design certification, SDA, or manufactured reactor. Hence, the applicants can control the portion of the design they wish to identify as the “common design,” but that portion needs to be identical for the benefits of this process to be realized. Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.4.B: A commenter wrote that they are concerned about the potential cumulative impacts from multiple reactor modules being installed over time at the same site, and it is not clear how the NRC would evaluate multi-module reactor designs. The commenter suggested that the NRC should provide clarity on how and when risk-informed performance-based processes will evaluate multi-unit sites (NYS2-0023).

NRC Response: The NRC acknowledges the comment.

The NRC understands the comment to be requesting information on how 10 CFR Part 53 addresses multi-unit sites. This issue is addressed in several provisions in 10 CFR Part 53. For example, the definition of “*Commercial nuclear plant*” in 10 CFR 53.020 states that it is a facility *consisting of one or more commercial nuclear reactors* [emphasis added]. Paragraph (i) of 10 CFR 53.440 requires that the design, analysis, staffing, and programmatic controls for each commercial nuclear plant consider the number of reactors, waste stores, and other significant inventories of radioactive materials and the associated operating configurations, common systems, system interfaces, and system interactions. In 10 CFR 53.610, paragraph (b)(1)(ii) requires that, for construction of a commercial nuclear plant involving multiple reactor units, plans and procedures must be in place to prevent or mitigate potential hazards to the SSCs of operating units resulting from construction activities. Applicants for licenses, certifications, and approvals under 10 CFR Part 53 must describe in any application for a multi-unit commercial nuclear plant the programmatic controls and interfaces for different modular configurations, including any restrictions that will be necessary during the construction and startup of any given unit to ensure the safe operation of the overall commercial nuclear plant to be licensed under 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

3.8.5. <u>RFC: Allowing OL or CP holders to reference an ML</u>

Comment Bin 3.8.5.A: Multiple commenters wrote that an applicant for or a holder of a CP or OL should be allowed to reference an ML (NEI2-0185, SCWG-0018, RAD-0004).

One of the commenters said that if a provision to reference an ML in a CP application is provided, and subsequent construction is managed while an OL is reviewed and issued, there would need to be provision for managing the ITAAC requirements in the ML in an alternative fashion (e.g., those inspections, tests, and analyses being incorporated into a site's construction quality assurance program and general NRC construction oversight, but not used as a license condition requiring closure notification and associated finding). Based on industry concepts, the commenter said that there are deployment scenarios where use of the CP and OL licensing approach would provide benefit in efficiently organizing regulatory decisions with site-specific work, which still presumed use of an ML largely for perceived administrative challenges in ITAAC management (NEI2-0185).

NRC Response: The NRC agrees in part with the comments.

The proposed rule only addressed COL applicants referencing an ML to simplify the provisions for licensing and deploying manufactured reactors. In response to the request for comment, some commenters suggested that there may be circumstances where the deployment of manufactured reactors could use the CP and OL licensing pathway and applicants could propose a means to reference an ML and address the associated ITAAC. While acknowledging that introducing the concept of manufactured reactors into the traditional two-step licensing process could be challenging for the factory fabrication model being considered by some potential applicants, including the allowance in 10 CFR 53.620(d) to load fuel in the factory, the NRC revised 10 CFR 53.1124 in the final rule to include the possible relationship of CP applications referencing an ML. The NRC has not included specific provisions within 10 CFR Part 53 outlining how this licensing pathway would be implemented, including how ITAAC required for an ML under 10 CFR 53.1282 would be addressed, but instead leaves the matter open to possible approaches to be addressed in future regulatory guidance or proposed by future applicants.

Accordingly, the NRC revised the rule language in 10 CFR 53.1124 in response to these comments and made conforming changes in other affected sections of the final rule.

3.8.6. <u>RFC: Timeline for beginning manufacture before license expiration (§ 53.1295)</u>

Comment Bin 3.8.6.A: Two commenters recommended revising the restriction on when manufacturing activities can begin under 10 CFR Part 52 from 3 years to 6 months (SCWG-0019, RAD-0005). One commenter wrote that this change would recognize the shorter lead times developers are estimating and planning for when building advanced reactors under an ML (RAD-0005).

NRC Response: The NRC agrees, in part, with these comments.

The comments are supportive of the provision in 10 CFR 53.1295 stating that the holder of an ML could not begin manufacture of a manufactured reactor less than 6 months before the expiration of the license. The 6-month time period used in the proposed 10 CFR Part 53 was in contrast to a 3-year time period used in 10 CFR Part 52. However, as described in the response to Comment Bin 3.8.6.B, the NRC has revised the final rule to delete any time limit related to beginning manufacturing in relation to the expiration of the manufacturing license. Regarding the suggestion to revise the wording in 10 CFR Part 52, the NRC will consider such reconciliation of requirements within the various parts of its regulations as part of a future activity.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.6.B: A commenter said that 6 months may be an appropriate timeline for when manufacturing activities can begin under 10 CFR Part 52 but may not be the most relevant metric. The commenter said that the more important question is whether the ML holder can go into a timely renewal period allowing continued possession of the SNM while the license renewal is under review. The commenter said that rather than a discrete temporal limit, the renewal activity could be managed with generic timely renewal period language or as a license condition based on the ML's specific technology implementation (NEI2-0186).

NRC Response: The NRC agrees with the comment.

The NRC agrees that the 6-month provision in proposed 10 CFR 53.1295 would likely have been appropriate in most circumstances but that it is preferrable to delete the temporal limit in favor of more generic rule language or the use of license conditions for MLs, as needed. The 6-month restriction in the 10 CFR Part 53 proposed rule was put in place to mirror the existing 3-year provision in 10 CFR 52.177, while adding flexibility to address potential advanced reactors that may have much shorter manufacturing timelines than those envisioned under 10 CFR Part 52. In the 2007 update to 10 CFR Part 52, the Commission explained that this provision was in accordance with the Timely Renewal Doctrine of the Administrative Procedure Act (APA) but noted the Commission's belief that an applicant's reliance upon timely renewal should be rare. Given the extension of the duration of an ML from 15 years under 10 CFR Part 52 to 40 years under 10 CFR Part 53, the submittal of an ML renewal application is itself expected to be a rare occurrence. It follows that the need to rely on timely renewal would be even rarer and codifying a "one-size-fits-all" time period after which manufacturing activities must cease is unlikely to prove beneficial. Such issues are more practically addressed in license conditions for particular MLs, if needed.

Accordingly, the NRC changed the rule language in response to this comment. Specifically, the NRC deleted the proposed rule language in 10 CFR 53.1295(a)(3) prohibiting the holder of an ML from beginning manufacture of a manufactured reactor less than 6 months before the expiration of the license.

3.8.7. RFC: Finality for MLs (§ 53.1288)

Comment Bin 3.8.7.A: A commenter said that it is unclear what requirements are being imposed by 10 CFR Part 53 "for the manufacture of the manufactured reactor" beyond the ability to load fuel in the factory and requirements to maintain subcriticality by "at least two independent physical mechanisms". The commenter stated that there are essentially two safety findings required, one to handle and load SNM under 10 CFR Part 70, and the other related to the safety of the reactor in operation under 10 CFR Part 53. Regarding the finality of reactor design-related matters, the commenter said that the similarity between DC and COL experience would carry into a 10 CFR Part 53-issued ML from the language selected (NEI2-0187).

NRC Response: The NRC agrees with the comment.

The NRC agrees that there would essentially be two safety findings related to a fueled manufactured reactor, one related to the handling of SNM under 10 CFR Part 70 and one related to the safety of the reactor under 10 CFR Part 53. The comment did not suggest changes to the rule language in 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.7.B: A commenter wrote that aligning 10 CFR 53.1288 with 10 CFR 52.171 ensures a stable and predictable framework without introducing unnecessary deviations (SCWG-0020).

NRC Response: The NRC agrees with the comment. The comment did not suggest changes to the rule language in 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

3.8.8. RFC: Financial protection for fueled manufactured reactors

Comment Bin 3.8.8.A: Two commenters said that indemnification under the Price-Anderson Act is warranted to flow directly to MLs necessitating the need for licensees to provide financial protection. However, the commenters stated that the amount of protection required should be commensurate with the factory fabrication activities and limitations preventing criticality (NEI2-0189, USNIC2-0031).

One of the commenters said that existing "CX license holders" provide precedent that may provide benefits in establishing reasonable limits and amounts of financial protection (NEI2-0189).

Another commenter stated that 10 CFR Part 53 should not include amounts of required financial protections for MLs for fueled manufactured reactors because this will be varied for different designs (SCWG-0022).

NRC Response: The NRC agrees, in part, with the comments.

The NRC has not included in 10 CFR Part 53 or 10 CFR Part 140 a specific amount of financial protection for licensees possessing a manufactured reactor loaded with fuel. Instead, section 170, ''Indemnification and Limitation of Liability," of the Price-Anderson Act will be satisfied by including a condition within such licenses that will require the licensee to have and maintain financial protection of such type and in such amounts as the NRC determines appropriate for the specific reactor and fuel designs.

Accordingly, the NRC did not change the rule language in response to these comments.

3.8.9. RFC: Categorization of fueled manufactured reactors as a utilization facility

Comment Bin 3.8.9.A: Several commenters wrote in response to the NRC's request for comment on proposed approaches for finding that a fueled manufactured reactor is not a utilization facility.

A few commenters wrote that the AEA does not define "utilization facility," but rather the AEA defers to the Commission to define it. The commenters highlighted that section 11 of the AEA in defining “utilization facility” uses the term “determined by the Commission” (NEI2-0190, RAD-0007, ROSE-0008).

One of the commenters wrote that in SECY-24-0008 and in the proposed rule, the Commission has proposed that fueling of a reactor in a factory setting requires a utilization facility license. The commenter stated that this conclusion overly complicates the licensing processes that are currently employed. Specifically, the commenter said that loading fuel under a possession and use license under 10 CFR Part 70, transporting fuel under 10 CFR Part 71, and storing used fuel under an independent spent fuel storage installation license under 10 CFR Part 72 can be done without requiring a utilization facility license.

The commenter wrote that the Commission has the authority, through its forthcoming direction to the NRC staff on SECY-24-0008, to clarify as a policy matter that a device specifically designed and controlled to preclude criticality is neither a nuclear reactor nor a utilization facility until such time as it is intentionally manipulated to “sustain nuclear fission in a self-supporting chain reaction”. The commenter stated that they believe 10 CFR Part 70 offers the best and safest framework for preventing inadvertent criticality.

The commenter suggested removing “designed or” from the definition of “commercial nuclear reactor,” writing that this should support a conclusion that the fueled manufactured reactor is not a utilization facility until measures to preclude criticality are removed.

The commenter stated that, absent an explicit Commission policy determination on this issue in response to SECY-24-0008, the 10 CFR Part 53 rulemaking offers a pathway to establish that a utilization facility license is not required, which would simplify the licensing process. The commenter expressed concern that, during the ACRS meeting regarding SECY-24-0008, the Committee appeared to question the purported need to designate a microreactor fueled at a manufacturing facility as a utilization facility. The commenter argued that this matters because the designation of a “vessel containing fuel” as a “utilization facility” ripples into various parts of the life cycle of a factory manufactured or fueled module. The commenter provided a table demonstrating this impact.

The commenter also wrote that it is possible that a facility that fuels a reactor may also be more vertically integrated because some businesses may combine fueling a reactor with a fuel fabrication facility capability that could begin at the early stages of fabrication, and then transition to fueling a factory fabricated module due to the cost of licensing and maintaining an NRC-licensed facility. These types of activities would necessitate a license under 10 CFR Part 70; therefore, requiring a utilization facility license for such facilities provides no safety or security benefit and would impose unnecessary administrative burden. The commenter added this would also be inconsistent with the ADVANCE Act section 208 (NEI2-0190).

One of the commenters wrote that, given this, the NRC should adopt a risk-informed definition of “utilization facility” that excludes low-hazard advanced reactors, including small and mobile reactors. The commenter wrote that the NRC should consider a fueled reactor undergoing testing at the manufacturing facility to be comparable to a test reactor, and distinct from a commercial nuclear reactor that is used to generate electricity, power and/or process heat. The commenter added that commencement of commercial reactor operation should no longer be marked arbitrarily by initial loading of fuel; nor should it be tied to initiating the physical removal of an independent physical mechanism to prevent criticality. Instead, commencement of commercial reactor operation should be defined by the nature of its commercial purpose (RAD-0007).

A commenter wrote that a fueled manufactured reactor with appropriate protections against criticality should not be categorized as a utilization facility. The commenter wrote that criticality is not inherently unsafe, and as a result the NRC should focus on uncontrolled or inadvertent criticality for this class of reactors. Regulations should focus on a performance-based framework that affords flexibility to demonstrate how risks from inadvertent criticality would be effectively managed through design features and/or programmatic controls, commensurate with those risks.

The commenter argued that if 10 CFR Part 53 is sufficiently performance-based and defines “utilization facility” in a manner that departs from convention, then the rule would satisfy NEIMA and the ADVANCE Act. The commenter added that the rulemaking presents a unique opportunity to redefine utilization under 10 CFR Part 50 as well, and the NRC should use this opportunity to streamline attendant requirements. The commenter urged against a separate rulemaking to address this writing that it would not meet the mandate from NEIMA and it would not conform to the NRC’s updated mission (ROSE-0008).

A commenter wrote that a fueled microreactor module with two methods to control criticality or which satisfies the double contingency principle, and is not connected to instrumentation and controls, should not be defined as a nuclear reactor and a utilization facility. The commenter wrote that such a module cannot support a self-sustaining chain reaction and as a result is not capable of making use of SNM in such quantity to be significant to the common defense, security, and health and safety of the public as defined in the AEA. The commenter added that the module should only be considered a utilization facility when one of the two methods to control criticality is removed and it is connected to instrumentation and controls that allows a reactor operator to insert positive reactivity into the core.

The commenter added that there would be numerous benefits to not classifying these types of modules as a nuclear reactor. It would define which physical security requirements in 10 CFR Part 73 would apply, clarify the license needed to receive a used module for defueling and refueling, and, if the module is not defined as a nuclear reactor or utilization facility, it would be clear that the requirements in 10 CFR 73.55 would not apply (WEST1-0006).

A commenter wrote that the lower risk profile of small, fueled manufactured reactors justifies reclassification. The commenter wrote that the NRC should consider a framework where a fueled manufactured reactor, with appropriate protections against criticality, is not automatically classified as a utilization facility, and suggested the NRC further engage stakeholders to determine the appropriate method to implement this (SCWG-0023).

NRC Response: The NRC agrees, in part, with these comments.

