AFFIRMATION ITEM

RESPONSE SHEET

TO:	Annette Vietti-Cook, Secretary
10:	Annette Vietti-Cook, Secreta

- FROM: CHAIRMAN SVINICKI
- SUBJECT: SECY-19-0062: Final Rule: Non-power Production or Utilization Facility License Renewal

Approved XX	Disapproved	Abs	tain _	Not Participating
COMMENTS:	Below	Attached	xx	None

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SIGNATU	RE	
07/	/2020	

Entered on "STARS" Yes XX No ____

Comments of Chairman Kristine L. Svinicki on SECY-19-0062 Final Rule: Non-power Production or Utilization Facility License Renewal (RIN 3150-A196, NRC-2011-0087)

I approve for publication in the *Federal Register* the draft final rule to revise the requirements for non-power production or utilization facility (NPUF) license renewal, as edited in the attached version. If my proposed edits are adopted by the Commission in its decision on the draft final rule, the staff should make conforming changes to Management Directive 8.4 and its Directive Handbook and should reflect the backfit clarification in this final rule in the revisions to NUREG-1409, "Backfitting Guidelines." I certify that this rule, if adopted, will not have a significant impact on a substantial number of small entities.

In this draft final rule, the Commission is presented with the opportunity to clarify our practices for applying the backfit rule in 10 CFR 50.109 and the limitation on regulation to the "minimum amount" necessary in Section 104 of the Atomic Energy Act of 1954, as amended (AEA), by drawing a distinction within the category of NPUF licensees, applicants, and certificate holders. Shortly after the 1985 amendments to the backfit rule, the Commission elected not to apply the revised backfit rule to a final rule, "Limiting the Use of Highly Enriched Uranium in Domestically Licensed Research and Test Reactors,"¹ agreeing that "the backfit rule should not be applied to this amendment of the regulations which relates only to non-power reactors."² While the Commission did not elaborate on the decision not to apply the backfit rule, that decision, coupled with the rulemaking record limiting the discussion to power reactors for the 1985 and 1988 amendments³ to the backfit rule, has been relied upon for the principle that the backfit rule does not apply to non-power production or utilization facilities in general.⁴

While the staff cites a 2012 final rule in SECY-19-0062 to support its position, the 2012 final rule was an action taken to make prior NRC orders generically applicable, taking into account the lessons learned in their implementation and the input of stakeholders, and thus could not include a backfit. Moreover, the underlying orders themselves were not based upon backfit analyses, but instead implemented a Congressional mandate.⁵ Having served on the Commission during the deliberation on that rule, I would portray the Commission's consideration on the sub-element of the generic applicability of the backfit rule to NPUFs in those rules as superficial, at best.

Given the lack of an expressed intent on the part of the Commission to exclude utilization or production facilities that are not power reactors from the scope of the backfit rule and the sparse regulatory record on the subject, I believe it is appropriate for the Commission to revisit this area. At present, the NRC has issued 10 CFR part 50 construction permits under Section 103 for industrial or commercial utilization facilities that are neither power reactors nor non-power reactors. While this is not the first instance of non-industrial or non-commercial NPUF licensees, if the Commission continues its current practice, these permit holders and potential

1 51 FR 6514 (February 25, 1986).

⁴ See, for example, SECY-19-0062 at pages 47-48.

 ² Staff Requirements – Affirmation/Discussion and Vote, 2:00 P.M., Thursday, February 6, 1986, Commissioners' Conference Room, D.C. Office (Open to Public Attendance) (SRM-M860206).
 ³ "Revision of Backfitting Process for Power Reactors," 50 FR 38097 (September 20, 1985) and "Revision of Backfitting Process for Power Reactors," 53 FR 20603 (June 6, 1988).

⁵ See, for example, NRC Order EA-07-074, "Issuance of Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Research and Test Reactors," ADAMS Accession No. ML070750140.

licensees would not have the benefit of the controls on regulation afforded by the backfit rule, including the availability of the administrative remedy of the backfit appeal. They also would not qualify for the controls on regulation to the minimum amount necessary of Section 104 of the AEA, which has historically applied to most NPUFs. Since NPUFs are not homogenous as a class of licensees, the basis for categorically treating non-power reactors differently than other part 50 permit holders and licensees is not tenable. Because the disparity in regulatory treatment among NPUFs cannot be cured by applying the controls on regulation of Section 104 of the AEA to Section 103 licensees, I have proposed to modify the text for the Backfitting and Issue Finality section of the *Federal Register* Notice for the final rule to clarify that industrial or commercial NPUFs are within the scope of the backfit rule. The intent is to provide greater regulatory equity within the heterogenous class of NPUF licensees and to draw appropriate distinctions among them that align with the reasoning for not applying the Backfit Rule to non-power reactors.

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NUCLEAR REGULATORY COMMISSION 10 CFR Parts 2, 20, 26, 50, 51, 55, 73, 140, 170, and 171 [NRC-2011-0087]

RIN 3150-AI96

Non-Power Production or Utilization Facility License Renewal

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule and guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations that govern the license renewal process for certain production or utilization facilities. In this final rule, the NRC collectively refers to these facilities as non-power production or utilization facilities (NPUFs). This final rule revises the definitions of "non-power reactor," "research reactor," and "testing facility." This final rule also eliminates license terms for licenses for facilities used for medical therapy or research and development, other than testing facilities; these licenses are issued under the authority of Sections 104a or 104c of the Atomic Energy Act of 1954, as amended (AEA). This final rule defines the license renewal process for licenses issued to testing facilities under the authority of Section 104c of the AEA or commercial or industrial NPUFs (including testing facilities) under the authority of Section 103 of the AEA. This final rule requires all NPUF licensees to submit to the NRC final safety analysis report (FSAR) updates at intervals not to exceed 5 years. In addition, this final rule provides an accident dose criterion of 1 Roentgen equivalent man (rem) (0.01 sievert [Sv]) total

effective dose equivalent (TEDE) for NPUFs other than testing facilities. The NRC is also issuing final implementation guidance for this final rule.

DATES: This final rule is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Please refer to Docket ID NRC-2011-0087 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

 Federal Rulemaking Web Site: Go to <u>http://www.regulations.gov</u> and search for Docket ID NRC-2011-0087. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: <u>Carol.Gallagher@nrc.gov</u>. For technical questions, contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

NRC's Agencywide Documents Access and Management System
 (ADAMS): You may obtain publicly-available documents online in the ADAMS Public

 Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the
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 301-415-4737, or by e-mail to pdr.resource@nrc.gov/reading-rm/adams.html. To begin the
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 contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at
 301-415-4737, or by e-mail to pdr.resource@nrc.gov. For the convenience of the
 reader, instructions about obtaining materials referenced in this document are provided
 in the "Availability of Documents" section.

 NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. FOR FURTHER INFORMATION CONTACT: Robert Beall, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-3874, e-mail: <u>Robert Beall@mrc.gov</u> and Duane Hardesty, Office of Nuclear Reactor Regulation, telephone: 301-415-3724, e-mail: <u>Duane Hardesty@nrc.gov</u>. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action

In April 2008, the Commission issued staff requirements memorandum (SRM) M080317B, "Briefing on State of NRC Technical Programs," which directed the staff to "examine the license renewal process for non-power reactors and to identify and implement efficiencies to that will streamline this process while ensuring that adequate protection of public health and safety are maintained." The need for improvement in the reliability and efficiency of the license renewal process was primarily driven by four issues: 1) historic NRC priorities and emergent issues; 2) limited licensee resources; 3) inconsistent existing license infrastructure; and 4) regulatory requirements and the broad scope of the renewal process.

B. Major Provisions

The major provisions of this final rule include changes that:

Create a definition for Non-power production or utilization facility and revise
the definitions for Non-power reactor, Testing facility, and Research reactor;

 Eliminate license terms for medical therapy or research and development facilities, other than testing facilities, licensed under paragraphs (a) or (c) of § 50.21 of title 10 of the Code of Federal Regulations (10 CFR);

 Define the license renewal process for all commercial or industrial NPUFs (including testing facilities) licensed under § 50.22 and testing facilities licensed under § 50.21(c);

 Require all NPUF licensees to submit to the NRC an updated FSAR and subsequent FSAR updates to the NRC at intervals not to exceed 5 years;

 Amend the current timely renewal provision under § 2.109, allowing NPUFs subject to license renewal to continue operating under an existing license past its expiration date if the licensee submits a license renewal application at least 2 years (rather than 30 days) before the current license expiration date;

 Provide an accident dose criterion of 1 rem (0.01 Sv) TEDE for NPUFs other than testing facilities;

Extend the applicability of § 50.59 to NPUF licensees regardless of their decommissioning status;

· Clarify an NPUF applicant's requirements for meeting the existing provisions

of § 51.45 for submitting an environmental report; and

 Eliminate the requirement for NPUF licensees to submit financial qualification information with license renewal applications under § 50.33(f)(2).

Concurrent with this final rule, the NRC is issuing Regulatory Guide (RG) 2.7, Revision 0, "Preparation of Updated Final Safety Analysis Reports for Non-Power Production or Utilization Facilities."

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C. Costs and Benefits

The NRC prepared a regulatory analysis to determine the expected quantitative costs and benefits of this final rule and the final implementing guidance, as well as qualitative factors to be considered in the NRC's rulemaking decision. Based on the analysis, the NRC concluded that this final rule will result in net savings to licensees and the NRC. The analysis examined the benefits and costs of the final rule requirements and the final implementing guidance compared to the baseline for the current license renewal process (i.e., the no-action alternative). Compared to the no-action baseline, the NRC estimates that total net benefits to NPUFs (i.e., cost savings minus costs) will be \$5.5 million (\$3.9 million using a 3-percent discount rate or \$2.6 million using a 7-percent discount rate) over a 20-year period. The average NPUF will receive net benefits ranging from approximately \$78,000 to \$166,000 over a 20-year period. The NRC will receive total net benefits of \$12 million (\$8.6 million using a 3-percent discount rate or \$5.9 million using a 7-percent discount rate) over a 20-year period.

The regulatory analysis also considered, in a qualitative fashion, additional benefits of this final rule and the final implementing guidance associated with regulatory efficiency, protection of public health and safety, promotion of the common defense and security, and protection of the environment.

The regulatory analysis concluded that this final rule and the final implementing guidance are justified because of the cost savings received by both licensees and the NRC while public health and safety are maintained. A detailed discussion of the methodology and complete results is presented in the "Regulatory Analysis" section of this document.

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I. Background

The NRC licenses NPUFs under the authority granted in Sections 103 and 104 of the AEA. Section 103 of the AEA applies to commercial and industrial facilities, and Sections 104a and c of the AEA apply to facilities used for medical therapy or research and development activities, respectively. The section of the AEA that provides licensing authority for the NRC corresponds directly to the class of license issued to a facility (e.g., Section 104a of the AEA authorizes the issuance of a "class 104a" license). Furthermore, Sections 104a and **9104c** of the AEA require that the Commission impose only the minimum amount of regulation needed to promote the common defense and security; protect the health and safety of the public; and permit, under Section 104a, the

widest amount of effective medical therapy possible and, under Section 104c, the conduct of widespread and diverse research and development.

The NRC regulates 36 NPUF licensees NPUFs, of which 31 are research reactors or testing facilities currently licensed to operate. TwoThe NRC has issued construction permits for two of the five remaining licensees have been issued

construction permits NPUFs (SHINE Medical Technologies, Inc. (SHINE) and Northwest Medical Isotopes, LLC), and the licensees of the other three licensees NPUFs are in the process of decommissioning their facilities (i.e., removing a facility or site safely from service and reducing residual radioactivity to a level that permits release of the site for unrestricted use or use under restricted conditions). Most NPUFs are located at universities or colleges throughout the United States. The NRC regulates one operating testing facility at the National Institute of Standards and Technology.

A. License Terms

The AEA dictates an initial license term of no more than 40 years for class 103 facilities, which the NRC licenses under § 50.22, but the AEA does not specify license terms for class 104a or <a href="https://www.icharelicensedunder.specifyle:es.items.specifyle:es.items.specifyle:es.items.specifyle:es.items.specifyle:es.items.specifies

Any application for license renewal must include an FSAR describing: 1) changes to the facility or facility operations resulting from new or amended regulatory requirements, and 2) changes and effects of changes to the facility or procedures and new experiments. The FSAR must include the elements specified in § 50.34. The NRC has guidance for preparing the FSAR in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content." The NRC reviews NPUF initial and renewal license applications according lousing NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria."

As a license term nears its end, a licensee must submit a license renewal application in order to continue operations. A "timely renewal" provision exists in § 2.109(a) to enable operations to continue beyond the license term during the NRC's review of a license renewal application. If the licensee files an application for a renewal or for a new license for the authorized activity at least 30 days before the expiration of an existing license, the existing license will not be deemed to have expired until the application has been finally determined.

B. Need for Improvement in the License Renewal Process

In 2008, the NRC recognized a need to identify and implement efficiencies in the NPUF license renewal process to streamline the process while ensuring that adequate protection of public health and safety is maintained. Four issues primarily drove this need for improvement in the reliability and efficiency of the process.

