NRC Response to Public Comments

Non-Power Production or Utilization Facility License Renewal

NRC-2011-0087; RIN 3150-AI96

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

[Insert Date]

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Abbreviations

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
CFR	*Code of Federal Regulations*
DG	draft regulatory guide
FR	*Federal Register*
FSAR	final safety analysis report
ISG	interim staff guidance
MW(t)	megawatt(s) thermal
NEI	Nuclear Energy Institute
NRC	U.S. Nuclear Regulatory Commission
NPUF	non-power production or utilization facility
RAI	request for additional information
rem	Roentgen equivalent man
RG	regulatory guide
SAR	safety analysis report
Sv	sievert
TEDE	total effective dose equivalent

U.S. NUCLEAR REGULATORY COMMISSION
RESPONSE TO PUBLIC COMMENTS RECEIVED ON THE PROPOSED RULE ON NON-POWER PRODUCTION OR UTILIZATION FACILITY LICENSE RENEWAL

Introduction

This document presents the U.S. Nuclear Regulatory Commission's (NRC's) responses to written public comments received on the proposed rule, "Non-Power Production or Utilization Facility License Renewal." The NRC published the proposed rule in the *Federal Register* (82 FR 15643) on March 30, 2017, for public comment with a 75-day public comment period. The NRC's proposed rule would amend its regulations that govern the license renewal process for non-power reactors, testing facilities, and other production or utilization facilities licensed under the authority of Section 103, 104a, or 104c of the Atomic Energy Act of 1954, as amended (AEA), that are non-power production or utilization facilities (NPUF) as defined in 10 CFR 50.2.

The proposed NPUF rule is available from the Federal e-Rulemaking Web site at https://www.regulations.gov (Docket ID No. NRC-2011-0087) and through the NRC's Agencywide Documents Access and Management System (ADAMS) (ADAMS Accession No. ML17068A031).

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, the supporting statement of considerations, or the supporting guidance, the NRC's response to the comment indicates where the change occurred.

Comment Overview

The NRC received 16 comment submissions on the proposed rule. Table 1 identifies these 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 responses use this unique identifier to identify which individual comments are addressed by each response. The annotated versions of the comment submissions can be found at https://www.regulations.gov.

Table 1. Comment Submissions on NPUF Proposed Rule

Comment Number	Commenter	Affiliation	Submission[1] Abbreviation	ADAMS Accession No.
1	Cameron Goodwin	Rhode Island Nuclear Science Center	RINSC	ML17150A407
2	WB Smith	Private Citizen	WBS	ML17158B440
3	Robert M. Dimeo	National Institute of Standards and Technology	NIST	ML17158B441
4	Jeffrey Geuther	Private Citizen	JG1	ML17166A393
5	Jeffrey Geuther	Private Citizen	JG2	ML17166A392
6	Timothy Enfinger	GE Hitachi Nuclear Energy	GE	ML17166A391
7	Cameron Goodwin	National Organization of Test, Research, and Training Reactors	TRTR	ML17166A396
8	Toby Threet	Dow Chemical Company	DOWCL, DOWA1	ML17166A395
9	Jeff Bartelme	SHINE Medical Technologies, Inc.	SHINE	ML17166A394
10	Ralph A. Butler	University of Missouri	MURR	ML17166A481
11	Steven R. Reese	Oregon State University	OSU	ML17177A194
12	Clive Townsend	Purdue University	PUR	ML17177A193
13	Amir Bahadori	Private Citizen	AB	ML17177A192
14	Daniel J. Cronin	Private Citizen	DC	ML17177A191
15	Jere Jenkins	Private Citizen	JJ1	ML17177A196
16	Jere Jenkins	Private Citizen	JJ2	ML17177A195

Public Meetings

On May 24, 2017, the NRC held a Category 3 public meeting at NRC Headquarters to discuss the NPUF proposed rule with external stakeholders (see meeting summary at ADAMS Accession No. ML17170A066). The NRC's goal for conducting this meeting was to explain the proposed rule and supporting guidance and answer questions to enable stakeholders to provide informed comments on the proposed rule.

On April 25, 2019, the NRC held a Category 3 public meeting at NRC Headquarters to discuss the basis for and obtain feedback on the proposed implementation schedule for the final rule (see meeting summary at ADAMS Accession No. ML19133A080).

Comment Categorization

This comment response document separates the comments into the 14 categories identified below. Within each category, the NRC summarizes each comment and responds to the comment. In general, the NRC addresses each individual comment. However, when similar

[1] The NRC has annotated the submissions to identify individual comments. Some submissions contained multiple individual comments, and others contained only one. The individual comments are denoted within each annotated comment submission by the submission abbreviation and a number (e.g., TRTR-1, TRTR-2). In some cases, the comment may be denoted as DOWCL-1 or DOWA1-1. This refers to a Dow Chemical Company comment provided in the comment submission cover letter (CL) or a Dow Chemical Company comment provided in an attachment (A1).

comments can be readily grouped together, the NRC has binned those comments and treated them as a single comment. The NRC's response addresses the binned comment. 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 categories:

A. General Comments on the Proposed Rulemaking

B. Creating a Definition for "Non-Power Production or Utilization Facility"

C. Eliminating License Terms for Facilities, Other Than Testing Facilities, Licensed under 10 CFR 50.21(a) or (c)

D. Defining the License Renewal Process for NPUFs (Including Testing Facilities) Licensed under 10 CFR 50.22 and Testing Facilities Licensed under 10 CFR 50.21(c)

E. Requiring All NPUF Licensees To Submit Final Safety Analysis Report Updates to the NRC

F. Amending the Current Timely Renewal Provision under 10 CFR 2.109

G. Providing an Accident Dose Criterion of 1 Rem (0.01 Sievert) Total Effective Dose Equivalent for NPUFs Other Than Testing Facilities

H. Eliminating the Requirement for NPUF Licensees To Submit Financial Qualification Information with License Renewal Applications under 10 CFR 50.33(f)(2)

I. Requirements Applicable to Industrial/Commercial Facilities

J. Draft Regulatory Analysis

K. Information Collection

L. Draft Regulatory Guide

M. Draft Environmental Assessment

N. Additional Comments on the Proposed Rule

A. General Comments on the Proposed Rulemaking

Comment A-1: Several commenters expressed support for the NPUF rule. Many of the commenters stated general support for the NPUF rule, while also providing other comments requesting revisions or clarifications. One commenter asserted that the creation of a non-expiring license for research reactors, coupled with the requirement that NPUFs keep final safety analysis reports (FSARs) up to date and submit updates to the NRC every 5 years, is a "good compromise to ensure the continued safe operation of the reactors, and protection of the public health and the environment." (RINSC-1, WBS-1, DOWCL-1, PUR-1, PUR-8, JJ1-1)

NRC Response: The comments contain no proposed changes to the final rule.

Accordingly, the NRC made no change to the final rule language in response to this comment.

B. Creating a Definition for "Non-Power Production or Utilization Facility"

Comment B-1: One commenter expressed concerns about the proposed definition of "non-power production or utilization facility" and suggested a revised definition. In particular, the commenter was concerned that the proposed definition was unclear as to whether the term "fuel reprocessing" referred to uranium scrap recovery at a fresh fuel fabrication facility or instead referred to a spent nuclear fuel reprocessing facility. In addition, the commenter was concerned that the proposed definition used both the terms "facility" and "plant" without explaining the difference between them. To address these concerns, the commenter recommended the following definition for "non-power production or utilization facility":

> *Non-power production or utilization facility* means a non-power reactor, testing facility, or other production or utilization facility, licensed under § 50.21(a), § 50.21(c), or § 50.22, of this part, that is not a nuclear power reactor or a spent nuclear fuel reprocessing facility. (WBS-2)

NRC Response: The NRC added a definition for "Non-power production or utilization facility" in 10 CFR 50.2 in the final rule on Emergency Preparedness for Small Modular Reactors and Other New Technologies (88 FR 80050; November 16, 2023). As a result, the NRC removed the definition from the final NPUF rule.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment B-2: A commenter suggested that the NRC add an identical definition of "non-power production or utilization facility" to 10 CFR Part 73, "Physical Protection of Plants and Materials," reasoning that the facilities described as NPUFs under the proposed changes to 10 CFR Part 50 are also subject to the security regulations of 10 CFR Part 73. (WBS-4)

NRC Response: The NRC disagrees. The specific security requirements in 10 CFR Part 73 applicable to non-power reactors result from the form of the material possessed by the licensee and the licensee's use of the material. This basis for the security requirements would not necessarily apply to NPUFs other than non-power reactors. Likewise, the security requirements applicable to non-power reactors may not be applicable to other NPUFs. To clarify this point, the NRC added the definition of "non-power reactor" to 10 CFR 73.2, "Definitions."

The NRC made no other changes to the final rule language in response to this comment.