The NRC disagrees that 10 CFR Part 53 and the NRC staff proposal approved by the Commission in SRM-SECY-24-0008 overly complicate the licensing processes that are currently employed under 10 CFR Parts 70, 71, and 72 because of the approach taken where fueling of a reactor in a factory setting is integrated with the license for the manufacturing of a utilization facility. Many of the comments suggest delaying the designation of a manufactured reactor as a utilization facility until operations commence at its final place of use. However, the comments do not further explain the proposed relationships between licenses needed to manufacture such a reactor and the materials licenses under 10 CFR Part 70. Although the Commission may have the authority to find that features to prevent criticality support an argument that a particular device configuration involves minimal risks to public health and safety and therefore may not need to be designated as a utilization facility, the NRC did not identify any significant benefit to such an approach given the need to issue the manufacturing license as a utilization facility license under section 103 of the AEA.

Moreover, redefining the term “operation” as opposed to the term “utilization facility” facilitates compliance with other portions of the AEA, including those related to inspections, tests, analysis, and acceptance criteria (ITAAC), because the AEA requires both that ITAAC must be included in a COL for a utilization facility and satisfied prior to operation of the facility—the comments suggesting that the reactor not be considered a utilization facility until operation commences does not support this statutory process. Therefore, regarding the designation of a manufactured reactor loaded with fuel as a utilization facility, the NRC maintained an approach consistent with that described in SECY-24-0008.

For the same reason, the NRC disagrees with the suggestion to change the definition of a commercial nuclear reactor to remove "designed or" to support a conclusion that the fueled manufactured reactor is not a utilization facility until measures to prevent criticality are removed. Regarding the suggestion that the NRC should adopt a definition of utilization facility that excludes low-hazard advanced reactors, the NRC is undertaking a separate rulemaking effort to expedite licensing of qualified microreactors and other potentially low risk, low consequence reactors. This rulemaking effort is consistent with the ADVANCE Act and EOs issued in 2025.

The NRC agrees that it could consider a fueled reactor undergoing testing at the manufacturing facility to be similar to a test reactor and agrees with other comments suggesting that an approach similar to that described in SECY-24-0008 can be taken where applicants for or holders of an ML can request exemptions to specific NRC regulations, including those in 10 CFR Part 53, to accommodate the reduced risk profile that might be associated with factory testing of a microreactor. As a result, the NRC did not include specific provisions for factory testing in the final 10 CFR Part 53 but could pursue adding such provisions in a future rulemaking if such action is warranted.

The NRC agrees that commencement of reactor operation under 10 CFR Part 53 should not be marked for all commercial nuclear reactors by initial loading of fuel, as explained in the proposed and final rules, but disagrees that a reactor should not be considered in operation when initiating changes to the features to prevent criticality. Initiating the removal of features to prevent criticality provides a logical transition to an operational mode where the safety requirements under 10 CFR Part 53 should apply and this activity is a reasonable corollary to the loading of fuel for commercial nuclear reactors that do not involve a manufactured reactor.

The NRC agrees that that the potentially lower risk profile of small, fueled manufactured reactors (i.e., microreactors) may warrant consideration of a regulatory framework more tailored to a lower risk profile. To that end, the NRC is undertaking a separate microreactor rulemaking effort.

Accordingly, the NRC did not change the rule language in response to these comments.

3.8.10. <u>RFC: Physics testing of fueled manufactured reactors (use of COL vs. ML, applicability of requirements [§§ 53.610, 53.710, 53.715, 53.730 and others], selection of LBEs, design and analysis), including comments on low power physics testing white paper</u>

Comment Bin 3.8.10.A: In commenting on 10 CFR 53.1480(f)(2), which was part of an NRC Staff White Paper titled, “DRAFT Section 53.1480 – Combined license supporting testing of manufactured reactors," issued December 2024 (ML24344A037), a commenter wrote that the term "analytical safety margins" requires a clear definition. The commenter said that the term is addressed in 10 CFR 53.470, which refers to 10 CFR 53.450; however, PRA does not provide an accurate or comprehensive estimate of risk over time.

The commenter stated that in engineering practice, safety margins are fundamental to designing protections against hazards, particularly when uncertainty cannot be fully quantified. In some cases, sufficient statistical data are available to quantify reliability. The commenter wrote it is critical to outline how established engineering practices for protections against hazards align with the NRC's concept of "analytical safety margins." The commenter argued such alignment would clarify how the NRC intends to incorporate engineering safety principles into its regulatory framework.

The commenter wrote that the NRC recognizes PRA's limitations, given the requirements to report unexpected failures in protections such as defense in depth or safety margins. The commenter said that these requirements enable ongoing evaluation and prioritization of safety restorations, emphasizing the importance of a dynamic and adaptive risk management approach. The commenter cited research which they said describes the limitations of risk assessment in other contexts that are also applicable to the nuclear industry. The commenter argued these insights underscore the difficulty of reconciling PRA-based "analytical safety margins" with practical safety management and highlight the need for clearer definitions and methodologies in the NRC framework.

The commenter wrote that, as unexpected events unfold during facility operation, risk assessments must be revised to reflect the evolving understanding of risks. The commenter said that PRA can only include events known at the time of the analysis, rendering its "predictions" inherently incomplete and optimistic. The commenter stated that the "correct prediction" of accident risks can only be made retrospectively, after facility operations have concluded, as only at this point will all necessary information for a complete risk evaluation be available (EK-0001).

NRC Response: The NRC acknowledges the comment related to the discussions and white paper on a possible approach (including preliminary draft 10 CFR 53.1480) to address factory testing of fueled manufactured reactors. However, as explained in the NRC's response to Comment Bin 3.8.10.G, the NRC did not identify a consensus view on a preferred approach and has decided that, at least for the immediate future, the best approach is to use the flexibilities within 10 CFR Part 53, including the possible use of exemptions, for any first movers in the testing of manufactured reactors in a factory setting.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.10.B: A commenter wrote that 10 CFR 53.1480(f)(3), which was part of an NRC Staff White Paper titled, "DRAFT Section 53.1480 – Combined license supporting testing of manufactured reactors," issued December 2024 (ML24344A037), raises important issues by recognizing limitations of risk-informed performance-based approaches and PRA. The commenter said that operators do not regard the single-parameter risk calculated by their PRA as a meaningful representation of operational risk. The commenter argued that the approach fails to account for the dynamic, time-dependent nature of real-world hazards, such as the arrival process of seismic events or the escalating risks of severe weather (EK-0002).

NRC Response: The NRC acknowledges the comment related to the discussions and white paper on a possible approach (including preliminary draft 10 CFR 53.1480) to address factory testing of fueled manufactured reactors. However, as explained in the NRC's response to Comment Bin 3.8.10.G later in this section, the NRC did not identify a consensus view on a preferred approach and has decided that, at least for the immediate future, the best approach is to use the flexibilities within 10 CFR Part 53, including the possible use of exemptions, for any first movers in the testing of manufactured reactors in a factory setting.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.10.C: With regards to 10 CFR 53.1480(f)(5), which was part of an NRC Staff White Paper titled, "DRAFT Section 53.1480 – Combined license supporting testing of manufactured reactors," issued December 2024 (ML24344A037), a commenter asked (EK-0003):

- How will each manufactured reactor be tested for the specific thermodynamic application for which it is intended?
- Will the heat removal system and the calorimetric power calibration method be specified as part of the reactor's configuration?
- In a restricted power mode, how will nuclear instrument calibration be achieved for power levels up to 100 percent?

NRC Response: The NRC acknowledges the comment related to the discussions and white paper on a possible approach (including preliminary draft 10 CFR 53.1480) to address factory testing of fueled manufactured reactors. However, as explained in the NRC's response to Comment Bin 3.8.10.G later in this section, the NRC did not identify a consensus view on a preferred approach and has decided that, at least for the immediate future, the best approach is to use the flexibilities within 10 CFR Part 53, including the possible use of exemptions, for any first movers in the testing of manufactured reactors in a factory setting.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.10.D: With regards to 10 CFR 53.1480(f)(8), which was part of an NRC Staff White Paper titled, "DRAFT Section 53.1480 – Combined license supporting testing of manufactured reactors," issued December 2024 (ML24344A037), a commenter stated that while long-term operational requirements may not be applicable during testing, short-term preparatory measures such as instrumentation and protection actuation calibration remain essential prior to achieving criticality. The commenter wrote that such instrumentation and protection actuation calibration require much of the same controls as those required for long term operation. The commenter added because power excursion events can be reasonably hypothesized, additional protection actuations such as containment require instrument calibration with actuation circuits (EK-0004).

NRC Response: The NRC acknowledges the comment related to the discussions and white paper on a possible approach (including preliminary draft 10 CFR 53.1480) to address factory testing of fueled manufactured reactors. However, as explained in the NRC's response to Comment Bin 3.8.10.G later in this section, the NRC did not identify a consensus view on a preferred approach and has decided that, at least for the immediate future, the best approach is to use the flexibilities within 10 CFR Part 53, including the possible use of exemptions, for any first movers in the testing of manufactured reactors in a factory setting.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.10.E: Regarding 10 CFR 53.1480(f)(9), which was part of an NRC Staff White Paper titled, "DRAFT Section 53.1480 – Combined license supporting testing of manufactured reactors," issued December 2024 (ML24344A037), a commenter wrote that the operational scope of manufacturing facilities differs significantly from that of conventional fuel manufacturing facilities as reactor manufacturing facilities are designed to achieve initial criticality for testing purposes, similar to initial operations in commercial power reactors. The commenter stated that it is unclear how licensing for manufacturing facilities should differ from or align with existing requirements under 10 CFR Part 30. The commenter wrote that key considerations include (EK-0005):

- Criticality events are intentional and controlled within the manufacturing facility.
- Subcritical configurations, as mandated in fuel manufacturing facilities, are intentionally violated to conduct testing.
- Depending on realistic accident scenarios, actinide accumulation during operations could exceed levels envisioned in 10 CFR Part 30, necessitating reevaluation of applicable licensing criteria.

NRC Response: The NRC acknowledges the comment related to the discussions and white paper on a possible approach (including preliminary draft 10 CFR 53.1480) to address factory testing of fueled manufactured reactors. However, as explained in the NRC's response to Comment B in 3.8.10.G later in this section, the NRC did not identify a consensus view on a preferred approach and has decided that, at least for the immediate future, the best approach is to use the flexibilities within 10 CFR Part 53, including the possible use of exemptions, for any first movers in the testing of manufactured reactors in a factory setting.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.10.F: Regarding 10 CFR 53.1480(f)(11), which was part of an NRC Staff White Paper titled, "DRAFT Section 53.1480 – Combined license supporting testing of manufactured reactors," issued December 2024 (ML24344A037), a commenter wrote that this section seems to imply that once a first reactor is built and tested, subsequent testing equipment maintenance and operation requirements can be discontinued. The commenter stated that this disregards the practical reality that, over the facility's lifetime, changes to both the manufactured reactor designs and the manufacturing facility configuration will inevitably occur as each reactor is produced. The commenter added that a change process as under 10 CFR 50.59 may be necessary to address minor changes, writing that even minor manufacturing or design adjustments can significantly impact reactor safety. The commenter also said that the apparent assumption that ITAAC requirements for testing equipment and manufacturing processes can be "permanently retired" does not account for the iterative nature of reactor design, operation, and maintenance (EK-0006).

NRC Response: The NRC acknowledges the comment related to the discussions and white paper on a possible approach (including preliminary draft 10 CFR 53.1480) to address factory testing of fueled manufactured reactors. However, as explained in the NRC's response to Comment Bin 3.8.10.G later in this section, the NRC did not identify a consensus view on a preferred approach and has decided that, at least for the immediate future, the best approach is to use the flexibilities within 10 CFR Part 53, including the possible use of exemptions, for any first movers in the testing of manufactured reactors in a factory setting.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.10.G: A commenter said that the NRC should clarify which testing is achievable under 10 CFR Part 70 versus that which would require a license under 10 CFR Part 50, 52, or 53. The commenter stated that subcritical testing that cannot meet the performance requirements of 10 CFR Part 70 for subcriticality would enter the regime of a utilization facility and require a 10 CFR Part 50, 52, or 53 license, and critical and lower power testing would be in the utilization facility regime. The commenter said that an applicant who wants to perform critical testing on the site should obtain licenses based on guidance in NUREG-1537. Given that 10 CFR Part 53 as proposed does not currently cover Class 104 licenses, the commenter stated that one path would be to obtain a 10 CFR Part 50 license that can be combined with a 10 CFR Part 70 and 10 CFR Part 53 license. The commenter mentioned that this would require the ability to transition between a 10 CFR Part 50 and 10 CFR Part 53 license. The commenter said that a 10 CFR Part 50 Class 104 license developed using NUREG-1537 is specifically suited to the unique activities of the critical experiments and provides appropriate assurance of safety and safeguards for the experiment or test. The commenter also suggested another option would be to add Class 104 license to 10 CFR Part 53 (NEI2-0196).

Another commenter wrote that testing of reactors manufactured and fueled in a factory should be included in 10 CFR Part 53 and added that they do not have detailed recommendations at this time but would welcome future workshops and engagement.

The commenter stated that they do not support individual COLs specific to lower power testing due to increased application time and annual costs. Instead, the commenter suggested these three alternative approaches in order of preference (RAD-0010):

- A service provider license with an integrated approach to rapid, high-volume deployment of small and mobile reactors as described in the concept paper submitted to the NRC as a separate comment on this rulemaking ("Service Provider Licensing and Oversight: An Alternative Conceptual Strategy for Regulating Fleet-wide Small and Mobile Reactors," dated February 6, 2025 (ML25037A347)).

- Define a path for specifying multiple operating locations in a COL to encompass the manufacturing site, the operating site, and additional operating sites for reactors that undergo a series of deployments prior to refueling.

- A single, factory testing COL which would be an acceptable but least preferable approach.

A commenter wrote that the NRC should pursue a more performance-based approach that would integrate licensing and oversight functions with high-level performance requirements.

This would allow for maximum use of performance indicators and minimal need for inspection to ensure safety and security. The commenter recommended that the NRC consider an integrated approach to rapid, high-volume deployment of small and mobile reactors as described in "Service Provider Licensing and Oversight: An Alternative Conceptual Strategy for Regulating Fleet-wide Small and Mobile Reactors," (ML25037A347). The commenter wrote that this would allow 10 CFR Part 53 to meet the requirements of the ADVANCE Act (ROSE-0011).