1. Historic NRC Priorities and Emergent Issues

Under the Atomic Energy Commission (AEC), the NRC's predecessor agency, NPUFs were some of the first reactors licensed and the first reactors to undergo license renewal. Most of these reactors were initially licensed in the late 1950s and 1960s for terms that varied from 10 to 40 years. The AEC started renewing these licenses in the 1960s. License renewal was primarily an administrative activity until 1976, when the NRC decided to also conduct a technical review, which was equivalent to the initial licensing of the facility. The licenses that had been issued with initial 20-year terms were due for renewal during this timeframe. As the NRC started developing methods for conducting these technical reviews, an accident occurred at Unit 2 of the Three Mile Island (TMI) nuclear power plant.

The NRC's focus on post-TMI activities resulted in a suspension of NPUF license renewal activities for several years. After license renewal activities were reinitiated, the NRC issued numerous renewals in a short period of time, primarily by-relying on generic evaluations. These 20-year renewals expired starting in the late 1990s. The original 40-year-licenses issued with 40-year terms also started expiring in the late 1990s, creating a new surge of license renewal applications.

Beginning in late 2001, as a result of the NRC's response to the events of September 11, 2001, the NRC deferred work on a number of NPUF license renewal applications. In addition, the NRC's NPUF licensing activities focused on the higherpriority activity of implementing § 50.64, "Limitations on the use of highly enriched uranium (HEU) in domestic non-power reactors," to convert non-power reactor licensesreactors to the use of low-enriched uranium. Therefore, reviews of these license renewal applications extended for many years. In all cases, the timely renewal provision enabled these NPUFs to continue operating during the NRC's review period.

2. Limited Licensee Resources

Many NPUF licensees have limited staff resources available for licensing support. The number of NPUF staff can range from one part-time employee for some low-power facilities to four or five full-time employees for higher-power facilities. The NPUF staff that perform the licensing function typically do so in addition to their normal organizational responsibilities, which. This often results in delays (in the license renewal process, particularly in responding to the NRC's requests for additional information)-in the license renewal-process.

3. Inconsistent Existing License Infrastructure

The NPUFs licensed under § 50.21(a) or (c) are primarily at college and university sites. Staff turnover and limited staffing resources at an NPUF often contribute to a lack of historical knowledge of the development of the licensee's FSAR and changes to the FSAR. During the most recent round of license renewals, the NRC found that some of the submitted FSARs did not adequately reflect the current licensing babiebases for the respective licensees. Because the only required FSAR submission comes at license renewal, which can be at 20-year or greater intervals, submitted FSARs often contain varying levels of completeness and accuracy. Consequently, the NRC has issued requests for additional information to obtain missing information, seek clarifications and corrections, and document the current licensing bases.

4. Regulatory Requirements and Broad Scope of the Renewal Process

For power reactors, license renewal reviews have a defined scope, primarily focused on aging management, as described in 10 CFR part 54. For NPUFs, there are no explicit requirements on the scope of issues to be addressed during license renewal. Therefore, the scope of review for license renewal was initially treated the same as that for an original license.

In response to Commission direction in SRM-SECY-91-061, "Separation of Non-Reactor and Non-Power Reactor Licensing Activities from Power Reactor Licensing Activities in 10 CFR Part 50," the NRC developed licensing guidance for the first time since many NPUF applicants were originally licensed. In that guidance (NUREG-1537, Parts 1 and 2), the NRC provides detailed descriptions of the scope, content, and format of FSARs and the NRC's process for reviewing initial license applications and license renewal applications. However, at the time of the first license renewals using NUREG-1537, some license renewal applications had varying levels of consistency with NUREG-1537. These licensees did not propose an acceptable alternative to the guidance. This

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resulted in the NRC sending requests for additional information and some of the issues already described in Section I.B. of this document.

C. NRC Response to These Issues

As a result of these issues, a backlog of NPUF license renewal applications developed and persisted. The Commission and other stakeholders voiced concerns not only about the backlog, but also about the burdensome nature of the license renewal process itself. The Commission issued SRM-M080317B, "Briefing on State of NRC Technical Programs," in April 2008, which directed directing the staff to "examine the license renewal process for non-power reactors and/o identify and implement efficiencies to streamline this process while ensuring that adequate protection of public health and safety are maintained."

In October 2008, the staff provided the Commission with plans to improve the review process for NPUF license renewal applications in SECY-08-0161, "Review of Research and Test Reactor License Renewal Applications." In SECY-08-0161, the staff summarized a public meeting held with stakeholders to gather feedback on the current process, ways the process could be improved, and options for improving the review process. The staff provided a detailed description of five options for streamlining the NPUF license renewal process:

 The<u>An</u> "alternate safety review approach" <u>that</u> would limit the review of license renewal applications to changes to the facility since the previous license review occurred and compliance with the current regulations. Safe operation of the facility would also be assured by the previous NRC analysis, the review of the changes to the facility, compliance with the current regulations, and the NRC's inspection process.

 TheA "graded approach" that would base the areas of review on the relative risk associated with the facility applying for a renewed license. The graded approach would ensure safe operation by properly identifying the Inherent risk associated with the facility and ensuring those risks are minimized.

 TheA "generic analysis approach" that would require the NRC to review and approve a generic reactor design similar to the NRC topical report process. The NRC would rely on the previously approved generic analysis and would not reanalyze those items for each licensee.

TheA "generic siting analysis approach" that would require the NRC to develop a
generic communication that contains information related to each of the licensee sites.
The licensees could then reference this generic communication in their license renewal
submittals.

 The<u>An</u> "extended license term approach" that would permit extended or indefinite terms for NPUF licenses. The staff described this approach in

SECY-08-0161:

In order to permit an extended term (including possibly an indefinite term), the NRC staff would have to explain why it is appropriate and, more importantly, demonstrate that there are no aging concerns.

Environmental conditions such as temperature, pressure and radiation levels in most [research and test reactors] are not significant. With surveillance, maintenance and repair, [research and test reactors] can have indefinite lives.

For a facility to be eligible for an extended license term, the NRC staff would complete a detailed renewal with a licensing basis reviewed against NUREG-1537. To maintain the licensing basis over time, the NRC staff would propose a license condition or regulation that requires licensees to revise their [safety analysis reports] on a periodic basis such as every 2 years. The inspection program would be enhanced to place additional focus on surveillance, maintenance and repair, and changes to the facility made under 10 CFR 50.59. The licensee would still be required to adhere to changes in the regulations.