Comment B-3: One commenter proposed that the NRC "revise the definition of 'testing facility,' and of 'research reactor,' to apply consistent risk-based criteria, including the 1 rem accident dose criterion proposed by NRC for research reactors" in 10 CFR 50.2 and 10 CFR 171.11(b)(2). The commenter asserted that more research is necessary to support "the arbitrary 10 MW(t) [megawatts thermal] testing facility threshold issued more than a half-century ago." The commenter argued that "'testing facility'…appears to be a concept unique to NRC regulations" as it is not referenced in Series 15 of the American Nuclear Society's standards. The commenter also stated that "the implication…that a testing facility somehow inherently differs from a research reactor and therefore does not present the lower potential radiological risk of a research reactor to the environment and the public, is not correct." (NIST-1, NIST-2, NIST-5, NIST-6, TRTR-3)

NRC Response: The NRC agrees, in part. The technical basis associated with the 10 MW(t) threshold, while generally based on safety significance, is not explicitly documented. Similarly, the technical basis for the 1 MW(t) threshold under the current definition of "testing facility" is also not explicitly documented. These prescriptive power thresholds do not account for the safety features that are engineered into the facility design and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. The use of a postulated accident dose is a more risk-informed, performance-based approach than using the power level of the reactor to distinguish between research reactors and testing facilities.

However, the definition of "research reactor" in 10 CFR 171.11(b)(2) is based on language from the Omnibus Budget Reconciliation Act of 1990, as amended (OBRA-90), which is a statutory requirement enacted by Congress. Further, a substantively similar definition of "research reactor" was included in the provisions of the Nuclear Energy Innovation and Modernization Act (NEIMA) that relate to the NRC's fee recovery structure. Without a legislative change to the definition, the NRC cannot revise the definition in 10 CFR 171.11(b)(2). The definition of "research reactor" in § 170.11(a)(9) is not based on OBRA-90, but the basis for that exemption from fees parallels the basis for the exemption from annual fees in 10 CFR 171.11(b)(2). Changing the definition of "research reactor" in 10 CFR 170.11(a)(9) would be a substantive change beyond the scope of this rulemaking. Nevertheless, because the NRC uses the term "research reactor" in other sections of 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended," and Part 171, "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC," the NRC revised the definition of "research reactor" in 10 CFR 170.3, "Definitions," and 10 CFR 171.5, "Definitions." The revised definitions will not apply to the specific exemption provisions for Federally-owned and State-owned research reactors in 10 CFR Parts 170 and 171.

Accordingly, in the final rule, the NRC revised the definition for "testing facility" in 10 CFR 50.2, "Definitions" and the definition for "research reactor" in 10 CFR 170.3 and 10 CFR 171.5 to use a 1 Roentgen equivalent man (rem) (0.01 sievert (Sv)) total effective dose equivalent (TEDE) accident dose criterion instead of reactor power level as discussed in the NRC response to Comment B-5.

Comment B-4: One commenter suggested two ways in which the proposed regulatory text could be modified for clarity and consistency. The commenter recommended that the NRC (1) add a definition of "non-power production or utilization facility" to 10 CFR 51.4, "Definitions," to support the proposed rule's additions to 10 CFR Part 51, "Environmental Protection

Regulations for Domestic Licensing and Related Regulatory Functions," and (2) clarify whether any conforming changes are required to 10 CFR 51.4(1)(i)(J) in the definition of "construction." (WBS-6, WBS-7)

NRC Response: The NRC disagrees. The addition of a definition is unnecessary and would be inconsistent with the scope of definitions included in 10 CFR 51.4 in support of the NRC's environmental protection regulations in 10 CFR Part 51, which implement the National Environmental Policy Act of 1969, as amended (NEPA). The scope of the definitions codified in 10 CFR 51.4 is limited to those related to the conduct of environmental reviews and the NRC staff's preparation of associated documentation in accordance with NEPA. In contrast, the NRC's regulations that pertain to the licensing of NPUFs (i.e., 10 CFR Part 50) include facility definitions. The revised definition of "non-power reactor" and "testing facility" are appropriately included in 10 CFR 50.2.

In addition, conforming changes are not needed in 10 CFR 51.4(1)(ii)(J) in the definition of "construction" because the term "production or utilization facilities" in 10 CFR 51.4(1)(ii)(J) covers the scope of licensees the NRC intends to exclude from the definition of "construction." Therefore, the current regulations remain valid and do not need to be updated in the final rule. Because there is no 10 CFR 51.4(1)(i)(J), the commenter's reference should have been to 10 CFR 51.4(1)(ii)(J).

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment B-5: One commenter stated that the accident dose criterion is also appropriate for use in developing a risk-based definition for "testing facility." (NIST-9)

NRC Response: The NRC agrees. As stated in the "Regulatory Basis To Support Proceeding with Rulemaking To Streamline and Enhance the Research and Test Reactor (RTR) License Renewal Process," dated August 27, 2012 (ADAMS Accession No. ML12240A677), the technical basis for the testing facility power threshold of 10 MW(t) is not well documented. The NRC is revising the definition of a "testing facility," from a threshold of 10 MW(t) to a radiation dose in excess of the accident dose criterion of 1 rem (0.01 Sv) TEDE because accident consequence is a more risk-informed approach than power level. The 1 rem (0.01 Sv) TEDE accident dose criterion is consistent with the U.S. Environmental Protection Agency's Protective Action Guides, which were developed to prevent acute effects and reduce the risk from chronic effects of offsite releases of radioactive material. Revising the definition of "testing facility" will continue to provide reasonable assurance of adequate protection of public health and safety and the environment.

Accordingly, in the final rule, the NRC revised the 10 CFR 50.2 definition of a "testing facility" to include an accident dose criterion.

C. Eliminating License Terms for Facilities, Other Than Testing Facilities, Licensed under 10 CFR 50.21(a) or (c)

C-1. Eliminating license terms

Comment C-1.1: Two commenters supported the proposed elimination of license terms for certain NPUFs. One of the commenters stated that the proposed revision "has the potential to result in a reduction of unnecessary administrative burden on both licensees and the NRC staff." (DOWA1-1, DJC-2)

NRC Response: The NRC agrees. One of the goals of the rulemaking is to reduce the administrative burden on both licensees and the NRC staff.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment C-1.2: Two commenters recommended that the NRC offer a choice to individual reactor licensees, allowing them to opt into a non-expiring license or continue with the current 20-year license renewal process. One of the commenters asserted that some licensees would prefer the license renewal process over non-expiring licenses with required FSAR updates. The commenter argued that university-owned research reactors would likely opt for non-expiring licenses, while a few licensees would choose to retain their license terms. (TRTR-2, JJ1-3)

NRC Response: The NRC disagrees. As discussed in Section I.B of the final rule, one of the issues that drove the need for the final rule was the observation that FSARs submitted every 20 years often contained varying levels of completeness and accuracy. As a result, the final rule language in 10 CFR 50.71(e) requires all NPUF licensees to submit updated FSARs and subsequent FSAR updates, regardless of the license term. Without a requirement to submit the FSAR at intervals not to exceed 5 years, this observed issue would not be addressed and licensees and the NRC would face the same challenges encountered in the past. Therefore, the final rule does not provide an option for licensees to continue with license renewal and forego periodic FSAR updates.

Accordingly, the NRC made no change to the final rule language in response to this comment.

C-2. <u>The NRC's question on unintended consequences associated with removing license terms by using an order</u>

***Comment C-2.1*:** One commenter stated that removing license terms using an order will have no unintended consequences. (MURR-1)

NRC Response: The NRC agrees. The NRC considered incorporating these requirements into its regulations but determined that orders would be a more efficient and effective regulatory approach.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment C-2.2: One commenter urged the NRC not to require licensees to re-perform prior analyses in the FSAR when more advanced methods become available. The commenter stated that "the requirement of performing better thermal hydraulic analysis, even though prior analysis remains conservative, would increase the burden on a licensee." (PUR-4)

NRC Response: The NRC agrees. As discussed in the NRC's response to Comment E-1.2, the final rule language in 10 CFR 50.71(e) does not require licensees to perform new or updated analyses solely for the purpose of submitting the updated FSAR or subsequent FSAR updates.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment C-2.3: One commenter indicated that licensees assigned to Group 2 may have difficulty meeting the implementation timeframe proposed by the NRC.[2] The commenter stated that additional time (i.e., 3 years rather than 2 years) would allow enough time for the initial update. (OSU-3)

NRC Response: The NRC disagrees, in part. The NRC anticipates that licensees will document changes in their licensing bases as they occur, which would maintain the continuity of knowledge for the licensee for the understanding of changes and effects of changes on the facility. The 2-year requirement would result in minimal additional burden on licensees because only a small number of changes occur per facility per year, and licensees will have either evaluated these changes under 10 CFR 50.59, "Changes, tests, and experiments," or justified them in license amendment requests under 10 CFR 50.90, "Application for amendment of license, construction permit, or early site permit."