One commenter offered the following recommendations (SCWG-0024):

- The NRC should include provisions to regulate the testing of fueled manufactured reactors at the manufacturing facility in implementing guidance.
- In guidance, the NRC should discuss the nuclear physics testing of manufactured reactors and outline safety, security, and oversight measures.
- The NRC should clarify which provisions of Subpart H apply to COL applicants conducting testing of fueled manufactured reactors at a manufacturing facility, and the NRC should acknowledge that certain precriticality testing activities may be permissible under 10 CFR Part 70 without requiring a COL.
- The NRC should provide guidance on what constitutes “low power testing” at a manufacturing facility and how this differs from full operational testing at a deployment site for future applicants.
- Staffing and oversight requirements should be adapted to reflect the lower risk profile of low-power testing but ensure sufficient engineering expertise is available.
- The NRC should engage with stakeholders to further clarify the roles and responsibilities of ML holders versus COL applicants during the testing phase.
- The NRC should pursue a licensing framework that allows a single license to cover the testing of multiple fueled manufactured reactors, provided they meet consistent design and safety criteria. This approach should distinguish between subcritical testing–potentially allowable under Part 70–and critical testing, which may necessitate a different licensing pathway, such as a Class 104 license under the AEA.

A commenter stated that 10 CFR Part 53 should provide a regulatory approach that clearly and efficiently allows for factory fuel loading of reactors with factory-focused inspections and testing of production units. The commenter recommended incorporating SECY-24-0008 into 10 CFR Part 53, although they cautioned that the outline approach should not be limited to only microreactors. The commenter wrote that recommended options 1b, 2b, and 3b are acceptable; however, options 1a, 2a, and 3a rely mostly on established policies and processes for power reactor licensing and would be viable only in certain circumstances (USNIC2-0014).

NRC Response: The NRC agrees, in part, with these comments.

The 10 CFR Part 53 proposed rule did not include specific provisions for the testing of manufactured reactors within the manufacturing facility. The NRC considered adding such provisions, solicited comments on possible approaches, and further discussed concepts during the comment period at a public meeting held on January 8, 2025. The NRC did not identify a consensus view on a preferred approach and has decided that, at least for the immediate future, the best approach is to use the flexibilities within 10 CFR Part 53, including the possible use of exemptions, for any first movers in the testing of manufactured reactors in a factory setting. The introduction of byproduct materials by operational testing at the manufacturing facility will need to be addressed within any exemption requests from any part of NRC regulations. Some comments received favored such an approach where applicants for or holders of an ML would request exemptions from specific requirements in 10 CFR Part 53 to allow reactor testing at the manufacturing facility in lieu of the NRC including specific exclusions in 10 CFR Part 53. As explained in the proposed and final rules, future rulemakings to address scenarios such as the development and deployment of microreactors will provide an opportunity to include specific provisions for the testing of manufactured reactors within the manufacturing facility.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.8.10.H: With respect to other microreactor considerations, a commenter discussed that licensing considerations from SECY-20-0093 could be addressed by a more technology-inclusive 10 CFR Part 53. Additionally, the commenter discussed that a pathway to testing of a fueled microreactor at the manufacturing facility, such as under an AEA section 104 license and using methodologies similar to NUREG-1537, would be important to address. The commenter stated that it is essential that as many of the ADVANCE Act issues as possible be addressed under the performance-based framework of the proposed rulemaking (NEI2-0254).

NRC Response: The NRC agrees, in part, with the comment.

As explained in the NRC's response to Comment Bin 3.1.1.B, 10 CFR Part 53 is intentionally limited to utilization facilities licensed under section 103 of the AEA. In addition, the NRC did not identify a consensus view on a preferred approach for factory testing of fueled manufactured reactors and has decided that, at least for the immediate future, the best approach is to use the flexibilities within 10 CFR Part 53, including the possible use of exemptions, for any first movers in the testing of manufactured reactors in a factory setting. As discussed in SECY-24-0008, applicants can use insights from the licensing and regulation of research and test reactors, including NUREG-1537, in identifying and proposing justification for exemptions from the requirements in 10 CFR Part 53 for the limited operations associated with factory testing of manufactured reactors.

Accordingly, the NRC did not change the rule language in response to this comment.

Consistent with the ADVANCE Act and EOs issued in 2025, the NRC has initiated development of an additional rulemaking to expedite licensing of qualified microreactors and other potentially low risk, low consequence reactors. This activity, along with other NRC guidance development activities, are intended to address questions such as those raised by the comments.

3.9. Subpart I: Maintaining and Revising Licensing-Basis Information (§§ 53.1500-53.1595)

3.9.1. Comments on Subpart I requirements (e.g., amendments, backfitting) not related to RFC

Comment Bin 3.9.1.A: A commenter stated that the NRC report, "Best Practices for Establishment and Operation of Local Community Advisory Boards Associated with Decommissioning Activities at Nuclear Power Plants," required by section 108 of NEIMA and delivered to Congress on July 1, 2020 (ML20113E857) demonstrated that the CAB is a useful tool which can support all nuclear power and fuel cycle facilities, starting with initial planning and siting stages all the way through facility construction, long-term operations, major licensing amendments and renewals, and incident and emergency planning and responses. The commenter discussed that the licensing processes for new, advanced reactors under 10 CFR Part 53 are extremely complex from the perspective of stakeholders and suggested that the expanded use of CABs could help achieve the policy goals of NEIMA, such as local outreach and coordination. The commenter added that proposed 10 CFR 53.1515 only addresses CP and OL licensing processes, but that 10 CFR Part 53 includes a total of seven different processes, including ESP, LWA, SDA, SDC, and ML licensing processes. The commenter discussed that the CAB could support reviews and communications during each of these processes (UT1-0002).

The commenter additionally requested that the NRC revise the 2020 CAB Report to include best practices and lessons learned, including longstanding program rules, guidance, and other implementation and management methods, from the EPA’s Technical Assistance Grant (TAG) program. The commenter stated that the TAG program has assisted the EPA in engaging and funding State and local governments and stakeholders involving complex, technical fields. The commenter further suggested that the NRC consider engagement with and provide technical grant assistance to community organizations such as the Energy Communities Alliance (ECA) to develop the CAB program, as the ECA functions similarly to the CAB and works with communities with existing reactors to bridge complex relationships with Federal, State, and local governments (UT1-0003).

NRC Response: The NRC agrees, in part, with these comments.

As noted in the 2020 CAB report to Congress, the NRC encourages the formation of CABs to foster communication and information exchange between the licensee and the members of the community. The NRC disagrees that 10 CFR 53.1515 only addresses CP and OL processes. 10 CFR 53.1515 establishes requirements for public notices and state consultations associated with the NRC’s processing of a license amendment request. This section is equivalent to 10 CFR 50.91 for the NRC’s existing processes related to applications to amend an OL or COL.

The NRC also disagrees that it is necessary to revise the CAB Report to include best practices and lessons learned from the EPA’s TAG program. The NRC has undertaken a rulemaking to revise its regulations related to the decommissioning of production and utilization facilities. The amended regulations, which were issued for public comment in 2022, would incorporate best practices and lessons learned from nuclear power plants that have transitioned to decommissioning and would improve the effectiveness and efficiency of the NRC's regulatory framework. Moreover, updates to the CAB report are outside the scope of this rulemaking.

The NRC acknowledges the suggestion that the NRC should consider engagement with community organizations, and the NRC should consider technical grant assistance to community organizations such as the ECA to develop the CAB program. However, the NRC’s grant program is separate from the rulemaking process. More information about the NRC grant programs can be found on the NRC public webpage.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.9.1.B: A commenter recommended specific edits to proposed Subpart I of 10 CFR Part 53:

- Change “4 months” to “2 months (if operating)” in 10 CFR 53.1502(d)(1);
- Change “and, normally, the amendment will not be granted until after this comment period expires” to “and the amendment will not be granted until after this comment period expires” in 10 CFR 53.1515(a)(1)(iii);
- Delete 10 CFR 53.1515(a)(4) and 10 CFR 53.1515(a)(5);
- Change “24 months” to “8 years” in 10 CFR 53.1545(a);
- Delete 10 CFR 53.1550;
- Rewrite 10 CFR 53.1560 to address costs or to clarify the value added; and
- Rewrite 10 CFR 53.1565 to simplify the proposed conditions and requirements.

Additionally, the commenter questioned whether the second sentence of 10 CFR 53.1515(a)(3) is necessary and whether “decrease” should be changed to “differ” in 10 CFR 53.1550(a)(2)(vii) (TG14-0002).

Another commenter relatedly expressed concern that proposed 10 CFR 53.1515(a)(1)(ii) and 10 CFR 53.1515(a)(1)(iii) as written allows the NRC to make decisions to grant amendments before the public comment period expires (TG19-0001).

A commenter discussed that proposed 10 CFR 53.1515 allows for limited stakeholder involvement in connection with the consideration of applications for an amendment to an OL, but that the proposed rule should be more consistent with the policy objectives of NEIMA to implement measures supporting the predictable, efficient, and timely licensing of advanced nuclear reactors. The commenter suggested that the NRC should take advantage of current State and local policy support for nuclear power to improve collaboration and cooperation amongst stakeholders and to more fully implement NEIMA and the NRC’s internal management directives and plans (UT1-0001).

A commenter said that the proposed change process for emergency preparedness programs in Subpart I, 10 CFR 53.1565(d)(3) is essentially the same as that contained in 10 CFR 50.54(q), and said that there is an opportunity to improve this process. The commenter suggested that NRC adopt a risk-informed approach to the change evaluation requirements by making the “reduction in effectiveness” assessment applicable only to changes affecting the functions needed to implement risk-significant planning standards. The commenter said that for changes affecting other (non-risk-significant) functions, the licensee would simply need to demonstrate that the plan, as changed, continues to meet the applicable regulatory requirements (NEI2-0144). Another commenter expressed support for this comment (NEX-0015).

NRC Response: The NRC agrees, in part, with these comments.

The NRC disagrees with the suggestion that the time made available in 10 CFR 53.1502(d)(1) for a licensee to correct deficiencies related to emergency preparedness be reduced from 4 months to 2 months. The allowable time for corrective actions is consistent with the equivalent provisions in 10 CFR 50.54(s)(2)(ii), which experience has shown to be appropriate.

The NRC disagrees with the suggestion that the language in 10 CFR 53.1515(a) be revised and that 10 CFR 53.1515(a)(4) and (a)(5) be deleted such that the NRC could not issue a license amendment before the comment period expires. The NRC has many years of experience with the equivalent provisions in 10 CFR 50.91 and history has shown that circumstances do occasionally occur that would require a license amendment request to be issued under the emergency or exigent provisions of 10 CFR 53.1515(a)(4) and 10 CFR 53.1515(a)(5).

The NRC disagrees with the suggestion of changing the updating of FSARs under 10 CFR 53.1545(a) from every 24 months to 8 years. The reporting frequency is consistent with the equivalent provisions in 10 CFR 50.71(e).

The NRC disagrees with the suggestion to delete 10 CFR 53.1550 but notes that changes were made to the change evaluation criteria in response to Comment B in 3.9.1.F.

The NRC disagrees with making major revisions to 10 CFR 53.1560 and 10 CFR 53.1565 on updating program documents and evaluating changes to program documents. As explained in the proposed and final rules, the safety of commercial nuclear plants is provided by combinations of design features, human actions, and programs. The flexibility afforded by 10 CFR Part 53 in how these elements are used provides benefits to applicants and licensees but also comes with responsibilities to evaluate changes to designs, staffing, and program documents and having appropriate NRC interactions on the maintenance of the licensing basis for each commercial nuclear plant.

The NRC agrees that the proposed change process for emergency preparedness programs in Subpart I, 10 CFR 53.1565(d)(3) is essentially the same as that contained in 10 CFR 50.54(q). The NRC also agrees that the emergency preparedness change process could be further risk-informed. EO 14300, in part, requires the NRC to reform and modernize the NRC's regulations. In accordance with this EO, the NRC is undertaking a review and wholesale revision of its regulations and guidance documents. The NRC is considering whether to further risk inform the emergency preparedness change process during this effort.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.9.1.C: A commenter requested that the NRC rewrite proposed 10 CFR 53.1590 to clarify the logic regarding backfitting and license compliance. The commenter suggested that the NRC could recruit resident inspectors or senior resident inspectors to conduct the rewrite (TG15-0001).

NRC Response: The NRC disagrees with this comment.

The licensing of commercial nuclear facilities is not a simple matter, and the NRC is operating within the statutory and legal framework for doing so that has been established over several decades. The backfitting requirements in 10 CFR 53.1590 are consistent with those governing the existing processes for commercial nuclear power plant licensing under 10 CFR Parts 50 and 52 that are found in 10 CFR 50.109 and the various sections on issue finality found in 10 CFR Part 52. The NRC's experience has shown that these existing provisions are adequate to ensure an appropriate level of finality.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.9.1.D: A commenter said that the second sentence in 10 CFR 53.1510 is significantly more prescriptive than equivalent language in 10 CFR 50.90 and suggested that the level of detail should be made more consistent with a performance-based regulation (NEI2-0139).

NRC Response: The NRC disagrees with this comment.

The second sentence of 10 CFR 53.1510 as proposed ensures that the evaluation of a license amendment explicitly accounts for potential impacts to safety requirements in Subpart B and the underlying, systematic analyses required by 10 CFR 53.450. These considerations are explicitly included as a requirement because of the licensing construct under 10 CFR Part 53. The requirement in 10 CFR 53.1510 to describe an assessment of the results of a change on the underlying safety analysis is more performance-based and predictable than the current wording in 10 CFR 50.90. The inclusion of an analysis of whether the amendment involves no significant hazards consideration using the standards in 10 CFR 53.1520, and a consideration of environmental factors is not a new requirement and was simply included in 10 CFR 53.1510 for completeness and clarity.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.9.1.E: A commenter said that the specific language in 10 CFR 53.1545 presumes the licensee has made use of the PRA-based approach in Subparts B and C, and that the requirements do not reflect other risk-informed approaches or more traditional approaches. The commenter proposed that the language in 10 CFR 53.1545(a)(2)-(4) should be modified to reflect FSAR updates where other risk-informed approaches or more traditional approaches have been used in supporting licensing of the plant (NEI2-0140).

NRC Response: The NRC agrees, in part, with the comment.

The NRC disagrees that further changes are needed to reflect more traditional licensing approaches, as these deterministic approaches do not support the licensing construct of 10 CFR Part 53. However, in response to Comment Bin 3.3.2.2.E, the NRC has revised the rule language related to PRA in 10 CFR 53.1545 consistent with the revisions to the rule language in 10 CFR 53.450, which allows systematic risk evaluations other than PRA to be used to meet the analysis requirements.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.9.1.F: A commenter said that the requirement in 10 CFR 53.1550 is only applicable to one type of risk-informed approach in which the safety case is based almost entirely on the PRA and therefore cannot be applied to other risk-informed approaches. The commenter further noted that it appears that the outcome of the change control criteria here would be identical to the use of the criteria in 10 CFR 50.59, so that there is no regulatory advantage other than the ability to solely use the PRA to evaluate changes. The commenter also said that guidance is crucial to implementing 10 CFR 50.59, and no such guidance has been provided for 10 CFR 53.1550, and so the PRA-based criteria could be found to be undesirable once the details are developed in guidance. The commenter provided appropriate criteria for a 10 CFR 50.59-like evaluation for licensees following LMP in NEI 22-05:

Technology-Inclusive Risk-Informed Change Evaluation. The commenter suggested that NRC use the criteria in NEI 22-05 to inform an update to the 10 CFR 53.1550(a)(2) criteria. Additionally, the commenter said that the 10 percent change criterion in 10 CFR 53.1550(a)(2)(ix) and 25 percent change in 10 CFR 53.1550(a)(2)(vii) is too prescriptive for rule language and should be included in guidance, if at all (NEI2-0142).