The Commission issued SRM-SECY-08-0161, "Review of Research and Test

Reactor License Renewal Applications," in March 2009. The Commission directed the

staff to: 1) immediately implement appropriate short-term program initiatives to address

the backlog of license renewal applications; 2) work with the regulated community and other stakeholders to develop an interim streamlining process to focus the review on the most safety-significant aspects of the license renewal application; and 3) streamline the review process to ensure that it becomes more efficient and consistent, thereby reducing uncertainties in the process while ensuring compliance with regulatory requirements.

As part of its direction to develop the program initiatives, the Commission Instructed the staff to implement a graded approach commensurate with the risk posed by each facility, incorporate elements of the alternate safety review approach, and use risk insights from security assessments to inform the dose threshold. In addition, the Commission told the staff to develop an interim staff guidance (ISG) document that employs the graded approach to streamline the license renewal application process.

Lastly, the Commission instructed the staff to submit a long-term plan for an enhanced NPUF license renewal process. The Commission directed that the plan include development of a basis for redefining the scope of the process as well as a recommendation regarding the need for rulemaking and guidance development.

The staff responded to the Commission's direction by implementing short-term actions to address the license renewal application backlog and developing ISG-2009-001, "Interim Staff Guidance on the Streamlined Review Process for License Renewal for Research Reactors," hereafter referred to as the ISG. The ISG called for employing a graded approach to streamline the license renewal application process. Since October 2009, the NRC has reviewed license renewal applications according to streamlined review process presented inof the ISG. The ISG identified the three most safety-significant sections of an FSAR: reactor design and operation, accident analysis, and technical specifications. The NRC also has reviewed licensees' radiation protection and waste management programs and compliance with financial requirements. The ISG divided facilities into two groups: 1) those facilities with licensed power of less than 2 megawatts thermal (MW(t)), which would undergo a limited review focusing on the safety-significant aspects, considering the decisions and precedents set by past NRC reviews; and 2) those facilities with licensed power of 2 MW(t) and greater, which would undergo a full review using NUREG-1537, Part 2. The process outlined in the ISG facilitated the NRC's review of license renewal applications and enabled the NRC to review applications in a timelier manner.

In addition, the staff issued SECY-09-0095, "Long-Term Plan for Enhancing the Research and Test Reactor License Renewal Process and Status of the Development and Use of the Interim Staff Guidance," in June 2009, to provide the Commission with a long-term plan for enhancing the NPUF license renewal process. In the long-term plan, the staff proposed to develop a regulatory basis to support rulemaking to streamline and enhance the NPUF license renewal process. The Commission issued SRM-M090811, "Briefing on Research and Test Reactor (RTR) Challenges," in August 2009, which directed the staff to look for ways to accelerate the rulemaking to establish a more efficient, effective, and focused regulatory framework.

D. 2012 Regulatory Basis

In August 2012, the staff completed the "Non-Power Reactor (NPR) License Renewal Rulemaking: Regulatory Basis Document," hereafter referred to as the regulatory basis.¹

The NRC, in the regulatory basis, analyzed the NPUF license renewal process's technical, legal, and policy issues; effects on public health, safety, and security; effects

At the time of publication of the regulatory basis, the rulemaking title was "Non-Power Reactor (NPR) License Renewal Rulemaking." During the development of the proposed rule, the scope of the rulemaking expanded to include licenses for certain facilities that are not reactors, based upon the receipt of recent license applicants (e-g-for medical radioisotope irradiation and processing facilities). In order to encompass all affected entities, the NRC has changed the title of the rulemaking to "Non-power Production or Utilization Facility License Renewal."

on licensees; effects on the NRC; and stakeholder feedback. The NRC also considered lessons learned from implementation of the streamlined review process <u>outlined inol</u> the ISG. The NRC concluded that a rulemaking was warranted. A public meeting was held on August 7, 2014, to discuss the regulatory basis and rulemaking options. The NRC held another public meeting on October 7, 2015, to afford stakeholders the opportunity to provide feedback and comment on preliminary proposed rule concepts. Participant comments and questions focused on the potential effects of eliminating license terms, the scope of review under the new process, and how the amended regulation would work compared to the existing license renewal process. The NRC considered the comments when developing the proposed rule.

E. 2017 Proposed Rule

On March 30, 2017, the NRC published the proposed rule, "Non-Power Production or Utilization Facility License Renewal" in the *Federal Register* (82 FR 15643). The NRC proposed to eliminate license terms for facilities used for medical therapy or research and development licensed under the authority of Sections 104a or **104c** of the AEA, other than for testing facilities. Other proposed amendments addressed the license renewal process for licenses issued to testing facilities under the authority of Section 104c of the AEA and licenses issued to non-power commercial facilities under the authority of Section 103 of the AEA (including testing facilities). The proposed rule also included a provision to require all NPUF licensees to submit FSAR updates to the NRC every 5 years. The NRC also proposed an accident dose criterion of 1 rem (0.01 Sv) TEDE for NPUFs other than testing facilities. The NRC requested public feedback on specific questions, including **questions concerning** the criteria, other than power level, to use when determining the applicability of requirements for low-risk commercial production or utilization facilities and low-risk testing facilities. The proposed rule provided a public comment period of 75 days. The NRC received 16 comment submissions on the proposed rule and draft implementation guidance, as discussed further in Section IV of this document. The NRC considered those comments in developing this final rule.

II. Discussion

This final rule: 1) creates a definition for *Non-power production or utilization facility*, and revises the definitions for *Non-power reactor*, *Research reactor*, and *Testing facility*; 2) eliminates license terms for NPUFs licensed under § 50.21(a) or (c), other than testing facilities; 3) defines the license renewal process for NPUFs (including testing facilities) licensed under § 50.22 and testing facilities licensed under § 50.21(c); 4) requires all NPUF licensees to submit to the NRC an updated FSAR and subsequent FSAR updates at intervals not to exceed 5 years; 5) amends the current timely renewal provision under § 2.109, allowing an NPUF subject to license renewal to continue operating under an existing license past its expiration date if the licensee submits a license renewal application at least 2 years before the current license expiration date; 6) provides an accident dose criterion of 1 rem (0.01 Sv) TEDE for NPUFs other than testing facilities; 7) extends the applicability of § 50.59 to NPUFs regardless of their decommissioning status; 8) clarifies the requirements for NPUF license applicants to meet the existing provisions of § 51.45; and 9) eliminates the requirement to submit financial qualification information with license renewal applications under § 50.33(f)(2).

This final rule enhances the effectiveness and efficiency of the NPUF license renewal process, consistent with the AEA's criterion for imposing minimum regulation on facilities of these types that is needed to promote the common defense and security and protect the health and safety of the public. Each of the nine main objectives of this final rule are discussed in detail in this section.

1. Creates a definition for Non-power production or utilization facility and revises the definitions for Non-power reactor, Research reactor, and Testing facility.