However, as described in the response to Comment E-2.3, the NRC agrees that changes were needed in the approach for determining the submittal date of the updated FSARs required by the licensee-specific orders. The NRC's revised approach allows for additional flexibility in the time granted to each licensee to submit the updated FSAR, including consideration of licensee-specific circumstances.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment C-2.4: One commenter requested clarification that licensees will not need a second license renewal before receiving a non-expiring license term. The commenter recommended that the NRC clarify the preamble to indicate that "when the NRC issues 'orders' to set the date for each licensee's submittal of the first FSAR update, the Agency intends to use the 'order' to amend the license so that it no longer has a fixed term." The commenter suggested the following text for the final rule preamble:

> A commenter requested clarification that its existing license will not need to be renewed at the end of its 20-year term, in order to obtain a license without a fixed term. The NRC intends to issue orders which will establish the date for the first FSAR update. The orders will also revise existing licenses so that they no longer have a fixed term. Therefore, as of the date of the order, the licensee will possess a license that does not have a fixed term. This means there will be no requirement to prepare a renewal application for such licenses, after issuance of the order. (DOWA1-2)

NRC Response: The NRC agrees. The only NPUFs that would undergo license renewal before receiving non-expiring license terms would be those that have not undergone the license renewal process using the guidance in NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048). Licensees that have undergone relicensing using the guidance in NUREG-1537, Part 2, will be eligible to receive a non-expiring license term without renewing their existing license.

Accordingly, the NRC revised Section II of the final rule to clarify the conditions necessary to receive a non-expiring license term.

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[2] See Exhibit 3-2 (p. 12) in "Regulatory Analysis and Backfit Considerations: Non-Power Production or Utilization Facility License Renewal," dated March 2017 (ADAMS Accession No. ML17068A038), for the list of NPUFs grouped by license renewal period referenced in Comment C-2.3.

C-3. The NRC's question on granting non-expiring licenses to testing facilities

Comment C-3.1: Several commenters addressed the idea of granting non-expiring license terms to testing facilities. Two commenters expressed concern that testing facilities would be subject to increased regulatory burden if the NRC requires a 20-year license renewal in addition to periodic FSAR updates. One commenter asserted that the additional requirements placed on testing facilities are contrary to Section 104c of the AEA. The commenters suggested that the NRC should grant non-expiring licenses to NPUFs (including testing facilities) based on the facility's risk. (NIST-4, TRTR-1, MURR-5)

NRC Response: The NRC disagrees. For NPUFs that will continue to undergo license renewal, the requirements for updated FSARs, subsequent FSAR submittals, and the amended timely renewal provision will create efficiencies during the license renewal process by reducing the number and scope of requests for additional information and shortening the period of time a license renewal application is pending. As a result, the NRC and licensees will expend fewer resources during the license renewal process. Therefore, the requirements under 10 CFR 50.71(e) will not increase burden on testing facilities and are not contrary to Section 104c of the AEA.

The NRC disagrees that testing facilities should be granted non-expiring licenses. The potential risk of testing facilities has been established since 1962 in regulations, such as 10 CFR Part 100, "Reactor Site Criteria," which contains the requirements for constructing and operating stationary power and testing reactors. Similarly, testing facilities are included with power reactors and other commercial facilities licensed pursuant to 10 CFR 50.21(b) or 10 CFR 50.22 for the regulations in 10 CFR Parts 2, "Agency Rules of Practice and Procedure," 50, and 51. The revised definition of "testing facility" in the final rule reflects the higher risk profile of testing facilities, compared to other NPUFs. The NRC maintains that the higher risk of testing facilities requires these facilities to continue to undergo license renewal.

Accordingly, the NRC made no change to the final rule language in response to this comment.

D. Defining the License Renewal Process for NPUFs (Including Testing Facilities) Licensed under 10 CFR 50.22 and Testing Facilities Licensed under 10 CFR 50.21(c)

D-1. The NRC's question on the scope of the license renewal process for NPUFs (including testing facilities) licensed under 10 CFR 50.22 and testing facilities licensed under 10 CFR 50.21(c)

Comment D-1.1: One commenter expressed support for the proposed license renewal process for facilities licensed under 10 CFR 50.22 and testing facilities licensed under 10 CFR 50.21(c), stating that no additional elements were necessary and none of the proposed elements should be removed. (MURR-3)

NRC Response: The comment contains no proposed changes to the final rule.

Accordingly, the NRC made no change to the final rule language in response to this comment.

E. Requiring All NPUF Licensees To Submit Final Safety Analysis Report Updates to the NRC

E-1. Proposed requirements for FSAR submittals

Comment E-1.1: Three commenters expressed support for the proposed requirements for NPUFs to submit periodic FSAR updates. One commenter called it "a step in the positive direction," while another stated that it "is in the best interest of licensees, the NRC and the public to have FSARs that reflect a licensee's current operating conditions and equipment." (OSU-1, NIST-8, TRTR-4)

NRC Response: The NRC agrees. Periodic submittals of FSAR updates will encourage licensees to document changes in their licensing bases as they occur. The updates will also enhance safety because licensees will maintain a more current licensing basis than what has been observed during recent license renewal reviews. This will contribute to the continuity of knowledge both for the licensee and the NRC and the understanding of changes and effects of changes on the facility.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment E-1.2: Several commenters expressed concern that the FSAR updates will require NPUF licensees to perform new analyses, update existing analyses, or extensively reformat the FSAR. One commenter emphasized that the process should not "require onerous reformatting or additional analyses above and beyond those currently required." Another commenter questioned the "need to re-perform previous analyses if more advanced code [sic] or methods become available." A third commenter asked the NRC to "provide a written commitment to accept calculations and methods of calculation that were used in the original analysis and have not been affected by changes to the facility since the most recent license was issued." (NIST-8, PUR-4, JG1-1)

NRC Response: The NRC agrees, in part. The final rule language does not require an updated FSAR or subsequent FSAR updates to include additional analyses beyond those currently required, nor does it require reformatting of FSARs. NPUF licensees may need to incorporate new or updated analyses in the FSAR, if the analyses were already performed as part of the initial operating license review process, in support of license renewal, as required by 10 CFR 50.59 or other NRC requirement, or to support license amendment requests pursuant to 10 CFR 50.90. In addition, re-performing analyses or updating analyses using new codes or methods would itself need to be assessed pursuant to 10 CFR 50.59 and 10 CFR 50.90 and then incorporated in the FSAR appropriately. Further, licensee technical specifications typically require a written report to the NRC if there is a significant change in the transient or accident analysis as described in the licensee's FSAR.

However, the NRC will not provide a written commitment to categorically accept existing analyses. For example, licensees would be expected to revise analyses described in the FSAR that are found to be inaccurate as a result of new analyses performed by the licensee pursuant to NRC requirements.

Because regulations do not specify the format of the FSAR, the final rule language does not specify a particular format for the updates. The NRC has provided guidance for the preparation of FSARs in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," issued February 1996 (ADAMS

Accession No. ML042430055). The licensee may choose the format to be used for the updated FSAR or subsequent FSAR updates.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment E-1.3: Two commenters requested clarification that the proposed 10 CFR 50.71(e) requires only the changes to the FSAR to be submitted to the NRC. One commenter stated that the NRC "should clarify that licensees are not required to submit the entire updated FSAR, but only the actual updates." A second commenter noted that, for licensees that have made few changes pursuant to 10 CFR 50.59 and 10 CFR 50.90, a simple review of the FSAR in effect at that time would be sufficient before its submission to the NRC. (DOWA1-5, JJ2-2)

NRC Response: The NRC agrees, in part. In 10 CFR 50.71(e), the NRC specifies the changes that must be reflected in the updated FSAR or subsequent FSAR updates. As a result of this rulemaking, 10 CFR 50.71(e)(1) requires licensees, including NPUFs, to "submit revisions containing updated information to the Commission, as specified in § 50.4, on a replacement-page basis that is accompanied by a list which identifies the current pages of the FSAR following page replacement." The regulation in 10 CFR 50.4(b)(6) states that "Paper copy submissions may be made using replacement pages; however, if a licensee chooses to use electronic submission, all subsequent updates or submissions must be performed electronically on a total replacement basis."

In this case, "subsequent updates" refers to the updates submitted pursuant to 10 CFR 50.71(e)(4)(ii). This means that a licensee may submit signed originals of the paper copies of the change pages or a complete, updated electronic version of the FSAR. In both cases, the licensee must submit a list that identifies the current pages of the FSAR following page replacement. As noted in the second comment, a licensee that has made few changes pursuant to 10 CFR 50.59 and 10 CFR 50.90 would probably expend minimal effort to submit the change pages or the complete, updated FSAR.