Another commenter stated that proposed 10 CFR 53.1550 is of doubtful legality and should be deleted, as the NRC has "completely misconstrued" the relationship between reactor plant configuration control and FSAR changes (HPT36-0001). The commenter discussed that proposed 10 CFR 53.1550 represents completely new requirements, with no equivalent section in 10 CFR Part 50 and no clear relationship with the risk-informed requirements of NEIMA. The commenter said that the provision includes nearly incomprehensible technical language, there is no legal basis for using regulatory guides to establish requirements outside the CFR, and the need to alter the content of the FSAR would require a separate FSAR revision. The commenter additionally provided specific comments for several items within proposed 10 CFR 53.1550:

- The commenter discussed that a PRA cannot be used to establish specific licensing requirements, and that licensees would be subject to consequences with no discernable quantifiable acceptance standard in paragraphs (a)(2)(i) – (a)(2)(ii).

- The commenter expressed concern regarding the legality of sections referenced in paragraphs (a)(2)(iii), (a)(2)(vii), and (a)(2)(viii).

- The commenter advised that there is no legal basis for requiring the NRC approval or endorsement of consensus codes and standards as well as no precedent for making PRA analysis details part of the FSAR in paragraph (a)(2)(iv).

- The commenter stated that requirements attempting to link FSAR changes to SSC changes are not logical in paragraph (a)(2)(v).

- The commenter expressed that "defense in depth" is not a quantifiable number and presents a requirement that is impossible to meet in paragraph (a)(2)(vi).

- The commenter called the 25 percent margin "arbitrary" and that the requirement would be impossible to evaluate in paragraph (a)(2)(ix).

- The commenter advised that the aircraft impact analysis is illegal in paragraph (a)(2)(x).

The commenter concluded that these proposed requirements are ill-defined and outside of reasoned decision-making, as determined in *Michigan v. EPA* (HPT36-0002).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees with the suggestions regarding NEI 22-05 and revised the final rule language for the change evaluation criteria in 10 CFR 53.1550(a)(2) to align more closely with the suggestions. The changes include replacing specific margin reductions (e.g., result in a decrease by 10 percent or more in the margin between the consequence of any design- basis accident and the safety criteria in 10 CFR 53.210) with terminology more like that used in 10 CFR 50.59 (e.g., "does not result in more than a minimal increase in the consequences of any design-basis accident"). The criteria in 10 CFR 53.1550(a)(2) for the final rule can be used for systematic risk evaluations used in combination with or possibly as an alternative to PRA because they maintain the same relationships between design features, analysis of licensing-basis events, safety classification, and other elements of the framework established by 10 CFR Part 53. Criterion (v) in 10 CFR 53.1550(a)(2) in the final rule differs from the corresponding criterion in NEI 22-05 in that it does not include changes to safety classification of SSCs from non-safety related or NSRSS to SR because plant changes introducing new SR SSCs would require a change to technical specifications under 10 CFR 53.710. Accordingly, the NRC has revised the rule language in response to this comment. Specifically, the NRC has revised the change evaluation criteria in 10 CFR 53.1550(a)(2).

The NRC disagrees with the suggestion that 10 CFR 53.1550 has no parallel in 10 CFR Part 50 and is of doubtful legality because the NRC has modeled 10 CFR 53.1550 after 10 CFR 50.59 with the exception of the evaluation criteria that reflect the risk-informed framework of 10 CFR Part 53. For example, the evaluation criteria in 10 CFR 53.1550(a)(2) refer to evaluation criteria for each event or specific categories of LBEs under 10 CFR 53.450(e)(2) and sequences deemed significant for controlling the risks posed to public health and safety under 10 CFR 53.1550(e)(4). See also the NRC's responses to Comment Bin 1.3.A for a discussion on the use of guidance, Comment Bin 3.6.3.5.D on the NRC's endorsements of consensus codes and standards, Comment Bin 3.3.2.1.C on aircraft impact requirements, and Comment Bin 3.2.1.2.B for the principle established by *Michigan v. EPA*. Accordingly, the NRC did not revise the rule language in response to these comments.

Comment Bin 3.9.1.G: A commenter said that the language to add flexibility for COL holders during construction is greatly appreciated and appropriately addresses the lessons learned from Vogtle 3 and 4. The commenter also said that the rule would benefit from clarification that 10 CFR 53.1535 only applies to CP holders that have requested finality on "select design features or specifications" and that this section would be not applicable to CP holders that have not requested this finality. The commenter also suggested that NRC add a discussion to the preamble for the implications of 10 CFR 50.35(b) (NEI2-0143).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that the provisions of 10 CFR 53.1535 appropriately address the lessons learned from Vogtle 3 and 4. The NRC disagrees that 10 CFR 53.1535 only applies to CP holders that have already requested finality of "select design features or specifications" and would be not applicable to CP holders that had not already requested this finality. The rule language in 10 CFR 53.1336 (the 10 CFR Part 53 equivalent to 10 CFR 50.35(b)) regarding finality of CPs states that an applicant, at its option, may request approval of the safety of any design feature or specification in the CP *or by amendment to the CP*. Therefore, an applicant can request such finality for the first time in an amendment to the CP under 10 CFR 53.1535. The NRC did not include additional discussion in the 10 CFR Part 53 final rule since there is no difference between the implications for CP holders under 10 CFR Part 53 and CP holders under 10 CFR Part 50.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.9.1.H: A commenter wrote that the proposed rule does not adequately address the need for public consultation, and the application process should outline mechanisms for public feedback and transparency in decision-making related to the design certification (MR-0006). Another commenter wrote that States and the public could be foreclosed from providing feedback if the NRC approves a standard reactor design before a site is chosen. To address this, the commenter suggested expanding the State consultation provisions contained in 10 CFR 50.91 to apply to all applications for new reactor construction under 10 CFR Part 50, 52, or 53 (NYS2-0008).

Another commenter stated that the rule would be improved considerably if a provision for public consultation was included. The commenter discussed that this would increase the public's confidence and the NRC's accountability in the decision-making process (NA-0003).

NRC Response: The NRC disagrees with the comments.

The NRC disagrees that the rule does not adequately address the need for public or State consultation. The processes for public involvement and State consultation outlined in 10 CFR Part 53, in particular 10 CFR 53.1515, are consistent with the existing processes under 10 CFR Parts 50 and 52, such as 10 CFR 50.91, which provide sufficient opportunities for public and State involvement, as envisioned in the AEA.

Accordingly, the NRC did not change the rule language in response to these comments.

3.9.2. RFC: Placement, control, and submittal of PRA information (§ 53.1239(a)(18), § 53.1545, § 53.1560)

Comment Bin 3.9.2.A: A commenter said that 10 CFR 53.1545[(a)](4) is problematic because it references 10 CFR 53.220 which includes the cumulative risk metric in 10 CFR 53.220(b). The commenter said that there is a contradiction where 10 CFR 53.450(c) and 10 CFR 53.1545[(a)](3) would require a PRA update every 5 years, but to assess 10 CFR 53.220(b) in accordance with 10 CFR 53.1545[(a)](4), the PRA would need to be updated every 2 years. The commenter recommended that NRC remove 10 CFR 53.1545[(a)](4) because 10 CFR 53.1545[(a)](3) is adequate to update PRA information in the SAR and 10 CFR 53.1545[(a)](1) is adequate to address changes to facility and procedures (NEI2-0141). Another commenter expressed support for this comment and proposed resolution (NEX-0022).

A commenter said that the language in 10 CFR 53.1545 for PRA updates seem appropriate. By pointing to the 10 CFR 53.450 requirements, the commenter said that they interpret this requirement to mean that when the PRA is updated every 5 years in accordance with 10 CFR 53.450(c), that updated information needs to be incorporated into the SAR update which is required every 2 years. The commenter also said that their interpretation is that the requirement would not drive a PRA update every 2 years. The commenter also said that it would not be appropriate to have a "separate document related to the broader PRA analyses and related processes as a program document under 53.1560" as such a document would be informed by (NEI2-0208):

- PRA changes which are adequately covered under the maintenance requirement in 10 CFR 53.450(c);
- Design changes and changes to the method of evaluation that are sufficiently covered by 10 CFR 53.1550; and
- Changes to special treatments which may impact DID adequacy which is already covered in 10 CFR 53.1560 for updates to programs.

Another commenter expressed support for these comments (NEX-0022).

NRC Response: The NRC agrees, in part, with the comments.

The requirement in 10 CFR 53.450(c) is that PRAs or other systematic risk evaluations be maintained at least every 5 years. The NRC acknowledges that the PRAs or other systematic risk evaluations may be updated more frequently than every five years and that more frequent updates of the analyses could support the periodic updates of licensing basis documents such as the FSAR every 2 years under 10 CFR 53.1545(a). However, the NRC disagrees that this is necessarily problematic.

For example, it is possible that few changes to a commercial nuclear plant could be made in a particular 2-year period and that those changes might be evaluated more qualitatively and updates to the PRA or other systematic risk evaluations may not be needed to support the updating of the FSAR, including addressing the cumulative effects under 10 CFR 53.1545(a)(4). The NRC agrees with the statement that the 2-year updates to licensing basis documents do not necessarily require a concurrent update to the PRAs or other systematic risk evaluations.

The required maintenance of the PRA or other systematic risk evaluations at least every 5 years under 10 CFR 53.450(c) is included to ensure that a reasonable alignment is maintained between the analyses, plant design, and the operating experience of plant SSCs. The suggestion that there is no need for a program document for the PRA is addressed in the response to Comment Bin 3.9.2.D.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.9.2.B: A commenter discussed that transparency and accessibility for safety evaluations, the flexibility to integrate evolving risk insights, and efficiency in information management and NRC oversight would provide a balanced framework for managing risk evaluation-related information without imposing unnecessary burdens or restricting technological innovation. The commenter stated that the placement, control, and routine submittal of risk evaluation-related information should align with an applicant’s integrated safety assessment, chosen risk evaluation methodology, and overall approach to meeting performance objectives. The commenter stated that RG 1.253 provides clear expectations on PRA-related information for applicants using the LMP, but that a similar framework for alternative methodologies without rigid requirements should be available (SCWG-0015).

NRC Response: The NRC agrees with the comment.

The NRC agrees that available guidance related to the use of the LMP methodology is largely adaptable for 10 CFR Part 53 and as explained in the proposed and final rules, the NRC plans to provide guidance for the use of that methodology under 10 CFR Part 53. As explained in the final rule, the NRC also plans to issue guidance on items added to the final rule such as the use of other systematic risk evaluations to supplement PRAs or possibly as an alternative to PRAs.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.9.2.C: A commenter stated that a systematic evaluation of risk is prudent and necessary to achieve the policy objectives of NEIMA and directions in the ADVANCE Act and from the Commission, but that the proposed rule unnecessarily limits risk evaluation options by dictating that applicants use PRA. The commenter discussed that mandating the use of PRA may preclude alternative, equally robust methods better suited to specific designs or scenarios and would limit the transferability from existing frameworks to 10 CFR Part 53. The commenter recommended that the final rule allow applicants to use alternative methods to achieve equivalent safety outcomes.

The commenter further expressed that the language in proposed 10 CFR 53.450(b) is overly prescriptive, and that proposed 10 CFR 53.450(e) raises concerns regarding overreliance on PRA and unnecessary regulatory burdens. The commenter stated that the goal for 10 CFR Part 53 should be to provide sufficient predictability without limiting developers to a rigid framework. The commenter provided the example that Kairos Power Hermes and Hermes 2 used an alternative risk evaluation approach in its CP applications approved and issued by the NRC. The commenter concluded that the NRC should focus on defining clear performance outcomes and allow applicants to choose the most appropriate risk evaluation approach (BI1-0007).

NRC Response: The NRC agrees, in part, with the comment.

The response to Comment Bin 3.3.2.2.E describes the addition of "other systematic risk evaluations" to 10 CFR 53.450(a) to include other risk evaluation techniques which could be used to supplement a PRA or possibly be used as an alternative to a PRA. The NRC disagrees insofar as the risk evaluations need to be integrated with requirements governing other stages of the lifecycle for commercial nuclear plants and therefore risk evaluations cannot rely solely on maximum hypothetical accident type approaches. An additional use of PRAs or other SREs was added as 10 CFR 53.450(a)(6) to address the need to establish and update appropriate measures for plant operations, including availability controls, to ensure that the configurations and special treatments for SR SSCs and NSRSS SSCs provide the capabilities, availability, and reliability consistent with meeting the safety criteria under 10 CFR 53.220 and the analyses of licensing-basis events other than DBAs under 10 CFR 53.450(e).

Accordingly, the NRC did not make further changes to the rule language in response to this comment.

Comment Bin 3.9.2.D: A commenter stated that PRA models and evaluations should remain separate from the FSAR and expressed concern that proposed 10 CFR 53.220 represents a "significant obstacle" to advanced reactor projects under 10 CFR Part 53 (DOM-0002).

Relatedly, a commenter proposed that the NRC should only require PRA summary information in the SAR, alongside licensing basis information produced or informed by the PRA such as LBEs. The commenter discussed that the NRC endorsed NEI 21-07, Revision 1 in RG 1.253, and that the NEI 21-07, Revision 1 guidance for PRA overview and results to be provided in a SAR should be applied to applications under 10 CFR Part 53. The commenter suggested that PRA-related information not included in the SAR would be maintained under licensee control in plant records available for NRC inspection and audit.

The commenter discussed that 10 CFR Part 53 SARs include unnecessary details on the plant PRA, creating unnecessary burden on applicants, licensees, and the NRC. The commenter suggested that the PRA-related licensing basis information in the SAR be updated on the frequency specified in proposed 10 CFR 53.1545. The commenter additionally discussed that a proposed requirement to maintain a “one size fits all” PRA “program document” under 10 CFR 53.1560 would be inappropriate, as PRAs for the wide range of reactor designs and sizes that may fall under 10 CFR Part 53 may also differ in size and complexity. Further, the commenter discussed that proposed 10 CFR 53.450(c) is unclear and that the NRC should be more specific, such as by referencing a code or standard or providing guidance, on the expectation for PRA maintenance and the suitability of the 5-year interval. For proposed 10 CFR 53.1550, the commenter added that the NRC should ensure that 10 CFR Part 53 change control requirements are consistent with NEI 22-05 and relevant NRC regulatory guidance before finalizing the rulemaking (LMNT-0004).