This final rule addresses inconsistencies in definitions and terminology throughout 10 CFR chapter I to improve clarity in determining the applicability of the regulations associated with NPUFs. For example, before this final rule, the existing definitions for non-power facilities (e.g., *Non-power reactor, Research reactor, Testing facility*) did not cover new entities like SHINE's proposed accelerator-driven subcritical operating assemblies or other medical radioisotope irradiation and processing facilities. The final rule definition for *Non-power production or utilization facility* is more inclusive and recognizes that not all NPUFs are non-power reactors.

The NRC received public comments on the proposed definition of *Non-power production or utilization facility*. In reviewing the comments, the NRC identified that the proposed definition for *Non-power production or utilization facility* was too broad for defining production facilities that are NPUFs. Previously, the definition excluded fuel reprocessing plants, but did not exclude production facilities designed or used primarily for the formation of plutonium or uranium-233 or designed or used for the separation of the isotopes of plutonium. Accordingly, the NRC revised the definition for *Non-power production facility* in § 50.2. Production facilities of the type defined under paragraph (1) of the definition of *Production facility* in § 50.2 have been owned by the U.S. Department of Energy to produce plutonium or uranium-233 and have not been NRC licensees. If such a facility were to be licensed by the NRC, the facility's particular use of special nuclear material would require the Commission to determine the licensing path for the facility. Production facilities, as

defined under paragraph (2) of the definition of *Production facility* in § 50.2, are not NPUFs because these facilities have a higher potential of radiological risk to the environment and the public than NPUFs (e.g., an inventory of high-level liquid radioactive wastes). This The NRC's historical recognition of this higher risk is evidenced by the applicability to these facilities of NRC regulations in appendix B to 10 CFR part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" and appendix F to 10 CFR part 50, "Policy Relating to the Siting of Fuel Reprocessing Plants and Related Waste Management Facilities." The NRC revised the definition of *Non-power production or utilization facility* to exclude production facilities designed or used primarily for the formation of plutonium or uranium-233 or the separation of the isotopes of plutonium.

The NRC also received a comment from the National Institute of Standards and Technology on the definition of *Testing facility* in § 50.2 and *Research reactor* in § 171.11(b)(2). The commenter recommended that the NRC revise the definitions of *Testing facility* and *Research reactor* to "remove the arbitrary 10 MW(t) threshold, and apply instead a risk-based approach to its regulation of a testing facility." Further, the commenter stated that the risk "is best quantified by accident analyses performed under a licensing safety analysis" and linked the recommended definition to the NRC's accident dose criterion of 1 rem (0.01 Sv) in the proposed rule.

The NRC notes that while the thresholds for the definition of Testing facility was adopted by the Atomic Energy Commission in 1960 through a notice-and-comment nulemaking process, the technical basis associated with the 10 MW(t) threshold under the current definition for Testing facility, while generally based on safety significance, is not explicitly documented. Similarly, the technical basis for the 1 MW(t) threshold (coupled with specific design features) under the current definition for Testing facility is not explicitly documented. These prescriptive power thresholds also do not account for the safety features that are engineered into the facility design and those barriers that must be breached during an accident before a release of radioactive material to the environment can occur. Therefore, these thresholds do not accurately represent the risk associated with a particular facility. For these reasons, the use of a postulated accident dose is a more risk-informed, performance-based approach, rather than as compared to using the power level of the reactor for distinguishing between types of NPUFs, such as research reactors and testing facilities. As a result of this public comment, the NRC revised the definitions of *Testing facility* and *Research reactor* to reflect this riskinformed approach by incorporating an accident dose criterion of 1 rem (0.01 Sv) TEDE, the basis for which is discussed in section II.6 of this document.

Additionally, the NRC is making conforming changes to the definitions of *Testing* facility, Research reactor, and Non-power reactor wherever these definitions appear throughout 10 CFR chapter I. The regulations currently refer to many types of facilities that are categorized as NPUFs, such as non-power reactors, research reactors, training reactors, testing reactors, testing facilities, and critical assemblies. The NRC reviewed each instance of these various terms in 10 CFR chapter I. Where appropriate in this final rule, the NRC added, corrected, or standardized the terminology and definitions (e.g., replacing the term *Test reactor* with *Testing facility* in § 171.15).

While this final rule revises the definition of *Research reactor* in §§ 170.3 and 171.5 to conform to other definitions in 10 CFR chapter I, the NRC did not change the definition of *Research reactor* in the specific exemption for Federally-owned and State-owned research reactors in § 170.11(a)(9) or § 171.11(b)(2). The current definition in § 171.11(b)(2) is based on the language of the Omnibus Budget Reconciliation Act of 1990, as amended (Pub. L. No. 101-508) (OBRA-90), a statutory requirement imposed by Congress. Further, a substantively similar definition of *Research reactor* was included in the provisions of the Nuclear Energy Innovation and

Modernization Act (Pub. L. No. 115-439) (NEIMA) that relate to the NRC's fee recovery structure. Changing the definition of *Research reactor* in § 171.11(b)(2) would therefore be inconsistent with OBRA-90 and NEIMA. 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 § 171.11(b)(2). Changing the definition of *Research reactor* in § 170.11(a)(9) would be a substantive change beyond the scope of this final rule.

Where appropriate, this final rule standardizes the terminology in other parts of the regulations to modify the intended scope of regulations citing *Research and test reactors* to be either *Non-power reactors* or *Non-power production or utilization facilities*. For example, this final rule changes *Research and test reactors* to *Non-power production or utilization facilities* in appendix E to 10 CFR part 50, "Emergency Planning and Preparedness for Production and Utilization Facilities," while in § 55.40, this final rule changes *Test and research reactors* to *Non-power reactors*. Also, where appropriate, the final rule changes the uses in other parts of the regulations for *Testing facility, Research reactor*, and *Non-power reactor* to reference only one definition in the part where that definition is used most, unless the specific meaning is needed and different for a given part. In addition, the final rule adds the definition of *Non-power reactor*, as it is defined in § 50.2, to the definitions section in 10 CFR part 73 because the term is used many times throughout that part. These changes increase clarity by defining all NPUF-related terms consistently where they are most used in the regulations.

This final rule also revises the definition of *Non-power reactor* to distinguish between non-power reactors used for research and development activities and nonpower reactors used for commercial or industrial purposes. Before this final rule, all non-power reactors were defined in § 50.2 as "a research or test reactor licensed under Commented [A1]: Modified to use a non-breaking space.