However, the NRC disagrees that licensees are not required to submit the entire updated FSAR. The final rule in 10 CFR 50.71(e)(3)(iv) requires licensees that were issued their license after the effective date of the final rule to submit a complete updated FSAR, regardless of whether it is submitted on paper or electronically. The NRC will require, by order, other NPUF licensees to submit a complete updated FSAR. The FSAR required to be updated by the final rule or order is the original FSAR submitted as part of the application for the initial operating license, relicensing, or license renewal, as appropriate. The updated FSAR should appropriately incorporate the various supplements and amendments that may have been submitted either in response to NRC questions or on the applicant's or licensee's own initiative, following the original submittal to create a single and complete updated document that can then serve as the baseline for future changes. As an example, the updated FSAR should fully incorporate the licensee's responses to NRC requests for additional information (RAIs) that supported review of the license renewal application.

Accordingly, the NRC changed Section C of Regulatory Guide (RG) 2.7, Revision 0, "Preparation of Updated Final Safety Analysis Reports for Non-power Production or Utilization Facilities" (ADAMS Accession No. ML18031A007), in response to this comment.

Comment E-1.4: Two commenters addressed the timing requirements for FSAR submittals. One commenter expressed concern that "the wording of proposed section 50.71(e)(4)(ii) provided too rigid a deadline for submittal." The commenter suggested that the NRC allow

FSAR updates to be submitted in the fifth year, up to 2 months after the exact 5-year deadline. Another commenter stated that the proposed rule does not address noncompliance with the 5-year deadline and asserted that staffing levels at NPUFs might lead to missed deadlines. The commenter proposed a relaxed submittal timeline with a requirement goal of 5 years, but no later than 7 years. (DOWA1-3, DOWA1-4, PUR-3)

NRC Response: The NRC disagrees. The final rule language specifies two requirements for the timing of submittals. The final rule language in 10 CFR 50.71(e)(3)(iv) requires that a revision of the FSAR be filed within 5 years of issuance of the operating license, and the final rule language in 10 CFR 50.71(e)(4)(ii) requires NPUF licensees to submit FSAR updates at intervals not to exceed 5 years. In both cases, 5 years is the maximum time allowed, and licensees may submit updates at any time before the maximum. Both requirements also allow a "cutoff" date of up to 6 months before the date of submission during which additional changes to the FSAR do not need to be included in the update to the FSAR. These requirements are sufficiently flexible to allow licensees to develop their own procedures for updating the FSAR and submitting the information required by 10 CFR 50.71(e) to the NRC within the 5-year maximum time limit. To prevent situations in which temporary staffing issues could lead to missed deadlines, NPUF licensees should keep the FSAR up-to-date during the interval allowed by 10 CFR 50.71(e)(4)(ii) and not wait until the end of the 5-year interval.

If a licensee is unable to meet the 5-year deadline, then the licensee would be subject to the Commission's Enforcement Policy.

Accordingly, the NRC made no change to the final rule language in response to this comment. However, the NRC added guidance in Section C of RG 2.7 to describe the timing of submittals required by 10 CFR 50.71(e).

Comment E-1.5: Four commenters noted that the NRC review of the updated FSAR should be limited to the changes that have occurred since the previous review of the FSAR. One commenter stated that the benefits of the new process would be achievable only "if the USNRC accepts the initial FSAR submission as a solid safety basis document and only reviews the changes (essentially) to the existing FSAR in the future." Two commenters noted that if the NRC review is not limited to the changes to the FSAR, then it could result in "a flood of requests for additional information." The fourth commenter stated that the NRC review should be limited to verifying that the FSAR adequately reflects changes made pursuant to 10 CFR 50.59 and 10 CFR 50.90. Another commenter asked that the NRC "provide a draft guidance document describing what the expectations will be for the FSAR review." (OSU-2, RINSC-2, TRTR-4, JJ2-2, JJ2-3)

NRC Response: The NRC agrees, in part. The NRC's review of the updated FSAR and subsequent FSAR updates submitted in accordance with the final rule language in 10 CFR 50.71(e)(3)(iv) and 10 CFR 50.71(e)(4)(ii), respectively, would focus on verifying that changes to the FSAR have been adequately incorporated. As noted in the response to Comment E-1.3, fulfillment of the requirement in 10 CFR 50.71(e)(3)(iv) by the licensee and review of the updated FSAR by the NRC will result in a single, complete document that can be used as the baseline for future changes. In the case of subsequent FSAR updates, evaluations performed pursuant to 10 CFR 50.59 and analyses supporting license amendment requests pursuant to 10 CFR 50.90 will largely drive changes to the FSAR. In both cases, the NRC does not intend to re-review the entire FSAR or issue RAIs, as the submittal required by the final rule language in 10 CFR 50.71(e) is not part of a licensing action, but rather an administrative action by the licensee. Further, approvals of licensing actions, whether initial licensing, license

renewal, or amendments, are independent of the FSAR updating process and once approved would not be subject to further consideration simply because the FSAR is updated. This, of course, does not preclude the reevaluation of previous positions based on new information or new considerations and will not prevent the NRC from addressing any safety issues or inconsistencies identified during its review. In most cases, issues identified by the NRC review of the updated FSAR and subsequent FSAR updates will be resolved through the inspection and oversight program, without the need for RAIs.

The NRC disagrees that an additional guidance document describing the expectations for the FSAR review is needed. The FSAR review will consider the guidance in RG 2.7 and NUREG-1537, Part 1, as appropriate.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment E-1.6: Four commenters expressed concern that the NRC review of the updated FSAR will be more burdensome than the current license renewal process. Two commenters noted that the NRC review of the updated FSAR and subsequent FSAR updates could "serve as a de facto license renewal" or, in the absence of regulatory restraint, "become a process very similar to the full license reviews." Three commenters stated that NRC staff, not external contractors who may be unfamiliar with the facility, should review the FSAR. (RINSC-2, TRTR-4, JG1-1, JJ1-2, JJ2-1)

NRC Response: The NRC disagrees. As explained in the response to Comment E-1.5, the NRC review of the updated FSAR or an FSAR update will not be a licensing action. The review will focus on verifying that changes have been adequately incorporated in the updated FSAR or subsequent FSAR update. In conducting these reviews, the NRC will continue to rely on external contractors, as necessary and appropriate, under the supervision of NRC staff.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment E-1.7: One commenter cited the *Federal Register* notice (FRN) for the proposed rulemaking where it notes, "Should the NRC identify potential safety issues with the facility's continued safe operation in its reviews of FSAR updates, the Commission can undertake regulatory actions specified in 2.202 to modify, suspend or revoke a license." The commenter stated that this implies "that the licensee must take care to provide an updated FSAR with the same level of quality as would be issued with a license amendment application or risk having their license suspended." (JG1-1)

NRC Response: The NRC disagrees, in part. The final rule language in 10 CFR 50.71(e) does not change existing requirements or impose new requirements on the quality of the FSAR. An FSAR submittal made in accordance with the final rule language in 10 CFR 50.71(e) should be of the same quality as that for an application for an operating license, license renewal, or license amendment as required by the regulations in 10 CFR Chapter I and submitted in accordance with 10 CFR 50.4, "Written communications." As discussed in the response to Comment E-1.5, the oversight and inspection program should resolve most issues related to the quality of FSAR submittals.

The NRC does agree that in the review of an updated FSAR, the NRC can and would take action under its regulatory framework, including potentially issuing orders under 10 CFR 2.202, "Orders," to address any identified safety issues. However, issues solely related to updating the FSAR should not warrant suspension of a facility license.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment E-1.8: One commenter questioned the added value of NRC review of the updated FSAR and subsequent FSAR updates. The commenter stated, "It is unlikely that a 5-year recurring review of the FSAR would surface anything that knowledgeable and competent inspection staff would not identify in a more timely manner." (GE-4)

NRC Response: The NRC disagrees. The complexity of and level of effort required for NRC review of the updated FSAR and subsequent FSAR updates will depend largely on the nature of the changes to the FSAR. Given the typical inspection schedule for NPUFs, which is graded based on the power level of the facility and not the complexity of the changes to the FSAR, inspectors may not have adequate time to comprehensively review the changes to the FSAR, especially in the case of the updated FSAR required by the final rule language in 10 CFR 50.71(e)(3)(iv). In the case of extensive changes to the FSAR necessitated by license amendments or a high volume of evaluations performed pursuant to 10 CFR 50.59, review by the NRC licensing project manager in coordination with the oversight program is more appropriate to ensure identification of safety issues or inconsistencies in the FSAR.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment E-1.9: One commenter asserted that FSAR submittals "may prove to be a significant economic burden to the [research and test reactor] licensees that are non-university related, and are therefore required to pay the NRC an hourly rate for the agency's time in handling license actions related to these licenses." (JJ1-2)

NRC Response: The NRC disagrees. Although NRC reviews of FSAR submittals under 10 CFR 50.71(e) would not be licensing actions, as noted in the final regulatory analysis, hours (and therefore fees) associated with review of the updated FSAR and subsequent updates to the FSAR will be less than historical levels for relicensing and license renewal.

Accordingly, the NRC made no change to the final rule language in response to this comment.