A commenter discussed that PRAs must be carefully controlled and treated with a regulatory rigor similarly to all other parts of the FSAR. The commenter stated that changes to the PRA related to changes in the plant, its operations, or new or improved data and methods, must be fully assessed by the NRC to understand the implications for the fundamental safety and security analyses that supported the original plant license (UCS-0013).

NRC Response: The NRC agrees, in part, with the comments.

As explained in the proposed and final rules, the information to be provided in FSARs is limited to a description of the PRA required by 10 CFR 53.450(a) (or other systematic risk evaluations as added to the final rule) and their results. The discussion also explains that the NRC plans to build from the guidance developed for implementation of the LMP methodology (e.g., RGs 1.233 and 1.253). The NRC has not added to the final rule a new program document to the list of licensing basis information but expects that additional guidance will be developed to address how the maintenance and upgrading of PRAs or other systematic risk evaluations relate to monitoring of the availability and reliability of structures, systems and components warranting special treatment under 10 CFR 53.460.

Accordingly, the NRC did not change the rule language in response to these comments.

3.9.3. <u>RFC: Changes to manufacturing licenses (§ 53.1530)</u>

Comment Bin 3.9.3.A: A commenter said that guidance on the licensing requirements of design changes should be developed in collaboration with the industry and that cask manufacturing licenses and NEI 12-04 might provide a framework (NEI2-0209).

NRC Response: The NRC agrees with the comment.

The NRC agrees that guidance on requirements for design changes under a manufacturing license would be useful and collaborative development of such guidance with external stakeholders would be beneficial. Although this comment did not suggest changes to the proposed rule, the provisions controlling changes by an ML holder in 10 CFR 53.1530 and the provisions controlling changes by a COL holder referencing an ML in 10 CFR 53.1550 are being revised in the final rule in response to other public comments (see Comment Bin 3.9.3.B).

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.9.3.B: A commenter expressed that a well-defined, risk-informed approach to license amendment criteria for manufactured reactors is essential to ensure regulatory efficiency, maintain safety and security, and to allow for a practical and responsive regulatory framework. The commenter requested that the NRC develop clear, risk-informed criteria for when a license amendment request is required, with a focus on changes directly impacting safety, security, or regulatory compliance. The commenter discussed that design changes not requiring a license amendment may involve cosmetic or aesthetic features, administrative systems, maintenance tracking tools, or other non-safety-significant modifications. In contrast, the commenter suggested that design changes involving the primary cooling system, control systems, containment, core design, or other safety-significant modifications may require a license amendment. The commenter additionally requested that the NRC clarify the procedures for evaluating and documenting changes to manufacturing processes, conduct periodic audits of manufacturing facilities to verify compliance, and implement conforming changes throughout the rulemaking package (SCWG-0025).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that 10 CFR Part 53 should give holders of an ML the authority to make changes to the FSAR associated with an ML and has expanded the provisions in 10 CFR 53.1530 to give ML holders more flexibility in this regard. Accordingly, the NRC has revised 10 CFR 53.1530 in the final rule to allow changes to a manufactured reactor design by the ML holder using the evaluation criteria in 10 CFR 53.1550 in response to this comment. In addition, a COL holder referencing an ML can make changes to the facility or procedures as described in the FSAR (including changes related to the referenced ML) under 10 CFR 53.1550. To avoid confusion and duplication, the NRC has also deleted proposed 10 CFR 53.1530(b) from the final rule language to remove references to a COL holder that references an ML. The NRC also made a conforming change to 10 CFR 53.1540 to require periodic updates to the FSAR by the ML holder to reflect that changes may be made without NRC review and approval via license amendments under 10 CFR 53.1510.

The NRC did not receive specific suggestions for or change the rule language regarding finality or change control related to manufacturing processes. The focus for manufacturing licenses will likely remain the design of the manufactured reactor, manufacturing processes directly associated with referenced consensus codes and standards, and quality assurance measures. The manufacturing activities will be subject to NRC inspections and oversight.

Accordingly, the NRC revised the rule language as described above.

3.10. Subpart J: Reporting and Other Administrative Requirements (§§ 53.1600-53.1730)

3.10.1. Comments on Subpart J requirements (e.g., records, reporting, financial protection) not related to RFC

Comment Bin 3.10.1.A: A commenter provided the following feedback on the proposed provisions in Subpart J to 10 CFR Part 53 (TG15-0002):

- The commenter expressed approval of 10 CFR 53.1610(b)(5).
- The commenter requested clarification on whether “microform” or “microfilm” should be used in 10 CFR 53.1620(d)(1).

- The commenter requested that “30 calendar days” be updated to “15 calendar days” in 10 CFR 53.1620(e).
- The commenter requested that the NRC delete 10 CFR 53.1630(a)(ii).
- The commenter requested that 10 CFR 53.1640 be revised to reconsider the need for a 60-day licensing event reporting period, the acceptability of events caused by wear, the number of exceptions, and monitoring or averaging releases over time for one hour. Additionally, the commenter questioned whether anything more than a short description is needed to acquire information for Licensee Event Report (LER)-reportable events.

Another commenter also addressed the proposed LER provisions in 10 CFR 53.1640, stating that the proposed provision and NRC Forms 366, 366A, and 366B should be revisited to account for the risk-informed requirements established by NEIMA in 2019 and the efficiency improvement elements established by the ADVANCE Act of 2024 (HPT37-0001).

NRC Response: The NRC agrees, in part, with the comments.

The NRC acknowledges the favorable comment regarding the provision in 10 CFR 53.1610(b)(5), which requires that the arrival and presence of an NRC inspector is not announced unless requested by the inspector. This is consistent with the regulatory frameworks for existing reactors and an important element of NRC oversight. The suggested changes in other sections within Subpart J of 10 CFR Part 53 are addressed below:

- Regarding the requested clarification under 10 CFR 53.1620(d)(1), “microform” is the correct term. This is the same term used in existing NRC regulations in 10 CFR 50.71.

- The NRC disagrees with the request that “30 calendar days” be updated to “15 calendar days” in 10 CFR 53.1620(e). The primary purpose of including a notification of completion of startup testing is use of that milestone within 10 CFR Part 171 as the criterion for when a licensee is required to pay annual fees. In that context, the NRC has determined that 30 days is appropriate and sees no need to shorten the notification period.

- The NRC disagrees with the suggested deletion of 10 CFR 53.1630(a)(ii) on the reporting of nonemergency events under 10 CFR 53.1630(b) to the NRC Operations Center via the Emergency Notification System. For specifics on changes to existing non-emergency reporting requirements as outlined in SECY-24-0049, “Proposed Rule - Reporting Requirements for Nonemergency Events at Nuclear Power Plants (3150-AK71; NRC-2020-0036),” see response to Comment Bin 10.E.

- The NRC disagrees with the suggestion that the NRC reconsider the need for LERs or the information required to be in licensee event reports and the related forms because much shorter reports would not serve the purpose of the NRC and stakeholders in terms of using the reports to evaluate and, where appropriate, take actions to address the operating experience at commercial nuclear plants. The overall risk-informed framework used for 10 CFR Part 53 will facilitate making the reporting requirements correspondingly risk-informed (e.g., references in the reporting requirements to the design and analysis requirements from Subpart C to 10 CFR Part 53).

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.10.1.B: A commenter discussed that the proposed insurance requirement in 10 CFR 53.1720(a) includes an amount based on cost estimates to stabilize and decontaminate a plant but provides no discussion of the estimation process or acceptance criteria for the amount. The commenter requested that high-level language on the estimation process and acceptance criteria be incorporated into the proposed rule, adding that additional detail could be provided in guidance (NEI2-0154). Relatedly, a commenter requested that proposed 10 CFR 53.1720(a) be revised to replace "whichever is less" with "whichever is more" to avoid a scenario with a required minimum amount of $0 (TG16-0001).

A commenter discussed that proposed 10 CFR 53.1720 allows licensees to base minimum insurance coverage limits on plant-specific cost analyses rather than on an established minimum. The commenter stated that this provision is ambiguous and will be difficult for the NRC and other Federal agencies to enforce. The commenter requested that the proposed rule provide a more clear and structured process to allow for stakeholder and State regulator involvement throughout the entire advanced reactor licensing process (NYS2-0007).

NRC Response: The NRC agrees, in part, with the comments.

The NRC acknowledges that the estimation of costs to decontaminate a facility following postulated accidents can be a complex assessment. The NRC has added a reference within the final rule FRN to NUREG/CR-2601, "Technology, Safety and Costs of Decommissioning Reference Light Water Reactors Following Postulated Accidents," which provides part of the justification for the requirements in 10 CFR 50.54(w) and provides case studies for calculating post-accident costs with formulas, key considerations, and historical experience.

The NRC disagrees with the suggestion to revise the requirement in 10 CFR 53.1720 from the lesser of to the greater of "$1.06 billion, an amount based on plant-specific estimates of costs to stabilize and decontaminate a plant, or whatever amount of insurance is generally available from private sources." The NRC expects that the cost of decontaminating commercial nuclear plants licensed under 10 CFR Part 53 to be comparable to or less than the estimated costs for light-water reactors addressed under 10 CFR 50.54(w). The need to have the requirement be the lesser of cost estimations or the amount available from private insurers is explained in the final rule, "Changes in Property Insurance Requirements for NRC Licensed Nuclear Power Plants," (52 FR 28963; August 5, 1987) related to the addition of 10 CFR 50.54(w).

Accordingly, the NRC did not change the requirements in response to these comments but has revised the discussion in the final rule FRN to improve the clarity on the cost estimation process.

Comment Bin 3.10.1.C: A commenter discussed the immediate notification requirements for operating commercial nuclear plants proposed in 10 CFR 53.1630, stating that the proposed provision references 10 CFR 50.72 but that it is unclear why the provision has different requirements than 10 CFR 50.72(a)(4). The commenter expressed that proposed 10 CFR 53.1630(a)(4) appears to remove the activation time requirement for data links and leaves these details to the emergency plans and proposed that NRC ensure that provisions in 10 CFR Part 53 or associated guidance do not impose a more restrictive activation time than the one-hour requirement described in 10 CFR 50.72(a)(4).

The commenter also discussed that it is unclear why criteria for declaring an Emergency Class are included in 10 CFR 53.1630(a)(4) but not in 10 CFR 50.72(a)(4) and requested that NRC ensure the proposed criteria are not duplicated elsewhere in 10 CFR Part 53 and do not conflict with other requirements for Emergency Class declarations (NEI2-0145).

NRC Response: The NRC agrees with the comment.

10 CFR 53.1630(a)(4) does not include an activation time requirement for data links such as the activation time contained in 10 CFR 50.72(a)(4). As captured in the “Emergency Preparedness for Small Modular Reactors and Other New Technologies,” final rule FRN (88 FR 80065; November 16, 2023) the Emergency Response Data System (ERDS) requirement in 10 CFR Part 50, Appendix E, and the 10 CFR 50.72 ERDS activation requirement are not applicable to applicants and licensees choosing to comply with 10 CFR 50.160. Applicants and licensees choosing 10 CFR 50.160 are required to describe in their emergency plans the data link with the NRC for use in emergencies. Specific parameters to be reported are determined for the specific technology during the license application process. The NRC will review each applicant's data transmission capabilities on a case -specific basis.

The immediate notification requirements for operating commercial nuclear plants proposed in 10 CFR 53.1630 are different from the current requirements in 10 CFR 50.72(a)(4). The current 1-hour activation time requirement is specific to large-light-water reactor designs based on results from the 1975 “Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants (NUREG-75/014),” commonly referred to as WASH-1400, that determined that a significant radiological release could happen in as little as 30 minutes. Some advanced reactor designs are expected to have slower transient response times and relatively small and slow release of fission products. Therefore, it would not be appropriate to impose a 1-hour activation time on all licensees under 10 CFR Part 53 and that data link details and activation times will be described in the licensee’s emergency plan and approved by the NRC. The provisions in 10 CFR Part 53 do not impose a more restrictive activation time than the 1-hour requirement described in 10 CFR 50.72(a)(4).

The NRC agrees that the criteria for declaring an Emergency Class are included in 10 CFR 53.1630(a)(4) but not in 10 CFR 50.72(a)(4). The final rule FRN states that 10 CFR 53.1630 establishes immediate notification requirements for operating commercial nuclear plants and notes that these requirements are equivalent to 10 CFR 50.72 with minor changes to make the reporting criteria technology-inclusive. The criteria equivalent to declaring a typical Alert Emergency Class or greater was included in 10 CFR 53.1630(a)(4) because 10 CFR 50.160 does not have a requirement for a standard emergency action level scheme and, therefore, the licensee may not have an Alert declaration. The NRC confirmed the criteria are not duplicated elsewhere in 10 CFR Part 53 and do not conflict with other requirements for Emergency Class declarations.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.10.1.D: A commenter discussed that the proposed requirements in 10 CFR 53.1645 for reports of radiation exposure to members of the public are duplicative of requirements under 10 CFR Part 20 and should be removed (NEI2-0148). The commenter proposed the following specific edits if 10 CFR 53.1645 is not removed:

- Delete “radiological reports as required by 10 CFR Part 20, as well as” from 10 CFR 53.1645(a), as the phrase is redundant and unnecessary (NEI2-0148).

- Revise 10 CFR 53.1645 to use the term “discharge” instead of “release,” as appropriate, to provide consistency with definitions established in RG 1.2.1, Revision 3 and to ensure reporting focuses on discharge of radioactive material (NEI2-0149).
- Revise the title of 10 CFR 53.1645 to “Reports of Discharges of Radioactive Material in Liquid and Gaseous Effluents” to better reflect the content of annual reporting requirements (NEI2-0150).
- Remove the term “ALARA” from both 10 CFR 53.1645(a) and (b) to ensure consistency with the updated provisions in proposed 10 CFR 53.425 (NEI2-0151).

NRC Response: The NRC agrees, in part, with the comments.

Regarding the part of the comment on the inclusion of pointers to the requirements in other parts of NRC regulations, see the NRC’s response to Comment Bin 3.12.G.

Regarding the part of the comment on using “discharge” instead of “release” in the reporting requirements under 10 CFR 53.1645, the proposed and final rules explain that the requirements in 10 CFR 53.1645 result in essentially the same reporting requirements required by the regulations and licenses under 10 CFR Parts 50 and 52. An administrative difference is that 10 CFR Part 53 addresses the reports directly in the regulations instead of through the combination of regulations and requirements included in the technical specifications under 10 CFR 50.36a. Therefore, the language used in 10 CFR 53.1645 is intentionally similar to the language used in 10 CFR 50.36a and the associated technical specifications, which require similar reporting requirements for licenses under 10 CFR Part 50. Specifically, the phrase, “quantity of each of the principal radionuclides released to unrestricted areas,” is equivalent in both 10 CFR 50.36a and 10 CFR 53.1645. In addition, numerous other NRC regulations and guidance documents use the word “release,” instead of the word “discharge,” when referring to emissions that are not exclusive to only the onsite environment. For example, 10 CFR 20.1302(a) uses “released” to discuss material in unrestricted and controlled areas and 10 CFR 20.1302(b)(2)(i) discusses material “released” at the boundary of the unrestricted area. The NRC therefore concludes that changing 10 CFR 53.1645 to use the word “discharge” could create unnecessary confusion regarding differences in terminology between 10 CFR Part 53 compared to 10 CFR Part 50.