§§ 50.21(c) or 50.22 of this part for research and development." This final rule defines non-power reactors more precisely as one of three mutually exclusive categories of facilities: 1) testing facilities, 2) research reactors that are NPUFs licensed under § 50.21(c), or 3) commercial or industrial reactors that are NPUFs licensed under § 50.22. The second and third categories exclude testing facilities, and the facilities in those categories must meet the accident dose criterion in § 50.34(a)(1)(i). If they do not meet this criterion, then they will be considered testing facilities.

 Eliminates license terms for NPUFs, other than testing facilities, licensed under § 50.21(a) or (c).

The final rule language in § 50.51(c) eliminates license terms for NPUFs, other than testing facilities, licensed under § 50.21(a) or (c). Before this final rule, § 50.51(a) stated, "Each license will be issued for a fixed period of time to be specified in the license but in no case to exceed 40 years from date of issuance." This included all facility licenses issued under 10 CFR part 50, including licenses for facilities issued under § 50.21(a) or (c). However, the AEA does not establish specific license terms nor the need for license terms for class 104 facilities.

Historically, license renewal afforded both the NRC and the public the opportunity to re-evaluate the licensing basis of the NPUF. The purpose of license renewal was to assess the likelihood of continued safe operation of the facility, such that radioactive materials can be used for beneficial civilian purposes in a safe and secure manner. For several reasons that are unique to NPUFs, this objective can be achieved through existing oversight activities and review of FSAR updates submitted pursuant to the new requirements in § 50.71(e) of the final rule language (see Section II.4. of this document). This approach is consistent with the NRC's goal of efficient and effective licensing and will implement and reflect lessons learned from decades of processing license renewal applications. The NRC reached this conclusion based on three considerations: 1) low

overall radiological risk, 2) limited aging-related issues, and 3) slow evolution of the design basis.

First, compared to power reactors, the NPUFs licensed under § 50.21(a) or (c), other than testing facilities, operate at low power levels, temperatures, and pressures, and have a small inventory of fission products in the fuel. Therefore, these NPUFs present a lower potential radiological risk to the environment and the public. Additionally, the consequences of the maximum hypothetical accidents (MHAs) for these facilities fall below the standards in 10 CFR part 20 for protecting the health and safety of the public.

Of the 30 NPUFs that are currently licensed to operate and are eligible for nonexpiring licenses (excluding the one testing facility), 26 have cores that are submerged in tanks or pools of water that provide sufficient passive decay heat removal to prevent overheating of the fuel.² Of these 26 licensed facilities, 24 are not required to have emergency core cooling systems (ECCSs) because conservative accident analyses have shown that these NPUFs do not generate enough decay heat, even after extended operation at maximum licensed power, to be at risk of overheating, failure of a fission product barrier, or posing a threat to public health and safety. Additionally, many of the licensees monitor for leaks by routinely inspecting the facility, tracking and trending water inventory, and performing surveillance on installed pool-level instrumentation and sensors. Licensees sample the water periodically and analyze the radioisotopes in the primary and, if applicable, secondary coolant. Many licensees sample weekly for gross radioactive material content. This data also is used to establish trends to quickly identify fuel or heat exchanger failure. Most of these licensees analyze, in their FSARs, pool

² The three Aerojet-General Nucleonics reactors (University of New Mexico (Docket No. 50-252), Idaho State University (Docket No. 50-284), and Texas A&M University (Docket No. 50-59)), each rated at 5 watts, and the University of Florida Argonaut reactor (Docket No. 50-83), rated at 100 kilowatts, are not considered tank or pool reactors but have similarly low risk profiles.

and heat exchanger failures and the potential consequences for the safety of the reactor, workers, and public. In general, the radioisotope concentrations in pool or tank water at NPUFs are within the effluent concentration limits specified in appendix B to 10 CFR part 20, and therefore are not radiologically significant.

Only two of the NPUFs eligible for non-expiring licenses are required by their safety analyses to have an ECCS to maintain core cooling in the highly unlikely case that a loss-of-coolant accident uncovers the core.³ For these NPUFs, the ECCS is needed only to direct flow into the top of the tank or pool to provide cooling for a limited time after reactor shutdown. This period of time depends on the recent operational history of the reactor, which determines the decay heat present at reactor shutdown. After this relatively brief time, air cooling is adequate to remove decay heat without the ECCS. Additionally, required surveillance and testing of the ECCS at these facilities help ensure the performance of the system. Operation of the facility is not permitted if the ECCS has not been verified to be operable before reactor startup or if the system is deemed inoperable during reactor operation.

Second, the NRC has found that the simple design and operation of these facilities yield a limited scope of aging-related concerns. There have been no significant aging issues identified at the time of license renewal because the NRC currently imposes aging-related surveillance requirements on NPUFs via technical specifications, as needed. Aging of components is specifically addressed in the standard review plan and acceptance criteria used for evaluating license renewal applications (i.e., NUREG-1537, Part 2). Parts 1 and 2 of NUREG-1537 document lessons learned and known aging issues from prior reviews. Since NUREG-1537 was published in 1996, NRC reviews and assessments have not revealed any additional issues or need to

³ The two facilities are Massachusetts Institute of Technology (MIT) (Docket No. 50-20) and the University of California/Davis (Docket No. 50-607).

update the NUREG. Specifically, based on operating experience over the past 60 years and review of license renewal applications over the past 40 years, and as documented in NUREG-1537, Parts 1 and 2, the NRC has determined that for NPUFs, the two main areas related to aging that could need surveillance because of potential safety concerns are 1) fuel cladding and 2) instrumentation and control features.

Regarding fuel cladding, the NRC currently requires NPUFs to perform periodic fuel inspections. Through years of operational operating experience, the NRC has found that aging-related fuel failures either do not occur, or failures that do occur do not release significant amounts of fission products and are quickly detected by existing monitoring systems and surveillances. If fuel failures are detected, licensees are able to take the facility out of service without delay and remove any failed assemblies from service.

With regard to instrumentation and control, the NRC has found that failures in this area result in automatic facility shutdown. Failures reveal themselves to the licensee and do not prevent safe shutdown. Over the past 60 years of operation of these facilities, the potential occurrence of age-related degradation has been successfully mitigated through inspection, surveillance, monitoring, trending, recordkeeping, replacement, and refurbishment. In addition, licensees are required to report preventive and corrective maintenance activities in their annual reports, which are reviewed by the NRC. This allows the NRC to identify new aging issues if they occur. Therefore, the NRC has concluded that existing requirements and facility design and operational features will address concerns over aging-related issues during a non-expiring license term.

Third, the design bases of these facilities evolve slowly over time, with approximately five license amendment requests from all NPUF licensees combined each

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year and, on average, only five § 50.59 evaluations per facility per year for changes that do not require prior NRC approval.