E-2. <u>The NRC's question regarding the use of orders to establish the deadline for the updated FSAR submittal</u>

***Comment E-2.1*:** A number of commenters supported licensee-specific orders. Two commenters argued that staggering FSAR submittals will ease the burden on the NRC staff by avoiding simultaneous submissions. Another commenter did not foresee any unintended consequences of using orders to establish the initial deadline for FSAR submittals. (RINSC-3, TRTR-5, MURR-2)

NRC Response: The NRC agrees. Licensee-specific orders provide the operational flexibility for licensees to effectively submit the updated FSARs and thereby minimize the potential for undue burden on the licensee and the NRC.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment E-2.2: One commenter addressed the grouping of facilities and suggested that the NRC use five groups, as opposed to the three proposed. The commenter stated that these groups should be "determined by facility input, NRC direction, and time from previous license

renewal." The commenter recommended that the NRC develop strategies for facilities that may need to move among groups because of delays caused by the RAI process. (PUR-5)

NRC Response: The NRC agrees, in part. The NRC agrees that the conditions of the licensee-specific orders should take into account licensee-specific circumstances, NRC discretion, and time since the previous license renewal. The submittal date of the updated FSAR required by the licensee-specific orders will be determined as described in the response to Comment E-2.3, below.

The NRC disagrees that this approach will necessitate grouping licensees into five groups. Licensees will not be moved among groups because the groups are set by specific conditions of the previous license renewal, as described in Section II of the final rule FRN.

The NRC uses RAIs primarily to obtain information to resolve safety and environmental issues that are not adequately addressed in the application for a licensing action. The orders will require the FSAR submittals, but the submittals will not be reviewed as a licensing action. Any issues with the quality of the submittals will primarily be resolved through the NRC inspection program. This does not preclude regulatory actions that may be warranted if the NRC identifies any potential safety issues.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment E-2.3: Many commenters urged the NRC to provide additional time for the initial FSAR submittal. One commenter recommended 3 years for Group 1 to submit initial FSAR updates and 5 years for Group 2, "to enable the facilities to submit high-quality updated FSARs." Another commenter stated that licensees would need an additional year to prepare the initial update. A different commenter recommended that licensees that renewed a license within the previous 5 years should have 5 years from the renewal date to update the FSAR, or 1-year from the date of the order, whichever is longer. The commenter argued that staggering submissions in this way would lessen the administrative burden. (JG2-1, OSU-4, DC-3)

NRC Response: The NRC agrees, in part. The NRC modified the method for determining the submittal date for the updated FSAR required by the licensee-specific orders. The changes allow additional flexibility in the time granted for each licensee to submit the updated FSAR and distribute the submittal dates more evenly over the 5-year period following the effective date of the final rule. In determining the submittal dates, the NRC would use the groups described in Section II.4 of the FRN for the final rule:

- Group 1 consists of licensees that completed the license renewal process most recently using NUREG-1537. The NRC will establish a due date for the updated FSAR that will be at least 1 year and no later than 3 years from the effective date of this final rule. The NRC will require these licensees to submit an updated FSAR first because, with a recent license renewal, the FSARs should require minimal updates.
- Group 2 generally consists of licensees for which the NRC reviewed the license renewal application before Group 1 using NUREG-1537 and includes the three facilities currently in decommissioning. The NRC will establish a due date for the updated FSAR that will be at least 2 years and no later than 5 years from the effective date of this final rule. The NRC will allow these licensees more time to submit an updated FSAR than Group 1 licensees because more time has passed since license renewal, so additional time may be needed to update their FSARs.

The submittal dates in the licensee-specific orders will take into account licensee-specific circumstances, NRC discretion, and time since the previous license renewal, as stated in the response to Comment E-2.2. In doing so, the general approach will be to stagger the submittal dates such that licensees that most recently completed license renewal will be the first to submit the updated FSAR. The rationale for this approach is the same as for the grouping of licensees described in the FRN for the proposed rule: licensees that most recently completed license renewal should have the fewest changes to the FSAR. The NRC would also consider licensee-specific circumstances (e.g., licensee staffing, extent of the changes to the FSAR) when determining each licensee's submittal date in case special circumstances justify deviations from the general approach. This overall approach would lessen the administrative burden associated with updated FSAR submittals by distributing them over the 5-year period following the effective date of the final rule, as opposed to the 2-year period following the effective date of the final rule described in Section III.B of the FRN for the proposed rule.

The NRC disagrees that licensees that completed license renewal within the 5 years before the effective date of the final rule should have 5 years from the date of the renewal to submit the updated FSAR. As stated in the proposed rule, with a recent license renewal, the FSAR should require minimal updates. The updated FSAR submittal is necessary to establish the baseline for the subsequent FSAR updates required by the final rule language in 10 CFR 50.71(e)(4)(ii). The NRC will require these updates via licensee-specific orders for licensees in Group 1 and Group 2. The baseline will be determined by the final rule language in 10 CFR 50.71(e)(3)(iv) for facilities issued licenses after the effective date of the final rule, including renewed or non-expiring licenses.

Accordingly, the NRC revised Section II of the final rule FRN to reflect the method for determining the date of updated FSAR submittals.

F. Amending the Current Timely Renewal Provision under 10 CFR 2.109

Comment F-1: One commenter recommended that, in lieu of revising the timely renewal provision, the NRC staff should consider creating an internal checklist of documents and sections required for a sufficient renewal application submittal. The commenter contended that 30 days should be sufficient for an initial check of whether a renewal application is acceptable for further review. Asserting that the NRC's proposed change will result in informal reclassification of detailed review questions into "application deficiencies," thereby changing the intended purpose of the timely renewal provision, the commenter expressed concern that the proposed revision of the timely renewal provision will burden both licensees and the NRC staff in the form of RAIs, action items, and "Class 0"-type meetings for 2 years. Based on these impacts, the commenter predicted that the proposed timely renewal provision will lead to unplanned and premature facility shutdowns. Moreover, the commenter asserted that requiring FSAR updates every 5 years and eliminating fixed license terms render moot the rationale behind the proposed timely renewal provision change, because concerns about the technical adequacy of renewal documents should be mostly eliminated. The commenter suggested that a rule change of 45 days instead of 2 years would be more reasonable, because it would reduce the likelihood of unintended negative consequences, while only slightly increasing the burden on licensees. (DC-4)

NRC Response: The NRC disagrees, in part. The NRC disagrees with the comment's prediction of unplanned and premature facility shutdowns based on a revision of the timely renewal submission period. The last sentence of Section 9(b) of the Administrative Procedure

Act (5 U.S.C. § 558(c)) (APA), referred to as the "timely renewal doctrine," provides that, if a licensee of an activity of a continuing nature makes a "timely and sufficient" application for renewal in accordance with agency rules, the existing license does not expire until the application has been finally determined by the agency. The timely renewal doctrine is embodied in the Commission's regulations at 10 CFR 2.109, "Effect of timely renewal application," which allows licensees to continue operating while the NRC evaluates the license renewal application. The final rule will change only the date by which NPUFs (including testing facilities) licensed under 10 CFR 50.22 and testing facilities licensed under 10 CFR 50.21(c) must submit an application for renewal, so as to be considered in timely renewal under 10 CFR 2.109.

The requirements in 10 CFR 2.101(a) allow the NRC to determine the acceptability of an application for docketing and review by the agency. Experience with license renewal has shown that 30 days is not enough time for the NRC to adequately assess the sufficiency of a license renewal application. The NRC believes that 30 days or even 45 days (as suggested) for timely renewal would not allow the agency enough time to review an application and ensure that the application reasonably appears to contain sufficient technical information for the NRC to complete the acceptance review and docket the application. Additionally, a thorough acceptance review is integral to the efficient review of an application for license renewal. The early identification of insufficient information benefits both the NRC and the licensee. Therefore, the NRC is modifying 10 CFR 2.109 to require that an NPUF license renewal application be submitted at least 2 years before the NPUF's license expiration to take advantage of the timely renewal doctrine. Additionally, 10 CFR 2.109(e) incorporates the APA's provision requiring the submittal of a *sufficient* application to discourage the filing of pro forma renewal applications that would be filed simply for the sake of meeting the 10 CFR 2.109(e) deadline. Sufficiency is based on the required contents of an application specified in applicable requirements.

The NRC's procedures provide guidance on the process for performing acceptance reviews. The procedures specifically outline the difference between actions the staff performs during the acceptance review versus activities conducted during the licensing action. Further, Phase 0 ("Class 0" in the comment) meetings are pre-application meetings that are requested by the licensee (typically for license amendments). The NRC does not direct or mandate these meetings. In the past, the NRC has accepted license renewal applications and addressed their deficiencies during the license renewal process, largely by submitting RAIs to the licensee to supplement the application. Because this approach usually results in multiple rounds of RAIs, it increases the burden of the license renewal process on both licensees and the NRC.

The NRC agrees that renewal applications should be essentially complete and sufficient when filed because concerns about the technical adequacy of renewal documents should be mostly eliminated by the FSAR updates every 5 years. Additionally, eliminating fixed license terms for eligible licensees renders moot the rationale behind the proposed timely renewal provision because 10 CFR 2.109 does not apply to non-expiring licenses.