Regarding the part of the comment on removing the term “as low as reasonably achievable” or ALARA from 10 CFR 53.1645(a) and (b), as described in the NRC’s response to Comment Bin 3.2.3.A, the NRC agrees that referring to 10 CFR Part 20 is sufficient to address radiation protection standards.

Accordingly, the NRC revised the final rule to remove specific references within Part 53 to ALARA and only included direct references to 10 CFR Part 20.

3.10.2. <u>RFC: Financial qualifications</u>

Comment Bin 3.10.2.A: A commenter discussed that the proposed requirement in 10 CFR 53.1670 is presented at a high level and does not present details on application contents expected to demonstrate financial qualification. The commenter added that proposed 10 CFR 53.1109 and 10 CFR 53.1670 also do not reference details on content for financial qualification as described in 10 CFR 50.33(f). The commenter suggested that 10 CFR 53.1670 be expanded to provide appropriate content requirements for an applicant under 10 CFR Part 53, including at minimum a reference to technical criteria for reporting as described in 10 CFR 53.1366 and 10 CFR 53.1413. The commenter suggested that the proposed rule should only provide details equivalent to those expected for an applicant under 10 CFR Part 50 or 10 CFR Part 52, and additional details be presented in guidance (NEI2-0152).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that 10 CFR Part 53 should not provide more detailed requirements than 10 CFR Parts 50 and 52. The NRC has modified the financial qualification requirements in 10 CFR Part 53, Subparts H and J, as noted in the response to Comment Bin 3.10.2.C.

However, the NRC disagrees that 10 CFR 53.1670 should be expanded to provide appropriate application content requirements for an applicant under 10 Part 53. For the sake of clarity, all requirements related to the content of applications under 10 CFR Part 53 are found in Subpart H.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.10.2.B: The commenter stated that the proposed text in 10 CFR 53.1690 is nominally identical to 10 CFR 50.76, but that section references financial qualification information provisions specified in 10 CFR 50.33(f)(2). 10 CFR 53.1690 requires that licensees provide financial qualification information as specified in either 10 CFR 53.1366 or 10 CFR 53.1413. The commenter requested that NRC address the inconsistency in referencing financial qualification information provisions (NEI2-0153).

NRC Response: The NRC agrees with the comment.

The NRC understands the comment to be suggesting that 10 CFR 53.1690 should only be referencing the information equivalent of that in 10 CFR 50.33(f)(2), which is the information required for an initial OL. Proposed 10 CFR 53.1690 had instead required the financial qualifications information that would be required for obtaining an initial OL *or COL* [emphasis added]. The financial qualification information required of an applicant for an initial COL is more than the information required of an applicant for an initial OL because it includes information relating to the costs of construction. The NRC agrees with the comment’s suggestion that the manner in which 10 CFR 53.1690 makes reference to the financial qualification requirements should be modified for clarity and consistency with the existing requirements regarding a change in a licensee’s status from a utility licensee to a non-utility licensee.

Accordingly, the NRC has revised 10 CFR 53.1690(a) to remove the reference to information for an initial COL.

Comment Bin 3.10.2.C: A commenter provided feedback on NRC’s requests for comment regarding financial qualifications for merchant new reactor applicants.

The commenter responded to NRC’s request for comment regarding challenges of standards for merchant power plant applicants, stating that the current “reasonable assurance” financial qualifications standard imposes unnecessary and burdensome requirements which impede the development of advanced reactor projects. The commenter discussed there is no direct correlation between financial qualification reviews and the safety performance of nonelectric utility operators, citing SECY-79-299, “Generic Issue of Financial Qualifications: Licensing of Production and Utilization Facilities,” issued April 1979 (ML12236A723), and added that NRC’s safety requirements and related review, oversight, and inspection processes and programs are the most effective tools for assuring safety performance. The commenter also cited a 2014 study of industry experience conducted by Catherine Hausman and published in the American Economic Journal: Economic Policy, stating that Hausman’s findings demonstrate that transferring a reactor to “merchant” plant status does not adversely impact safety performance. Further, the commenter stated that no recent evidence since the publication of Hausman’s study suggest that financial issues for merchant plants have adversely impacted safety performance. The commenter suggested that an elimination of the financial qualifications review altogether may be supported, but discussed that a reduced level of financial qualifications review as described in SECY-18-0026, “Proposed Rule: Financial Qualifications Requirements for Reactor Licensing (RIN 3150-AJ43),” issued February 2018 (ML17172A565) would not compromise public health and safety and would allow NRC to readily identify any degradation in licensee performance during construction and operation (NEI2-0210).

The commenter expressed that 10 CFR Part 53 should have the same financial requirements as 10 CFR Parts 50 and 52, all based on the “appears to be financially qualified” standard in 10 CFR Part 70. The commenter discussed that utility applicants under 10 CFR Parts 50, 52, or 53 with “cost of service” recovery should be presumed to be financially qualified, and a detailed review of qualifications for nonelectric utility applicants is unnecessary. The commenter suggested NRC conduct limited initial screenings under the 10 CFR Part 70 standard to avoid projects incapable of success or to verify commitments for financing greater than 50 percent of the construction cost estimate prior to the start of licensed activities, in line with discussion in Enclosure 1 to SECY-18-0026 (NEI2-0211).

For NRC’s request for comment regarding categories of merchant new reactor applicants for which a 10 CFR Part 70 “appears to be financially qualified” standard would be more appropriate, the commenter discussed that traditional nonutility applicants for large commercial applicants all have the same basic characteristics and lack “costs-of-service” treatment and plans to sell power under appropriate power sales arrangements. The commenter stated an “appears to be financially qualified” standard would provide NRC flexibility in addressing unique circumstances involving nonelectric utility applicants (NEI2-0212).

The commenter agreed with NRC’s proposal that a 10 CFR Part 70 financial qualification standard apply to preconstruction license transfer applications, adding that any preconstruction or preoperation conditions should be assessed and revised or reimposed in the event of a license transfer. The commenter also suggested a review of financial projections for the initial five years of operation, including in connection with license transfers for operating licenses (NEI2-0213).

The commenter responded to NRC’s request for comment regarding another standard for financial qualification of merchant new reactor applicants, stating that the “appears to be financially qualified” standard under 10 CFR Part 70 offers sufficient flexibility for a financial review by limited staff without imposing undue burden on applicants or impeding the development of new reactor projects. The commenter cited NRC’s regulatory basis document and SECY-18-0026 as providing additional justification (NEI2-0214).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees that a reduced level of financial qualifications review as described in SECY-18-0026 would not compromise public health and safety and would allow NRC to readily identify any degradation in licensee performance during construction and operation. The NRC also agrees that financial requirements in 10 CFR Part 53 should be based on the “appears to be financially qualified” standard in 10 CFR Part 70.

The NRC disagrees with making similar changes to the requirements in 10 CFR Parts 50 and 52 in this rulemaking. Applicants under those parts are outside the scope of this rulemaking.

The NRC agrees that utility applicants with “cost of service” recovery should be presumed to be financially qualified, and this is already recognized in 10 CFR Part 53. For example, under 10 CFR 53.1670, electric utility applicants are excepted from the financial qualification requirements. The same is true in the corresponding requirements for utility applicants under 10 CFR Parts 50 and 52.

Accordingly, the NRC has revised the rule language related to financial qualifications in 10 CFR Part 53, Subparts H and J, in response to these comments.

3.11. Subpart M: Enforcement (§§ 53.9000 – 53.9010)

No comments are associated with this issue.

3.12. Other general comments on Part 53, including RFC on organization of 10 CFR Part 53 and references to other NRC regulations and RFC on ADVANCE Act

Comment Bin 3.12.A: Several commenters suggested that much of the rule language could be moved into guidance (NIA2-0002, NGO-0002, CP-0003, NEI2-0047, NEI2-0248, USNIC2-0024, BI1-0004, NIA2-0007). Two of the commenters said this would eliminate unnecessary and duplicative requirements and would be consistent with Enclosure 3 (ML24064A051) in the Commission's direction to staff in SRM-SECY-23-0021 (NIA2-0002, NGO-0002). Two of the commenters also mentioned that Chairman Wright in his vote record on the proposed rule suggested a “higher-level rule” with details provided in guidance (NEI2-0047, USNIC2-0024). One of the commenters said that the previous Frameworks A and B should be moved to guidance to support a high-level rule (CP-0007).

Two commenters urged the NRC to remove detail from 10 CFR 53.440 and 10 CFR 53.450 and place it into guidance (NEI2-0047, USNIC2-0024). One of the commenters specifically suggested that the NRC should delete 10 CFR 53.440 and 10 CFR 53.450 and develop guidance showing what are acceptable means of meeting the design criteria in 10 CFR 53.400 to 10 CFR 53.430 and the safety criteria in 10 CFR 53.210 to 10 CFR 53.270, respectively (NEI2-0047).

A commenter wrote that the NRC’s goals for the rulemaking can be accomplished by creating a high-level performance-based regulatory framework which would enable advanced reactor license applicants to justify their own safety case to satisfy a set of common, standard safety limits, and new regulatory guidance that would provide predictability for applicants and create multiple pathways to license their reactor technology. Specifically, applicants would submit a safety case that demonstrates compliance with performance-based regulatory requirements for normal and off-normal operation to protect workers, the public, and the environment, and would also propose and demonstrate compliance with an overall risk or safety metric. The commenter provided an overview of their previous comments on the rulemaking (NIA2-0007).

A commenter expressed agreement with another commenter that urged the NRC to relocate portions of the rule text to guidance to reduce the high level of prescription and excessive volume of the rule and said such changes would apply systems-engineering best practices. The commenter noted this could include the consideration of LBEs, which are not a consideration during the construction and decommissioning phases, but their inclusion in these phases would present a codification of unnecessary requirements (RAD-0013).

NRC Response: The NRC disagrees with these comments.

Moving the 10 CFR 53.440 and 10 CFR 53.450 requirements to guidance would eliminate key aspects of the 10 CFR Part 53 regulatory framework that ensure the analyses will support establishing design features and functional design criteria that will meet the safety functions in 10 CFR 53.230 and high-level safety criteria in 10 CFR 53.220. In addition, 10 CFR 53.440 includes specific design requirements to address areas beyond those directly associated with the evaluation of LBEs (e.g., 10 CFR 53.440(g) and (h)) or needed to capture key engineering principles (e.g., 10 CFR 53.440(a) and (b)).

The 10 CFR Part 53 framework attempts to provide considerable flexibility in how applicants and licensees can meet a requirement while still providing clear, stable, and predictable regulations. (See the response to Comment Bin 3.2.4.A regarding the hierarchy used within 10 CFR Part 53). The comments appear to suggest the inclusion of vague requirements in the rule and reliance on guidance documents to define acceptable approaches, including suggestions to reframe 10 CFR Part 53 to a high-level performance-based regulatory framework which would enable advanced reactor license applicants to justify their own frameworks for safety analyses and a suggestion to remove the consideration of LBEs during the construction and decommissioning phases. The NRC believes such a regulatory framework relying on case-by-case reviews would not provide clear, stable or predictable outcomes for applicants.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.12.B: A commenter emphasized the importance of the NRC adapting a regulatory framework that is risk-informed, performance-based, and technology-inclusive and promotes clarity, consistency, flexibility, and efficiency, noting this would ensure the rule supports innovation while maintaining safety. The commenter specifically recommended that the NRC clarify terminology, ensure consistent application of standards, allow for flexible risk evaluation methods which align with the goals of NEIMA and the ADVANCE Act, and streamline the rule language by removing redundant sections (BI1-0013).

Additionally, a commenter stated that the characterization of the proposed rule as performance-based is not in line with the NRC’s standard use of the term “performance” regarding nuclear facilities, citing Appendix D to NUREG-2150, “A Proposed Risk Management Regulatory Framework,” issued April 2012 (ML12109A277), which outlines the NRC's risk-informed and performance-based defense-in-depth regulatory approach (NYS2-0005).

Another commenter stated that the rule is too complicated, overly prescriptive, not in alignment with congressional direction and recent legislation, and difficult to follow (HPT3-0003, HPT19-

0001). The commenter further stated that the proposed rule introduces many new regulatory elements and involves unwarranted regulatory scope creep (HPT19-0001).

NRC Response: The NRC agrees, in part, with the comments.

The comments include discussion of general topics and regulatory philosophy that are addressed within the proposed and final rules in terms of attempts to balance flexibility and predictability. The NRC agrees, in part, with the comment that the NRC should allow for flexible risk evaluation methods which align with the goals of NEIMA and the ADVANCE Act. See the response to comments on the rule language for 10 CFR 53.450 in Section 3.3.2.2 of this document.

The NRC disagrees that the characterization of the proposed rule as performance-based is not in line with the NRC's standard use of that term, and the NRC disagrees that the rule is too complicated, overly prescriptive, and not in alignment with congressional direction. The NRC Glossary defines performance-based regulation as "[a] regulatory approach that focuses on desired, measurable outcomes, rather than prescriptive processes, techniques, or procedures. Performance-based regulation leads to defined results without specific direction regarding how those results are to be obtained." This is consistent with the construct of 10 CFR Part 53, where the measurable outcomes are defined in Subpart B without prescriptive direction on how the commercial nuclear plant must be designed to achieve those outcomes. In addition, 10 CFR Part 53 fulfills the congressional mandate in NEIMA to establish a technology-inclusive regulatory framework for optional use by commercial advanced nuclear reactor applicants for new reactor license applications.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.12.C: A commenter stated that NRC's current efforts to modernize the regulatory framework for advanced reactors, in response to directives under NEIMA, the ADVANCE Act, and EOs, do not adequately ensure an efficient and effective framework for enabling the safety and secure use of nuclear energy technologies (NEI2-0001). The commenter recommended performing a systematic and aggressive search for additional changes in requirements, policy, and guidance to reduce unnecessary regulatory burden consistent with the intent and direction of the ADVANCE Act (NEI2-0259, NEI2-0001).

The commenter expressed appreciation for the evolution of proposed 10 CFR Part 53 over the course of the rulemaking, including response to Commission directive in SRM-SECY-23-0021. However, the commenter stated that unresolved issues may prevent the widespread adoption of 10 CFR Part 53, if left unaddressed, but added that an efficient and technology-inclusive 10 CFR Part 53 rule should become the preferred licensing pathway for all new reactors and meet legislative and executive goals (NEI2-0002).