Given these considerations, the elimination of license terms for medical therapy or research and development facilities, other than testing facilities, licensed under § 50.21(a) or (c), combined with the addition of requirements for periodic FSAR submittals, will provide a new framework for enabling licensees to continue to operate safely while reducing burden on licensees and the NRC. The final rule at § 50.71(e) requires licensees to submit updated FSARs and subsequent FSAR updates to ensure that a facility's licensing basis is kept up-to-date, a major function previously provided by the license renewal process, while imposing significantly less burden on licensees. Eliminating license terms for these licensees will allow the NRC to focus its resources on oversight of these facilities, through the conduct of activities such as conducting routine. inspection activities inspections and reviewing the review of annual reports and FSAR updates. Recurring FSAR updates by licensees and reviews by the NRC will increase licensees' focus on maintaining their facilities' licensing bases. Should the NRC identify potential issues with the facility's continued safe operation in its reviews of FSAR updates, the Commission can undertake regulatory actions specified inunder § 2.202 to modify, suspend, or revoke a license. In addition, the public will remain informed about facility operations through the publicly available FSAR submittals and will continue to have opportunities to participate in the regulatory process through licensing actions and the § 2.206 petition process. By eliminating license terms and requiring periodic FSAR update submittals, coupled with existing oversight processes, the NRC will reduce the burden on the affected licensees and the NRC, which is consistent with the AEA and supports the NRC's goal of efficient and effective licensing.

Most licenses of existing NPUFs licensed under § 50.21(a) or (c), other than testing facilities, will be modified by order to remove the license terms after the effective

date of this final rule (see Section II.4. of this document). Facilities licensed under § 50.21(a) or (c), other than testing facilities, that have undergone relicensing using the guidance in NUREG-1537, Part 2 will be eligible to receive a non-expiring license without again renewing the current license. The current NPUF licensees that have not undergone the license renewal process using the guidance in NUREG-1537, Part 2, will each need to submit an application for license renewal if they wish to continue facility operation beyond the current license term. The NRC will review the application using NUREG-1537, Part 2, and the ISG. <u>IQuon reaching</u> the <u>NRC concludesconclusion</u> that a licensee's application meets the standard for issuing a renewed license, then the licensee will receive<u>NRC would issue</u> a non-expiring renewed license. If, in the future, the NRC issues an operating license to a new facility, other than a testing facility, under § 50.21(a) or (c), the <u>operating</u> license would also be non-expiring and would be subject to periodic FSAR submittal requirements applicable to all NPUF licensees.

This final rule makes conforming changes to requirements for facilities that are decommissioning by revising § 50.82(b) and (c). These provisions currently use the expiration of the operating license-terms as a reference point to address license termination applications and collection periods for shortfalls in decommissioning funding for NPUFs. This final rule clarifies that NPUFs (including testing facilities) licensed under § 50.22 and testing facilities licensed under § 50.21(c) are the only NPUFs with license terms. The reference point for NPUFs licensed under § 50.21(a) or (c), other than testing facilities, is the NPUF's date of permanent cessation of operations.

 Defines the license renewal process for NPUFs (including testing facilities) licensed under § 50.22 and testing facilities licensed under § 50.21(c).

For NPUFs (including testing facilities) licensed under § 50.22 and testing facilities licensed under § 50.21(c), this final rule defines the license renewal process in

§ 50.135. This one section consolidates existing regulatory requirements (e.g., requirements regarding written communications, application filing, application contents, and the issuance of renewed licenses) for current and future licensees. This final rule does not impose new regulations on these facilities. The NRC also is making a conforming change to § 50.8 to reflect the approved information collection requirement of § 50.135.

Section 103 of the AEA establishes a license term of no more than 40 years for commercial or industrial facilities licensed under § 50.22. Although the AEA does not establish a fixed license term for testing facilities, licensees for these facilities are currently subject to additional license renewal requirements (e.g., siting subject to 10 CFR part 100, Advisory Committee on Reactor Safeguards review, and environmental impact statements) because of the potential for higher radiological risks associated with their facilities' design, operation, or use as compared to other class 104a or <u>e104p</u> licensees. Therefore, all commercial or industrial NPUFs (including testing facilities) licensed under § 50.22 and testing facilities licensed under § 50.21(c) will continue to have fixed license terms and undergo license renewal. As described in § 50.135(c)(2), these NPUFs will be able to submit a license renewal application to the Commission no more than 10 years in advance of the expiration of the operating license currently in effect. The requirement in § 50.135(c)(2) is not intended to affect the term of operating licenses granted to NPUFs.

The NRC is making renewed operating licenses for these facilities effective, and thereby replacing the previous operating license, immediately upon the date of issuance. The applicant for the renewed license can propose a schedule for implementation of the renewed licensee. This implementation schedule would ensure that the licensee can make any necessary and conforming changes to the facility processes and procedures required by the applicable conditions of the renewed license. The NRC will review and,

make the schedule, if approved, a condition of the renewed license. The immediate effectiveness of the renewed license is a change from the proposed rule, which would have made the renewed license effective 30 days after issuance. This final rule provides a substantively similar result as <u>would have resulted from</u> the proposed rule and provides licensees additional flexibility in the timing of their implementation of the renewed license.

If administrative or judicial appeal affects the renewed license, then the previous operating license will be reinstated unless its term has expired and the facility has failed to submit a license renewal application in a timely manner according to $\frac{5}{50.135}$ (c)(2), under $\frac{5}{2}$.109.

During the development of this final rule, the NRC recognized that § 50.135(e)(2) in the proposed rule could have unnecessarily restricted the license term for a renewed NPUF license to less than 40 years. Section 103 of the AEA allows for license terms of up to 40 years. To address this issue, this final rule clarifies that renewed licenses are issued for a fixed period of time, not to exceed 40 years.

 Requires all NPUF licensees to submit to the NRC updated FSARs and subsequent FSAR updates at intervals not to exceed 5 years.

Maintaining up-to-date FSARs facilitates safe management of a facility, including current understanding of the licensing bases and effective training of personnel, and enables the NRC to fulfill its statutory obligations and regulatory responsibilities effectively. TheSection 50.71(e) of the final rule requires all NPUF licensees to submit to the NRC updated FSARs and subsequent FSAR updates at intervals not to exceed 5 years, according to § 50.71(e). The updated FSAR will incorporate the various supplements and amendments that may have been submitted, either in response to NRC questions or on the 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. Given the requirement to submit subsequent FSAR updates, the NRC anticipates that licensees will document changes to the licensing bases as they occur, which will maintain aid in maintaining the continuity of knowledge both for the licensee and the NRC and the understanding of changes and effects of changes on the facility both for the licensee and the NRC. The NRC anticipates that these changes will result in minimal additional burden on licensees and the NRC, because experience has shown only a small number of changes have occurred per facility pereach year. In addition, licensees should have already documented these changes under § 50.59 or through a license amendment request under § 50.90.