Accordingly, the NRC made no change to the final rule language in response to this comment.

F-2. <u>The NRC's question on undue burden from revising the timely renewal provision</u>

Comment F-2.1: Several commenters addressed the impact on licensees of the proposed revision to the timely renewal provision from 30 days to 2 years before license expiration. Two commenters asserted that this change will not cause an undue burden on licensees. One of the commenters stated that the proposed revision to 2 years will not cause an undue burden on licensees, provided that the NRC's intent is to limit the review of the renewal application to aging

issues and changes in the facility. To clarify such uncertainty for licensees, the commenter suggested that the NRC issue a draft procedure on reviewing license renewal applications and FSARs. (MURR-6, OSU-5)

NRC Response: The NRC agrees, in part. The NRC agrees that the proposed revision to the timely renewal provision would not cause undue burden on licensees. As described in the response to Comment F-1.1, the NRC has procedures that outline the process for performance of acceptance reviews for NPUF licensing applications.

However, the NRC disagrees that the burden would be reduced only if the NRC's intent is to limit the review of the renewal application to aging issues and changes in the facility. The scope of the NRC license renewal review is determined using the graded approach of Interim Staff Guidance 2009-001, "Interim Staff Guidance on the Streamlined Review Process for License Renewal for Research Reactors," dated October 2009 (ADAMS Accession No. ML092240244), hereafter referred to as "the ISG." The extent of the detailed review is determined by the application (e.g., a focused review for limited scope of changes since the last renewal for facilities less than 2 MW(t) or a full review for major changes such as a request for a power increase). In either case, the staff reviews the entire FSAR. Regardless, the scope of the review is unrelated to the timely renewal provisions of 10 CFR 2.109.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment F-2.2: Other commenters asserted that the proposed revision to the timely renewal provision will impose additional regulatory burdens on facilities undergoing license renewal. While acknowledging that the NRC may have a difficult time conducting an acceptance review in 30 days, two commenters asserted that the proposed revision from 30 days to 2 years will eliminate the incentive for the NRC to review renewal applications in a timely manner. One of these commenters suggested that the NRC should extend the application deadline to 90 days before license expiration instead, reasoning that a 90-day deadline would help ensure that the reviewed documents reflect more up-to-date conditions at the facility. (NIST-10, TRTR-7)

NRC Response: The NRC agrees, in part. The NRC agrees that experience has shown that the 30 days allowed by the current timely renewal provision is not sufficient for the NRC staff to adequately assess the acceptability of a license renewal application for review and docketing.

However, the NRC disagrees that a 90-day deadline allows adequate time to complete a full acceptance review of an NPUF license renewal application. Similar to the response for Comment F-1.1, 90 days is also considered an inadequate timeframe for the NRC to perform an acceptance review and provide sufficient time for the licensee or applicant to resolve deficiencies in the applications, based on significant experience gained from the license renewals recently completed. The early identification of insufficient information benefits both the NRC and the licensee or applicant. The NRC benefits by identifying information needs earlier in the review process. The licensee benefits by understanding potential NRC staff concerns and needs earlier, in addition to getting faster decisions on renewal applications. Based on experience, 2 years should allow adequate time for the NRC to make a final determination that the application reasonably appears to contain sufficient technical information, both in scope and depth, for the NRC staff to complete the detailed technical review. This timeframe also allows time for the licensee to supplement the application, if necessary, to address identified insufficiencies before the existing license expires. Furthermore, the NRC anticipates that many license renewal reviews could be completed within the 2-year window, limiting the number of licensees that exercise the timely renewal period. The NRC perceives the amount of burden to

be no different whether the application is prepared 30 days or 2 years in advance, especially since the FSAR will presumably be up-to-date pursuant to 10 CFR 50.71(e)(4)(ii). However, the regulatory process will be greatly improved, which will reduce burden through an improved application.

Accordingly, the NRC made no change to the final rule language in response to this comment.

G. Providing an Accident Dose Criterion of 1 Rem (0.01 Sv) Total Effective Dose Equivalent for NPUFs Other Than Testing Facilities

G-1. Proposed accident dose criterion

Comment G-1.1: One commenter expressed multiple concerns about the criterion. The commenter asserted that the wording is vague and creates additional burden on licensees, because the regulation does not specify that the evaluation of applicable radiological consequences of a postulated accidental release must be "credible," as stated in 10 CFR Part 100. This difference "could be interpreted as effectively codifying any maximum hypothetical accident evaluation requirement the staff might desire well beyond what is required by regulation of test reactors and power reactors." In addition, the commenter stated that the use of the term "licensed material" rather than "fission product" expands the evaluation source term beyond that currently required by regulation of either power or test reactors. The commenter further argued that the additional reasonable assurance could be used "as justification to reclassify detailed review questions into application deficiencies." The commenter also requested that the NRC clarify the purpose of the added proposed rule language stating that any individual located in the unrestricted area would not receive a radiation dose in excess of the criterion "for the duration of the accident." Furthermore, the commenter expressed concern that the new dose criterion will lead to expanded emergency planning requirements. The commenter recommended that the NRC add a clarifying statement that the intention of this regulation is not to increase future emergency planning requirements for NPUFs. (DC-5)

NRC Response: The NRC disagrees. The guidance in NUREG-1537, Parts 1 and 2, specifies that accident analyses should distinguish "credible" accidents of lesser consequence from the maximum hypothetical accident (MHA), which can be a conservative "non-credible" accident scenario. This guidance and the proposed accident dose criterion do not imply that licensees evaluate the MHA beyond that required of testing facilities. The phrase "reasonable assurance" is not new and appears in most, if not all, research reactor license safety evaluation reports. NUREG-1537, Part 2, Chapter 14, "Technical Specifications," states that "[a]ll conditions that provide reasonable assurance that the facility will function as analyzed in the SAR should be in the technical specifications."

The NRC also disagrees that the use of the term "licensed material" in 10 CFR 50.34(a)(2) in the proposed rule expands the evaluation source term for NPUFs. As defined in 10 CFR 20.1003, "Definitions," "licensed material" means "source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the Commission." Processes or experiments that could be authorized by the NRC at NPUFs can use materials that may not necessarily result in the release of solely fission products. However, the NRC has revised the proposed rule language to replace "postulated accidental release of licensed material" with "postulated accident." This revision makes the final rule requirement consistent with the current practice of applicants and licensees to consider potential exposure from sources, such as direct or scattered radiation from

an unshielded source inside the reactor building, in addition to potential exposure from a release of radioactive materials in their evaluation of the postulated accident conditions. Under the new requirement, these evaluations need to demonstrate that the dose to any individual located in the unrestricted area will not be in excess of 1 rem (0.01 Sv) TEDE for the duration of the accident.

In addition, the NRC included the language "for the duration of the accident" in the proposed rule to continue to ensure the public health and safety. The risk-informed accident dose criterion of 1 rem (0.01 Sv) TEDE, which includes dose assessments of projected external and internal radiation exposures to members of the public for the duration of the accident, ensures the prevention of acute effects and reduces the risk of chronic effects, while also limiting the need to evacuate areas near the facility in the unlikely event of an accident.

Further, the new accident dose criterion does not expand existing emergency planning requirements for NPUFs. The new accident dose criterion does not affect emergency planning at NPUFs.

Accordingly, the NRC made no change to the final rule language in response to this comment.

G-2. The NRC's question on appropriateness of the proposed accident dose criterion

Comment G-2.1: A number of commenters stated that the proposed dose criterion is necessary and appropriate. (TRTR-6, MURR-7, OSU-6, PUR-6, RINSC-4)

NRC Response: The comment contains no proposed changes to the final rule.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment G-2.2: One commenter recommended that the NRC broaden the meaning of the term "unrestricted area" to include areas that are not directly managed by the licensee, because some NPUFs may share facilities with other entities that are more easily evacuated compared to nearby permanent housing structures that are continuously occupied. (PUR-7)

NRC Response: The NRC disagrees. The term "unrestricted area" is defined in 10 CFR 20.1003 as "an area, access to which is neither limited nor controlled by the licensee." The unrestricted area is defined in a licensee's FSAR and will be different for each licensee, based on the site, license, and procedures.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment G-2.3: One commenter stated that the accident dose criterion is appropriate because the limit is consistent with both the threshold for offsite emergency response planning and the projected offsite dose from the maximum hypothetical accident at a 1-MW(t) research reactor facility. The commenter asserted that the proposed criterion also would be achievable by research reactors with power levels up to the 10-MW(t) threshold used to define a testing facility, which would be consistent with the existing definition. (OSU-6)

NRC Response: The NRC agrees. As discussed in the response to Comment B-3, the NRC revised the definition of "testing facility" in the final rule to include a 1 rem accident dose criterion.