The commenter added that protecting public health and safety without imposing undue burden is important for the nation and consistent with NRC's mission (NEI2-0001).

Another commenter wrote that the NRC staff should incorporate a new section in the rule that outlines efficient licensing in line with statutory requirements and the Commission's decisions (BI1-0034).

A commenter recommended that the NRC limit 10 CFR Part 53 applicability to modern reactors, instead of attempting to merge older and modern reactor approaches into a single regulation, specifically by adding the following language to 10 CFR 53.000 (HPT38-0001, HPT19-0001):

> This regulation applies to reactor types that require minimal operator action and minimal engineered systems to ensure that minimal offsite public radiation exposures occur following serious external and internal events that may challenge the reactor. The limiting design basis event risk to the public is an order of magnitude lower than earlier regulatory requirements involving water reactors.

NRC Response: The NRC agrees, in part, with the comments.

Regarding the comments suggesting a systematic and aggressive search for additional changes in requirements to reduce unnecessary regulatory burden consistent with the ADVANCE Act and those suggesting a new section in the rule that outlines efficient licensing in line with statutory requirements, the NRC has made several changes to the proposed rule based on commenters' suggestions about ways to reduce burden, as documented in various other responses in this document including, but not limited to, the NRC's responses to Comment Bins 3.3.2.1.A and 3.3.2.2.E related to 10 CFR 53.440 and 10 CFR 53.450, respectively. In addition, the NRC has initiated development of an additional rulemaking to expedite licensing of qualified microreactors and other potentially low risk, low consequence reactors, consistent with the ADVANCE Act and EOs issued in 2025.

The NRC disagrees that a new section needs to be added to the rule to outline efficient licensing because other factors, such as NEIMA, the ADVANCE Act, EOs issued in 2025, and changes to the NRC mission statement, are already serving this purpose.

The NRC also disagrees that the applicability of 10 CFR Part 53 should be limited to modern reactors because doing so would not be consistent with congressional direction in NEIMA to complete a technology-inclusive regulatory framework for optional use by commercial advanced reactor applicants. Additionally, NEIMA includes a definition of the term "advanced reactor," which could include older reactor designs with significant improvements.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.12.D: In response to the request for comment regarding the ADVANCE Act, two commenters discussed that the 10 CFR Part 53 proposed rule addresses to some extent many items from the ADVANCE Act, such as Section 203 requirements for flexible operation, including load following, the use of advanced reactors for non-electric applications, and a definition of construction that supports co-location with industrial facilities, and Section 208 requirements for flexibility in staffing and operations, safeguards and security, and emergency preparedness, as well as SRM-SECY-20-0045 (NEI2-0215, USNIC2-0035).

However, one of the commenters stated that the ADVANCE Act should be implemented for each of 10 CFR Parts 50, 52, and 53, with additional changes needed in 10 CFR Part 53. The commenter discussed that the flexibility provided by 10 CFR Part 53 addresses many Section 203 issues, but that regulatory uncertainty remains regarding requirements placed on adjacent facilities and consideration of nearby population densities (NEI2-0215).

To implement section 203 of the ADVANCE Act, two commenters suggested that 10 CFR Part 53 needs changes to address: guidance for various non-electric applications such as chemical production, water desalination, industrial heat, energy storage, isotope production, and district heating (NEI2-0215, USNIC2-0035).

To implement section 208 of the ADVANCE Act, two commenters suggested that 10 CFR Part 53 needs changes to address: risk-informed and performance-based strategies and guidance to license and regulate microreactors; the transportation of fueled microreactors and licensing mobile deployment; siting considerations; and other relevant policy and licensing considerations for microreactors discussed in SECY-20-0093 (NEI2-0215, USNIC2-0035).

One of the commenters discussed that they submitted a proposal paper entitled "Regulations of Rapid High-Volume Deployable Reactors in Remote Applications (RHDRA) and Other Advanced Reactors" to address issues in section 208 of the ADVANCE Act and recommended that NRC consider the report when updating 10 CFR Part 53 to be inclusive of microreactor technologies (NEI2-0250).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees that the 10 CFR Part 53 rule addresses many items from the ADVANCE Act to some extent but disagrees that additional changes are needed in 10 CFR Part 53. A key objective of the 10 CFR Part 53 rulemaking was to develop a technology-inclusive alternative to the existing licensing processes in 10 CFR Parts 50 and 52. As described in the response to Comment Bin 3.4.2.A, the NRC revised 10 CFR 53.530(b) to provide additional flexibility for the possible siting of commercial nuclear plants in areas with high population densities. However, the NRC acknowledges that the final rule may not completely address every regulatory issue for every potential future advanced reactor. For example, to address microreactor issues, such as those raised in the comments, the NRC has initiated development of an additional rulemaking to expedite licensing of qualified microreactors and other potentially low risk, low consequence reactors, consistent with the ADVANCE Act and EOs issued in 2025.

Regarding the comment's suggestion to allow risk evaluation techniques other than probabilistic risk assessments and other changes related to the possible deployment of microreactors, see the NRC's responses to Comment Bin 3.3.2.2.E, Comment Bin 3.4.2.A, Comment Bin 3.4.2.B, and Comment Bin 3.4.2.C.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.12.E: Several commenters provided recommendations on how the ADVANCE Act should be incorporated in 10 CFR Part 53. A few commenters stated that out of the options presented in the ADVANCE Act for implementing section 208, option B, implementation through 10 CFR Part 53, is the best pathway as it would be most efficient (RAD-0012, NEI3-0004). One commenter also supported this approach because 10 CFR Part 53 is meant to be technology-inclusive and would require fewer exemptions than 10 CFR Part 50 or 10 CFR Part 52, and flexibilities under 10 CFR Part 53 would be beneficial for microreactors (NEI3-0004). Recognizing the significantly reduced risk posed by advanced reactors, a commenter recommended that the NRC be responsive to ADVANCE Act provisions, including Section 208, to the maximum extent practicable, instead of initiating separate rulemakings (RAD-0016).

A commenter stated that the proposed rule provisions for microreactors do not accommodate varied business strategies and deployment models and explained that a practical alternative approach would integrate licensing and oversight functions with high-level performance requirements that define outcome objectives related to reactor safety, radiation safety and safeguards. The commenter recommended that 10 CFR Part 53 be revised to include provisions for licensing and regulating microreactors and better address the ADVANCE Act's provisions on microreactors. The commenter noted this would also satisfy NEIMA requirements. The commenter also stated that the NRC has been in preapplication engagement with several microreactor developers, yet there seems to be a lag in the NRC's responsiveness to this class of advanced reactors, which would be further exacerbated if the need for a framework for microreactors were to be addressed under a separate rulemaking (ROSE-0011, ROSE-0012, ROSE-0013).

The commenter emphasized that if 10 CFR Part 53 is sufficiently performance-based and the definition of "utilization facility" is modernized to exclude very low-hazard advanced reactors, the rule could easily accommodate small and mobile reactors. The commenter provided specific recommendations for making 10 CFR Part 53 more performance-based, including proposed definitions and a recommendation to not limit deployment of reactors to remote locations with low population density, particularly for small reactors (ROSE-0012, ROSE-0013). The commenter acknowledged that their recommendations represent a transformational departure from some regulatory practices, policies, and licensing frameworks, and they are prepared to work with the NRC to enable the deployment of advanced reactors (ROSE-0018).

The same commenter also provided a white paper presenting a risk-informed, performance-based strategy for regulating fleet-wide small and mobile reactors, noting the presented approach aligns with a modern risk-informed, performance-based and technology-inclusive regulatory framework, as mandated by NEIMA and reinforced in the ADVANCE Act, specifically in Section 208. The commenter stated that the proposed approach should be further developed with external stakeholders and included in 10 CFR Part 53 (RF-0002).

A commenter stated that the NRC should address section 401 of the ADVANCE Act in order to increase efficiency, and address section 501 of the ADVANCE Act and the updated NRC mission statement by explicitly incorporating principles of efficiency and societal benefit to enable and advance nuclear technologies. Additionally, in order to address Section 208 of the ADVANCE Act, the commenter urged the NRC to focus on tailoring 10 CFR Part 53 to the unique characteristics of microreactors, streamlining review processes, and enabling innovative deployment strategies. The commenter also recommended including language in the rule indicating that an efficient, risk-informed, and graded approach to application review should be used. The commenter also noted that existing "covered sites" and facilities may be located in areas that were once remote but have developed over time, and under existing regulations development of new facilities at these sites is limited or discouraged (BI1-0016). The same commenter also provided specific recommendations for addressing Sections 208, 401, 501 and 505 of the ADVANCE Act, including preamble language, proposed definitions, proposed regulatory revisions, and recommendations for guidance that should be developed (BI1-0020, BI1-0021, BI1-0022).

In order to address the ADVANCE Act provisions regarding regulatory efficiency, one commenter expressed support for another commenter's recommendation for the NRC to pursue more aggressive changes in 10 CFR Part 53 to enable the use and deployment of microreactors (WEST1-0003). The commenter also stated that the proposed rule contains prescriptive requirements that would be overly burdensome for microreactors and does not address all areas that would be needed for deployment of all types of advanced reactors, including those described in NEI's RHDRA report and items the commenter previously submitted correspondence on. The commenter stated this would include the licensing of replacement microreactor modules at an operating site or the reuse of a refurbished microreactor module. The commenter urged the NRC to take action on such topics to align 10 CFR Part 53 with the provisions of the ADVANCE Act (WEST1-0009).

One commenter stated that the ADVANCE Act contains many high-level goals that should be incorporated into 10 CFR Part 53 and listed sections of the ADVANCE Act that are related to 10 CFR Part 53, including Sections 203, 206, 207, 208, 401, 501, 504, 505, 506, and 507 (CP-0006).

NRC Response: The NRC agrees, in part, with the comments.

Regarding those comments suggesting that 10 CFR Part 53 address Section 208 of the ADVANCE Act related to microreactors, the NRC has included some provisions, such as those in 10 CFR 53.620 supporting factory loading of fuel in a manufactured reactor, to better accommodate deployment models for microreactors. The NRC disagrees that further changes to 10 CFR Part 53 are necessary to enable the use and deployment of the full range of technologies and reactor sizes, as 10 CFR Part 53 is already technology-inclusive and sufficiently performance-based. The NRC also acknowledges the comments that the NRC should address sections of the ADVANCE Act other than Section 208 within 10 CFR Part 53, and the NRC has strived to achieve many of the high-level principles from the ADVANCE Act within 10 CFR Part 53. However, while a key objective of the 10 CFR Part 53 rulemaking was to develop a technology-inclusive alternative to the existing licensing processes in 10 CFR Parts 50 and 52, the NRC acknowledges that the final rule may not completely address every regulatory issue for every potential future advanced reactor. Nevertheless, consistent with the ADVANCE Act and EOs issued in 2025, the NRC has initiated development of an additional rulemaking to expedite licensing of qualified microreactors and other potentially low risk, low consequence reactors. This activity, along with NRC guidance development activities, is intended to address questions such as those raised by the comments in a holistic manner.

The NRC cautions against broad arguments that there is a reduced risk profile for any general class of reactors. While reactor designs that use limited inventories of radionuclides and incorporate the attributes from the NRC's Advanced Reactor Policy Statement can justify added flexibility in areas such as staffing, siting, and emergency preparedness programs, there remains a fundamental need to demonstrate reactor safety through appropriate combinations of analysis, test programs, prototype testing, and operating experience.

The NRC disagrees with the recommendation that 10 CFR Part 53 include language indicating that an efficient, risk-informed, and graded approach to application review should be used, as it would not be appropriate to codify such direction to the NRC staff in rule language. Guidelines for NRC staff review of applications should be contained in NRC staff review guidance, which is being developed.

Regarding the comments related to the definition of "utilization facility," see the NRC's response to Comment Bin 3.1.1.B, Comment Bin 3.1.1.K, and Comment Bin 3.1.1.M.

Regarding those parts of the comment related to population-related siting considerations under 10 CFR 53.530, see the NRC's response to Comment Bin 3.4.2.A, Comment Bin 3.4.2.B, and Comment Bin 3.4.2.C.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.12.F: A commenter expressed support for retaining references to other regulations in 10 CFR Part 53, noting that applicants will still be required to meet those requirements and this is an efficient way to incorporate them into the rule (UCS-0005). Another commenter stated that some references in the proposed rule are valuable; for example, proposed 10 CFR 53.860 provides valuable references to specific performance-based regulations in 10 CFR Part 73.55 and 10 CFR 73.100. However, the commenter suggested that general references to the entirety of a CFR part be removed, such as references to 10 CFR Part 20 in 10 CFR 53.260 and 10 CFR 53.270. The commenter suggested other improvements or changes to references throughout 10 CFR Part 53 in Enclosure 2 to their comment submittal (NEI2-0178). Another commenter agreed with the previous commenter (NEX-0013).

A commenter said that the rulemaking should avoid unnecessary cross-references to existing regulations, in particular to 10 CFR Part 50 and 10 CFR Part 52. The commenter stated that including the text directly in 10 CFR Part 53 would provide a clearer understanding of the requirements, allow text to be modernized where appropriate, and decouple 10 CFR Part 53 from other regulations. The commenter noted, however, that decoupling 10 CFR Part 53 from other regulations is a not sufficient reason for creating stricter regulations than those applied to the existing fleet. The commenter stated that some references improve regulatory certainty and reduce burden, but others impose unnecessary constraints (BI1-0036).

A commenter stated that while the general organization of 10 CFR Part 53 appears to be effective, there are many references to other parts of the regulations. The commenter explained that while this works well for people familiar with the regulations, it may be confusing for those not as familiar, and 10 CFR Part 53 should be revised to be more easily understandable. The commenter suggested that in addition to referencing section numbers, the NRC also include descriptions of each section, and the commenter provided some examples of how this could be implemented (LMNT-0001).

NRC Response: The NRC agrees, in part, with these comments.

The NRC agrees that retaining references within the rule text is useful and has maintained these references in the final rule. The NRC disagrees with removing references to an entire CFR Part (such as in 10 CFR 53.260, 10 CFR 53.270, and other sections, as suggested by the comments), as the NRC believes that it is important to directly reference the relevant regulations. In these cases, an exhaustive list of the relevant individual sections of the regulations would be significantly more cumbersome to include in the regulations, than just the reference to the entire CFR Part.

The NRC agrees that avoiding unnecessary references, in particular to 10 CFR Part 50 and 10 CFR Part 52, provides a clearer understanding of the requirements and allows rule text to be modernized, where appropriate. The NRC does not believe that the references retained within the 10 CFR Part 53 rule are unnecessary, and generally the requirements in 10 CFR Part 53 are analogous to, but do not directly reference, 10 CFR Part 50 and 10 CFR Part 52.