H. Eliminating the Requirement for NPUF Licensees To Submit Financial Qualification Information with License Renewal Applications under 10 CFR 50.33(f)(2)

Comment H-1: Several commenters expressed support for the NRC's proposed elimination of financial qualification information. The commenters stated that eliminating the requirement will reduce the burden for licensees and the NRC. (NIST-11, TRTR-8, DC-1)

NRC Response: The comment contains no proposed changes to the final rule.

Accordingly, the NRC made no change to the final rule language in response to this comment.

I. Requirements Applicable to Industrial/Commercial Facilities

I-1. Applicability of regulations to industrial or commercial facilities

Comment I-1.1: One commenter stated that certain provisions of the NRC's existing regulations for non-power facilities are not applicable to the commenter's facility, despite its being included as an NPUF under the proposed definition in 10 CFR 50.2. The commenter provided several examples of such regulations, including 10 CFR 171.15(f), which "provides the annual fees for licensees authorized to operate a non-power reactor licensed under Part 50"; 10 CFR 140.11, "Amounts of financial protection for certain reactors," which "provides the amount of financial protection required of licensees to satisfy the requirements of the indemnification agreement, based on the nuclear reactor's thermal power level"; and 10 CFR 140.12, "Amounts of financial protection for other reactors," which is "intended to cover facilities for which the amount of financial protection is not determined in 10 CFR 140.11." The commenter requested that the NRC clarify this rulemaking regarding the applicability of existing requirements within 10 CFR Chapter I to the commenter's facility and other future entities like it. (SHINE-1)

NRC Response: The NRC agrees, in part. Some NRC regulations are specific to currently licensed non-power reactor technologies. To improve regulatory predictability and clarity for other non-reactor technologies, such as the accelerator-driven subcritical operating assemblies and the production facility proposed by SHINE Medical Technologies, Inc., the NRC amended 10 CFR 50.2 by the final rule on Emergency Preparedness for Small Modular Reactors and Other New Technologies to provide a technology-inclusive definition for "non-power production or utilization facility." This definition is intended to ensure that regulations with generic applicability to all NPUFs within 10 CFR Chapter I are identified and implemented appropriately.

The NRC systematically reviewed its regulations as a result of this comment to determine where the term "non-power production or utilization facility" is appropriate throughout 10 CFR Chapter I. However, changes to technology-specific regulatory requirements were determined to be outside the scope of this rulemaking.

The NRC disagrees that the financial protection and fee requirements in 10 CFR Part 140, "Financial Protection Requirements and Indemnity Agreements," and 10 CFR Part 171, respectively, are within the scope of this rulemaking. These regulations do not have generic applicability to all NPUFs. Various factors, such as license class and licensed activity will result in licensees maintaining different levels of financial protection and paying different annual fees. Other technology-specific regulatory requirements will be determined on a case-by-case basis,

including financial protection requirements under 10 CFR Part 140. The NRC updates the fee basis determination during the annual determination of fees rulemaking.

Accordingly, the NRC made no change to the final rule language in response to this comment.

I-2. The NRC's question on additional license application steps for commercial or industrial facilities

Comment I-2.1: One commenter stated that Section 104 of the AEA "should only apply to facilities that are designed and operated for the sole purpose of medical therapy and research and development," as was originally intended. The commenter urged the NRC to maintain the current licensing process for NPUFs licensed under 10 CFR 50.22. (MURR-4)

NRC Response: The NRC agrees, in part. NPUFs that are used for industrial or commercial purposes licensed under 10 CFR 50.22 would be subject to license renewal pursuant to 10 CFR 50.135 as defined in the proposed rule. Section 103c of the AEA requires that license terms be established for Class 103 facilities. However, NPUFs licensed under Section 104c of the AEA can perform some commercial activities and therefore may not be "operated for the sole purpose of … research and development."

Accordingly, the NRC made no change to the final rule language in response to this comment.

J. Draft Regulatory Analysis

Comment J-1: One commenter asserted that the estimate in Section 3-2 of the NRC's "Regulatory Analysis and Backfit Considerations Non-Power Production or Utilization Facility License Renewal," dated March 2017 (ADAMS Accession No. ML17068A038) (see pp. 19–20) of the total 20-year undiscounted cost to the National Institute of Standards and Technology under the proposed rule ($77,000 with an incremental operation cost of $18,000 per FSAR update) is "extremely conservative." (NIST-3)

NRC Response: The NRC disagrees. To estimate the costs to licensees, the NRC gathered data from several sources, including relevant information in regulatory analyses and from licensees as addressed in the regulatory analysis. The NRC used these data as input for this rulemaking's regulatory analysis model, which provides a range of impacts for the regulated community.

Accordingly, the NRC made no change to the final rule in response to this comment.

K. Information Collection

The NRC requested public comment on the potential impact of the information collections contained in the proposed rule. The NRC received no public comments in response to this request.

L. Draft Regulatory Guide

In the final rule, Draft Regulatory Guide (DG)-2006, "Preparation of Updated Final Safety Analysis Reports for Non-Power Production or Utilization Facilities," dated March 2017 (ADAMS Accession No. ML17068A041), is now RG 2.7, "Preparation of Updated Final Safety Analysis Reports for Non-Power Production or Utilization Facilities" (ADAMS Accession No. ML18031A007).

Comment L-1: One commenter expressed concern that facilities will be required to submit the entire FSAR every 5 years rather than just the sections or elements that have changed. The commenter recommended that the NRC revise DG-2006 to replace references to "the FSAR (as updated)" with "update[s] to the FSAR" and make other conforming changes to allow licensees to submit just the changes to the FSAR. The commenter stated that these edits to DG-2006, along with corresponding discussion in the final rule preamble, would provide sufficient clarity and that changes to the proposed regulatory text would not be required. (DOWA1-6)

NRC Response: The NRC disagrees, in part. The NRC is not requiring licensees to submit an entire FSAR every 5 years (unless it is submitted electronically). As discussed in the response to Comment E-1.3, the final rule language in 10 CFR 50.71(e)(1) and 10 CFR 50.71(e)(3)(iv) requires licensees to submit a complete updated FSAR in some cases and only FSAR change pages in other cases.

The NRC agrees that it needed to revise RG 2.7 to fully address the FSAR submittal requirements in the final rule language.

Accordingly, the NRC made no change to the final rule in response to this comment. However, the NRC did make changes to Section C of RG 2.7 in response to this comment.

Comment L-2: One commenter stated that the procedures for updating or revising FSAR pages that are outlined in NUREG-1537, Part 1 (see p. xxv), differ from the procedures that are outlined in DG-2006. The commenter suggested that the NRC make the procedures consistent to avoid confusion for licensees. (MURR-8)

NRC Response: The NRC agrees. As discussed in the response to Comment L-1, the NRC made changes to RG 2.7, Section C, such that the guidance for the FSAR submittals is consistent with the final rule. The next update to NUREG-1537 will include revisions to be consistent with the final rule and RG 2.7.

Accordingly, the NRC made no change to the final rule in response to this comment.

Comment L-3: One commenter suggested that DG-2006 should incorporate additional language from Nuclear Energy Institute (NEI) 98-03, Revision 1, "Guidelines for Updating Final Safety Analysis Reports," dated June 1999 (ADAMS Accession No. ML003779028), to clarify the intent of the proposed changes to FSAR submittal requirements (e.g., an FSAR update does not constitute a licensing action). The commenter also recommended that the "Role of the FSAR (as updated)" section in DG-2006 (see p. 3) should be revised as follows: (1) move the first three sentences to the "Background" section or delete them altogether and (2) add language "not[ing] that the FSAR is also a reference for evaluating changes, tests, and experiments" under 10 CFR 50.59 (being careful, however, to avoid providing guidance for 10 CFR 50.59 and 10 CFR 50.90, since that is not the purpose of DG-2006).

Additionally, the commenter suggested that the following elements should be removed from DG-2006: (1) the examples provided in Section C.1.a.ii.1 (see p. 5), because they appear to conflict with the proposed regulatory text as well as 10 CFR 50.59 and 10 CFR 50.90 (e.g., the discussion of maintenance operations "is inappropriate for the intended use when considered within the context" of 10 CFR 50.59) and (2) language that frames the FSAR updates as being "safety-related," because items that require updating include both those that relate to safety and those that do not. (DC-6)

NRC Response: The NRC agrees, in part. The NRC endorsed NEI 98-03, Revision 1, in RG 1.181, "Content of the Updated Final Safety Analysis Report in Accordance with 10 CFR 50.71(e)," dated September 1999 (ADAMS Accession No. ML003740112), for use by power reactor licensees. Although this guidance is not directly applicable to NPUFs, the NRC reviewed NEI 98-03, Revision 1, and incorporated similar guidance for NPUFs in RG 2.7, as appropriate. In addition, the NRC modified the sections of DG-2006 titled "Background" and "Role of the FSAR (as updated)" and some of the examples in Section C.1 in DG-2006 in consideration of the specific comments on the use of the term "safety-related," the relationship between RG 2.7 and 10 CFR 50.59 and 10 CFR 50.90, and editorial issues.