The NRC agrees with the need to have the regulations be understandable but disagrees that describing each section referenced in the regulations is the correct way to address this. Adding a description or referencing the title of a section may help with comprehension of an individual requirement, but doing this throughout the regulations would make the regulations much more difficult overall to navigate. The NRC notes that when using the eCFR (https://www.ecfr.gov/) there are linked references within the regulations so the user can easily navigate to the referenced part, section, or paragraph, in full.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.12.G: A commenter discussed that the NRC's restriction of applicability of the 10 CFR Part 53 proposed rule only to commercial nuclear plants licensed under AEA section 103 is unnecessarily restrictive. The commenter stated that a class 104 framework for an operating license is preferred to enable factory testing of a fueled microreactor. The commenter suggested that NRC expand the applicability of the proposed rule to all production and utilization facilities licensed under AEA sections 103 or 104 for consistency with 10 CFR 50.1 and 10 CFR 52.0. The commenter also recommended the following edit to proposed 10 CFR 53.000 and any necessary conforming changes throughout 10 CFR Part 53: "This part provides for the issuance, amendment, renewal, and termination of licenses, permits, certifications, and approvals for production and utilization facilities licensed under Section 103 and 104 of the Atomic Energy Act of 1954, as amended (AEA) (68 Stat. 919) and Title II of the Energy Reorganization Act of 1974, as amended (88 Stat. 1242)" (NEI2-0025).

NRC Response: The NRC disagrees with the comment.

The suggested revision to 10 CFR Part 53 to include licenses issued under section 104 of the AEA is addressed, in part, in the NRC's response to Comment Bin 3.8.10.H relating to testing of manufactured reactors at a manufacturing facility. The NRC disagrees with the more general suggestion to broaden 10 CFR Part 53 to include Class 104 licenses, and the NRC believes the level of effort and changes needed to address a wider range of facilities beyond the commercial advanced nuclear reactors addressed within NEIMA is not warranted. The NRC has initiated other activities consistent with the ADVANCE Act and EOs issued in 2025, including development of an additional rulemaking to expedite licensing of qualified microreactors and other potentially low risk, low consequence reactors. This activity, along with other NRC guidance development activities, is intended to address issues such as those raised by the comments in a holistic manner.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.12.H: A commenter stated that while requirements in 10 CFR Part 53 Subparts H and I cite equivalency to requirements in 10 CFR Part 50 and 10 CFR Part 52, these sections contain new requirements, which the commenter stated may not be in conformance with NEIMA and seems like an "expansion of the bureaucracy." The commenter recommended that these sections instead cite the equivalent 10 CFR Part 50 and 10 CFR Part 52 sections, with editorial modifications, or the NRC provide additional justification for the proposed changes (HPT41-0001).

NRC Response: The NRC disagrees with the comment.

The NRC disagrees that 10 CFR Part 53 is not in conformance with NEIMA just because some of the rule's provisions are different than similar provisions in 10 CFR Parts 50 and 52. Because an applicant's development of the licensing basis under 10 CFR Part 53 is significantly different than it would be under 10 CFR Part 50 or Part 52, there are necessary deviations in the provisions in 10 CFR Part 53 as compared to the equivalent requirements in 10 CFR Parts 50 and 52. For example, 10 CFR Part 53 requires that analyses be performed to establish design features and functional design criteria versus the prescriptive General Design Criteria that are required to be met under 10 CFR Parts 50 and 52.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.12.I: A commenter stated that while stakeholders may submit written statements for Commission consideration during a mandatory hearing on a 10 CFR Part 53 application, there is no provision for a contested hearing. The commenter explained that without the possibility of a contested hearing, the Commission and the NRC staff have little incentive to meaningfully review public feedback, and added that, based on their experience, contested hearings are a meaningful and effective way to engage the NRC staff and the Commission. The commenter emphasized that States play a unique role, and that if a host State determines that a contested hearing is in the interests of the State and its residents, the State should be permitted to request and participate in a contested hearing (NYS2-0010).

NRC Response: The NRC disagrees with the comment.

The proposed rule makes numerous amendments to 10 CFR Part 2 to clarify that the NRC's procedures for contested proceedings apply to applications submitted under 10 CFR Part 53. The NRC does not intend to limit hearings on 10 CFR Part 53 applications to only mandatory hearings.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.12.J: A commenter stated that several provisions in the proposed rule are ambiguous and will negatively impact State and public stakeholders and their ability to understand the licensing basis or participate in the process under 10 CFR 2.206. The commenter added it would also be difficult for the NRC to enforce such ambiguous provisions. The commenter urged the NRC to provide a more clear and structured process to allow for the involvement of State regulators and stakeholders in the entire licensing process (NYS2-0007).

NRC Response: The NRC disagrees with the comment.

As explained in the proposed and final rule FRNs, 10 CFR Part 53 is a risk-informed, performance-based, and technology-inclusive regulatory framework for commercial nuclear plants. 10 CFR Part 53 provides a framework, safety criteria, and definitions of relationships between major activities to accommodate a variety of reactor technologies, sizes, and designs. Guidance is or will be available regarding the structure of key licensing-basis documents to encourage consistency in the general organization of information. The differences in reactor technologies and differences in how individual commercial nuclear reactors are designed and operated may also result in the need for additional guidance to support NRC reviews, public participation, and NRC's inspection and oversight functions. Regarding the comment's discussion on the involvement of state governments and stakeholders, 10 CFR Part 53 has included the same provisions for openness and opportunities for participation as are included in and have been exercised through 10 CFR Parts 50 and 52, which provide appropriate opportunities for public engagement consistent with the AEA.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.12.K: A commenter stated that allowing applicants and licensees to justify an appropriate regulatory footprint unique to each design is likely to lead to substantial variation from plant to plant and thus challenge numerous safety aspects. The commenter added this could be exacerbated by the potential inconsistencies inherent to the review of applications. The commenter recommended that the NRC provide an oversight review function that would ensure consistency in NRC reviews of all aspects of nuclear safety from plant to plant. The commenter also stated that predictable review timelines are important, but there is no published schedule for a 10 CFR Part 53 review. The commenter added that PRAs have inherent uncertainties that could extend review times and costs, concluding that 10 CFR Part 53 offers flexibility that may come at the price of timeline unpredictability (NYS2-0009).

NRC Response: The NRC agrees, in part, with the comment.

As explained in the proposed and final rules, 10 CFR Part 53 is a risk-informed, performance-based, and technology-inclusive regulatory framework for commercial nuclear plants. As a technology-inclusive rule, 10 CFR Part 53 is intended to accommodate a variety of reactor technologies, sizes, and designs that would result in variations in the applications and underlying licensing-basis documents. Guidance is or will be available regarding the structure of key licensing-basis documents to encourage consistency in the general organization of information. Regarding the comment's discussion on oversight of NRC staff performing reviews and review schedules, these are matters addressed by NRC guidance for its staff and overseen by NRC managers. The NRC routinely establishes review schedules for specific applications and generic schedules for different types of licensing actions are available on the NRC's website.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.12.L: A commenter stated that it has been industry's position that 10 CFR Part 53 must be flexible in allowing various licensing approaches to meet the intent of NEIMA, the PRA Policy Statement, the ADVANCE Act, and SRM-SECY-23-0021, and that insight into risk-informed licensing processes that use different combinations of risk information and deterministic safety analysis should help inform the development of 10 CFR Part 53. The commenter added that the white paper they provided shows how 10 CFR Part 53 requirements can be met by a variety of methodologies and provides a roadmap for updating 10 CFR Part 53 to increase flexibility. The commenter added that their proposed rule language changes would address NEIMA, the ADVANCE Act, the new NRC mission statement, SRM-SECY-23-0021 and EOs addressing energy dominance, allow for the rulemaking to proceed on schedule and for guidance to be developed in time to support LMP users, while allowing more time for guidance development for applicants pursuing a more bounding or traditional approach. (NEI3-0001, NEI3-0002, NEI3-0006, NEI3-0016, NEI3-0017).

NRC Response: The NRC agrees, in part, with the comments.

The 10 CFR Part 53 proposed rule was developed to allow considerable flexibility regarding how an applicant could fulfill the design and analysis requirements. In addition, the NRC has changed the rule language in 10 CFR 53.450 in response to Comment Bin 3.3.2.2.E to further increase flexibility by allowing a greater range of types of systematic risk evaluations to be used together with other generally accepted approaches for systematically evaluating engineered systems, as addressed by the comment's proposed changes to the rule language and examples in the comment's referenced white paper on how those requirements could be met. The NRC has responded to the specific recommended rule language changes in various other parts of this document. While many of the NRC's changes to the 10 CFR Part 53 rule language agree with the suggested changes and allow for the use of different combinations of risk-informed and deterministic analyses, such combinations of analyses would not include the exclusive use of bounding assessments or evaluations as a means to satisfy the analyses requirements under 10 CFR Part 53, as suggested by one example in the referenced white paper. This is because 10 CFR Part 53 is a based on a fundamentally different regulatory construct than 10 CFR Part 50 and Part 52 whereas, for 10 CFR Part 53, the analyses that determine how the regulatory requirements are met must include systematic risk evaluations used together with other generally accepted approaches for systematically evaluating engineered systems as a means of achieving an equivalent level of safety as compared to 10 CFR Part 50 or Part 52. In that regard, the exclusive use of bounding assessments or an analyses approach developed similar to an application under 10 CFR Part 50 would not be able to meet certain requirements under 10 CFR Part 53 such as 10 CFR 53.450(b) and 10 CFR 53.450(e) related to the classifying SSCs based on safety significance and identifying significant event sequences.

Accordingly, the NRC did not make changes to the rule language in response to these comments.

Comment Bin 3.12.M: A commenter wrote that 10 CFR Part 53 must appropriately consider all technologies by clarifying through guidance and rule language how technologies below a defined performance threshold (such as microreactors or other designs with very small risk profiles) can be quickly and efficiently licensed (USNIC2-0003).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that 10 CFR Part 53 must be technology-inclusive but disagrees that the rule language needs to clarify how technologies below a defined performance threshold, such as microreactors, can be licensed more quickly than other technologies. The risk-informed and performance-based nature of the 10 CFR Part 53 requirements naturally lend themselves to provide flexibility for designs with very small risk profiles.

Note that the NRC is also responding to the ADVANCE Act and EOs issued in 2025 by developing an additional rulemaking to expedite licensing qualified microreactors and other potentially low risk, low consequence reactors. In addition, the NRC has undertaken extensive efforts in response to the ADVANCE Act to assess licensing strategies for microreactors and intends to apply any lessons learned from those activities to the development or revision of guidance for 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 3.12.N: A commenter recommended that simple changes focusing on the structure of the requirements be made to the proposed rule, which would achieve an overall organization that is performance-based using systems engineering principles and that results in the specification of requirements from within the framework with subparts providing technical, licensing, and administrative requirements specified for each of the stages in the lifecycle of a commercial nuclear plant. The commenter provided examples of such changes that should be made to the proposed rule. The commenter added that this approach is based on the framework described in ANSI/ANS-30.3, "Light Water Reactor Risk-Informed, Performance-Based Design," and described the benefits of such an approach. The commenter also noted this approach would meet NEIMA and ADVANCE Act requirements while also reducing the volume of 10 CFR Part 53.

Additionally, the commenter expressed support for referencing other regulations throughout 10 CFR Part 53 as a way to accomplish performance objectives in 10 CFR Part 53 without repeating the requirements from other regulations. The commenter stated that any references to 10 CFR Part 20, 10 CFR Part 26, 10 CFR Part 73, and 10 CFR Part 74 should state that the referenced requirements should be coherent with the performed-based approach of 10 CFR Part 53 as it relates to the primary safety objective. The commenter stated that a good example of this is the reference to 10 CFR Part 20 in 10 CFR 53.610, but the reference to 10 CFR Part 50, Appendix B in 10 CFR 53.610(a)(6)(i) does not follow this approach and should be removed. The commenter further stated that the QA program under 10 CFR Part 53 should enable performance-based approaches. Similarly, the commenter stated that requirements in 10 CFR Part 26, 10 CFR Part 73, and 10 CFR Part 74 should be identified as means to accomplish the primary safety or security objective associated with design features and programmatic controls, so that the entirety of the referenced regulation does not have to be repeated in 10 CFR Part 53 (ROSE-0014, ROSE-0005).

NRC Response: The NRC agrees, in part, with the comments.

As explained in the proposed and final rules, the subparts and sections in 10 CFR Part 53 reflect an overall hierarchy consisting of (1) plant-level safety criteria, (2) safety functions, (3) design features, human actions, and programmatic controls needed to fulfill the safety functions, and (4) functional design criteria that must be defined for each design feature. This hierarchy and related requirements for controls during construction; performance monitoring during operations; identification of appropriate staffing and providing training for those staff; and other requirements addressing the lifecycle of commercial nuclear plants are consistent with a systems engineering approach to regulation.

The NRC agrees that referencing other regulations can be an effective way to control the length of regulatory text and has maintained in the final rule references to other parts of NRC regulations. The NRC disagrees that referencing Appendix B to 10 CFR Part 50 precludes using particular consensus codes or standards related to quality assurance, or that it precludes performance-based approaches (see response to Comment Bin 3.3.2.1.A).

The NRC disagrees that there is a need to restructure 10 CFR Part 53 to identify requirements in 10 CFR Part 26, 10 CFR Part 73, and 10 CFR Part 74 as means to accomplish the primary safety or security objectives, or that the current 10 CFR Part 53 construct necessitates repeating the entirety of these regulations in 10 CFR Part 53 to achieve a performance-based regulation. As the commenters noted, 10 CFR Part 53 already uses references to other regulations as a way to accomplish performance objectives without repeating the requirements from other regulations, and the NRC does not believe that additional references are necessary.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 3.12.O: A commenter emphasized that 10 CFR Part 53 should be able to efficiently handle a large volume of applications in order to meet NEIMA requirements, but that stakeholders are concerned about whether this will be the case. The commenter stated that the preamble and rule text must be aligned to ensure consistency and clarity, and 10 CFR Part 53 should be revised to promote sufficient depth and breadth, promoting widespread adoption and ensuring effective implementation (BI1-0031).

NRC Response: The NRC agrees, in part, with the comment.

The regulations in 10 CFR Part 53 include provisions to efficiently license reactor designs and deployment sites by providing a systematic approach to addressing the performance measures for public health and safety and the common defense and security and flexible licensing processes for standardized plant designs that might be deployed at many sites.

Regarding promoting the adoption of 10 CFR Part 53, the rule provides an optional alternative using more risk-informed and performance-based approaches for the design, licensing, and operation of commercial nuclear plants. Applicants may choose to pursue licensing and deployment strategies under 10 CFR Part 53 or under the existing processes in 10 CFR Parts 50 and 52.

Accordingly, the NRC did not change the rule language in response to this comment.