However, the NRC disagrees that RG 2.7 needs to clarify that an FSAR submitted under the final rule language in 10 CFR 50.71(e) is not part of a licensing action nor is it intended for the purpose of re-reviewing the facility, as explained in the response to Comment E-1.5 and the final rule FRN. The NRC also disagrees that RG 2.7 needs to "make clear that it is not intended to alter the basic types of information or level of detail required in existing FSARs," because the regulations in 10 CFR 50.34, "Contents of applications; technical information," specify the information and level of detail required in the FSAR, and NUREG-1537 provides related guidance. Statements such as those recommended by the comment do not provide guidance on preparing the updated FSAR or subsequent FSAR updates required by the final rule language in 10 CFR 50.71(e) and therefore are not included in RG 2.7.

Accordingly, the NRC made no change to the final rule in response to this comment. However, the NRC did make changes to Sections B and C of RG 2.7 in response to this comment.

M. Draft Environmental Assessment

Comment M-1: One commenter stated that Table 1 in "Draft Environmental Assessment Supporting Proposed Rule: Non-Power Production or Utilization Facility License Renewal," dated March 2017 (ADAMS Accession No. ML17068A035) (see p. 10), incorrectly lists the power level for Kansas State University as 250 kilowatts thermal (kW(t)) rather than 1,250 kW(t). (AB-1)

NRC Response: The NRC agrees. The NRC revised Table 1 of the final environmental assessment in response to this comment.

N. Additional Comments on the Proposed Rule

Comment N-1: Two commenters expressed concern that the proposed rule will place additional regulatory burdens on licensees with already limited resources (e.g., small staffs, limited budgets, staff members with teaching obligations). The commenters argued that these burdens (e.g., rewriting and updating the safety analysis report and revising facility procedures accordingly) could lead to unintended negative consequences, such as redirecting resources from safety-significant activities to administrative activities or causing the businesses and universities that underwrite research and testing facilities to view them as unsustainable expenses. (GE-2, JJ1-4)

NRC Response: The NRC disagrees. The rulemaking is designed to reduce the administrative burden on both the licensees and the NRC. For those NPUFs licensed under the authority of Section 104 of the AEA, the Commission is directed to impose the minimum amount of regulation on the licensee consistent with its obligations under the AEA to promote the common defense and security, protect the health and safety of the public, and permit the conduct of widespread and diverse research and development and the widest amount of effective medical therapy possible. As discussed in the responses to Comments E-1.2 through E-1.9, the licensee's updates to the FSAR and the NRC review of FSAR updates are critical to achieving both the safety benefit and reduction in regulatory burden intended by this rulemaking. Any safety-significant activities performed by the licensee should only be completed based on current technical specifications, documented licensing bases, updated procedures, and applicable regulations. Resources should already be allocated for maintaining the FSAR, which provides the current safety and licensing basis for the facility, as required by the regulations.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment N-2: Two commenters addressed the frequency of the NRC's inspection of NPUFs. One commenter indicated that the NRC's statement in the proposed rule that it currently completes an inspection once every 2 years is not totally accurate. The commenter stated that "the NRC typically performs roughly half of an inspection annually and completes the remaining items the following calendar year" and suggested that the proposed 2 -year inspection schedule be revised to better align with the 5-year timing of the FSAR updates (e.g., "every 2.5 years not to exceed 3 years"). The other commenter stated that the Kansas State University facility has been inspected annually in recent years and requested clarification regarding whether the proposed rule will change the inspection schedule to every other year. (PUR-2, AB-2)

NRC Response: The NRC agrees, in part. The inspection program, including inspection frequencies and topics such as operations, health physics, and security, is defined by the NRC Inspection Manual. While the program is designed to be completed every 2 years for NPUFs licensed at less than 2 MW(t), inspector availability and licensee availability sometimes dictate that an inspection cycle is longer than 2 years. In some cases, the inspection cycle can be carried out in multiple inspections over the 2-year cycle. The NRC has clarified in the final rule that inspection cycles could take more than 2 years.

The NRC disagrees that the inspection schedule should be changed as part of this rulemaking. The submittal of updated FSARs and subsequent FSAR updates is independent of the inspection schedule for NPUFs.

Accordingly, the NRC revised Section II of the final rule FRN in response to this comment.

Comment N-3: One commenter recommended that the NRC add the phrase "of this part" or "of this chapter," as appropriate, after citations where only a section symbol and section number are currently indicated. (WBS-2, WBS-5)

NRC Response: The NRC disagrees. The use of section symbols and numbers in the NPUF rulemaking documents is in accordance with NUREG-1379, Revision 2, "NRC Editorial Style Guide," dated May 2009 (ADAMS Accession No. ML093280744), and guidance provided by the Office of the Federal Register.
Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment N-4: One commenter recommended that the NRC docket the commenter's submission (which requests a change in the definition of "testing facility"; see Comment B-3) as a petition for rulemaking and respond to it as part of the current rulemaking process. The commenter stated that, alternatively, the NRC could docket the submission as a petition for rulemaking and consider the petition separately from the rulemaking. (NIST-7)

NRC Response: The NRC disagrees. The NRC docketed the submittal as a comment on the proposed rule and made it publicly available. The NRC did not treat the comment submittal as a petition for rulemaking. The topics addressed in the submission are consistent with the scope and content of the proposed rule. In addition, as part of the proposed rulemaking's public comment period, the NRC received additional comments supporting this comment, indicating that the public had an opportunity to comment on the recommendation. The NRC determined that docketing the comment as a petition for rulemaking would not have provided additional new information on the recommendation.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment N-5: One commenter asserted that the NRC's statements in the proposed rule on "the minimum amount of regulation needed" under Sections 104a and 104c of the AEA could be interpreted as meaning that imposing environmental reporting requirements on a small research reactor in operation for over 40 years meets the 10 CFR 51.22(a) criterion for categorical exclusion. (GE-1)

NRC Response: The NRC agrees, in part. The NRC agrees that for those NPUFs licensed under the authority of Section 104 of the AEA, the Commission is directed to impose the minimum amount of regulation on the licensee consistent with its obligations under the AEA to promote the common defense and security, protect the health and safety of the public, and permit the conduct of widespread and diverse research and development and the widest amount of effective medical therapy possible. In the final rule, the NRC eliminated license terms for licenses issued under the authority of Sections 104a or 104c of the AEA, other than for testing facilities. As a result, covered NPUFs would no longer undergo license renewal reviews under 10 CFR Part 50, including the license renewal process defined by 10 CFR 50.135 under the final rule, nor would they be subject to the NRC's regulations governing environmental reviews in 10 CFR Part 51.

The NRC disagrees that continued operation of an NPUF presumptively satisfies the NRC's criteria for categorical exclusion at 10 CFR 51.22, "Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review." For those licensing and regulatory actions that are not listed in 10 CFR 51.20(b) or covered by a categorical exclusion under 10 CFR 51.22(c), the NRC will prepare, at minimum, an environmental assessment.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment N-6: One commenter asked if the NRC will clarify other provisions in 10 CFR Chapter I not addressed in the proposed rule (e.g., 10 CFR 50.54, "Conditions of licenses") to indicate their applicability to NPUFs, power reactors, or all reactors. (AB-3)

NRC Response: The NRC disagrees. Clarifying the applicability of regulations, such as 10 CFR 50.54, is beyond the scope of this rulemaking. However, the NRC made conforming changes that reflect the definitions (e.g., "non-power production or utilization facility") that are within the scope of this rulemaking.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment N-7: A commenter recommended that the NRC create a definition of "spent nuclear fuel" because 10 CFR Part 50 does not define the term. The commenter suggested that the NRC use the definition of "spent nuclear fuel" used in the 2011 proposed rule, "Enhanced Weapons, Firearms Background Checks, and Security Event Notifications" (76 FR 6200; February 3, 2011):

> *Spent nuclear fuel* or *Spent fuel (SNF)* means the fuel that has been withdrawn from a nuclear reactor following irradiation and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with a fuel assembly. (WBS-3)

NRC Response: The NRC disagrees. The definition of "non-power production or utilization facility" in 10 CFR 50.2 does not contain the terms "spent nuclear fuel" or "spent fuel." Thus, the NRC considers the recommendation to define "spent nuclear fuel" beyond the scope of this rulemaking.

Accordingly, the NRC made no change to the final rule language in response to this comment.

Comment N-8: One commenter recommended that the NRC staff "revisit the [F]SAR format/content guidance and assess what is truly important to safety, especially for the lower power facilities." (GE-3)

NRC Response: The NRC disagrees. Licensees and applicants are responsible for including adequate information in the FSAR to meet the requirements of 10 CFR 50.34 for their facility. The guidance in NUREG-1537, Part 1, and the ISG is intended to apply to a wide range of facility designs and operating characteristics. Licensees and applicants should use the relevant portions of NUREG-1537, Part 1, and the ISG to assist with providing the information required by 10 CFR 50.34 for their particular facility.

Accordingly, the NRC made no change to the final rule language in response to this comment.