This final rule requires licensees to submit, in accordance with § 50.4, a complete updated FSAR within 5 years of receipt of a facility operating license (§ 50.71(e)(3)(iv)) and subsequent FSAR updates at successive intervals not to exceed 5 years (§ 50.71(e)(4)(ii)). The NRC will issue orders to existing facilities licensed under § 50.21(c) that have undergone the license renewal process using the guidance in NUREG-1537, Part 2. These licensee-specific orders will direct these licensees to submit their updated FSARs, after which they will be subject to the new requirement in § 50.71(e)(4)(ii) to submit subsequent FSAR updates.

To issue the licensee-specific orders, the NRC will group the facilities by based upon when they have undergone license renewal using NUREG-1537. The orders will dictate when a licensee's initial updated FSAR will be due to the NRC. The NRC plans to stagger the dates over a 5-year period following the effective date of this final rule. The NRC will place existing operating and decommissioning NPUF licensees in three groups as follows:

 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.

2) 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.

3) Group 3 consists of the remaining NPUF licensees that have not undergone license renewal using NUREG-1537. The licenses for these facilities are all due to expire in less than 5 years from the effective date of this final rule. If these licensees choose to renew their facility operating licenses, they will be subject to the requirements in § 50.71(e) after issuance of the renewed license.

The general approach will be to stagger the submittal dates within Groups 1 and 2 such that licensees that most recently completed license renewal will be the first to submit their updated FSAR. However, the licensee-specific orders will also consider facility-specific circumstances and NRC discretion.

This final rule also corrects a grammatical error in footnote 1 to § 50.71(e). The footnote previously stated, "Effects of changes includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate." This final rule changes "includes" to "include" so that the plural subject is followed by a plural verb.

5. Amends the current timely renewal provision under § 2.109, allowing an NPUF subject to license renewal to continue operating under an existing license past its

expiration date if the licensee submits a license renewal application at least 2 years before the current license expiration date.

The requirements in § 2.101(a) allow the NRC to determine the acceptability of an application for review by the NRC. However, before this final rule, § 2.109 allowed an NPUF licensee to submit its license renewal application as late as 30 days before the expiration of the existing license. Historical precedent indicates that 30 days is not a sufficient period of time for the NRC to adequately assess the sufficiency of a license renewal application for review. As a result, the NRC accepted license renewal applications and addressed their deficiencies in the license renewal process by issuing licensee-requests for additional information to licensees. This approach increased the duration of the license renewal process and resulted in multiple facilities operating many years into a "timely renewal" period without renewed licenses.

To address this issue, the NRC is revising the timely renewal provision for NPUFs (including testing facilities) licensed under § 50.22 and testing facilities licensed under § 50.21(c) to establish a length of time adequate for the NRC to review the sufficiency of a license renewal application. Specifically, this final rule amends § 2.109, allowing <u>a these</u> facilityies to continue operating under an existing license past its expiration date if the licensee submits a sufficient license renewal application at least 2 years before the current license expiration date. In such cases, the existing license will not be deemed to have expired until the application has been finally determined by the NRC. This final rule ensures that the NRC has adequate time <u>prior to the expiration of the current license</u> to review the sufficiency of license renewal applications while the facility continues to operate under the terms of its current license.

The proposed rule proposed aliminatingwould have eliminated this provision for medical therapy or research and development facilities, other than testing facilities, licensed under § 50.21(a) or (c), because these facilities willwould no longer have

license expiration dates. The NRC reinstates the provision in this final rule to enable its use for the remaining license renewal applications that may be submitted after this final rule is published. The NRC anticipates that there is one research reactor licensee that would use this provision.

6. Provides an accident dose criterion of 1 rem (0.01 Sv) TEDE for NPUFs other than testing facilities.

The standards in 10 CFR part 20 for protection against ionizing radiation provide a limit on the maximum yearly radiation dose a member of the public can receive from the operation of any NRC-licensed facility. Licensees are required to maintain programs and facility design features to ensure that these limits are met. In addition to the dose limits in 10 CFR part 20, accident dose criteria are also applied during licensing to determine the acceptability of the licensed facility. The accident dose criteria are not dose limits; they inform a licensee's accident analyses and the development of successive safety measures (i.e., defense in depth) so that in the unlikely event of an accident, the NRC has reasonable assurance that no acute radiation-related harm will result to any member of the public. Before this final rule, the accident dose criterion for NPUFs, other than testing facilities, was the 10 CFR part 20 dose limit to a member of the public. For testing facilities, accident dose criteria are found in 10 CFR part 100: 25 rem (0.25 Sv) to the whole body and 300 rem (3 Sv) to the thyroid.

Before January 1, 1994, the NRC had generally found acceptable accident doses for applicants applying for an initial or renewed NPUF license, other than for testing facilities, that were less than 0.5 rem (0.005 Sv) to the whole body and 3 rem (0.03 Sv) to the thyroid for members of the public. On May 21, 1991,⁴ the NRC amended 10 CFR part 20 to reduce the dose limit to a member of the public to 0.1 rem (0.001 Sv) TEDE

⁴ In the proposed rule, the NRC misidentified the part 20 rulemaking date as January 1, 1994.

(56 FR 23360) with an implementation date of January 1, 1994. Since January 1, 1994, for applicants applying for an initial or renewed NPUF license, other than for testing facilities, the NRC has compared the results from the accident analyses submitted in initial or renewed license applications with the standards in 10 CFR part 20.

The NRC has determined that the public dose limit of 0.1 rem (0.001 Sv) TEDE in 10 CFR part 20 is unduly restrictive to be applied as accident dose criteria for NPUFs. other-than except for testing facilities, which are subject to 10 CFR part 100. The NRC bases this determination on the NRC Atomic Safety and Licensing Appeal Board's decision that the standards in 10 CFR part 20 are unduly restrictive as accident dose criteria for research reactors (Trustees of Columbia University in the City of New York, ALAB-50, 4 AEC 849, 854-855 (May 18, 1972)). At the time of this decision, the 10 CFR part 20 public dose limit was 0.5 rem (0.005 Sv) whole body.

However, the NRC considers the accident dose criteria in 10 CFR part 100 to be too high for NPUFs other than testing facilities, because those NPUFs have lower risk profiles than testing facilities. For these reasons, this final rule modifies § 50.34 to add an accident dose criterion of 1 rem (0.01 Sv) TEDE for NPUFs not subject to 10 CFR part 100. The accident dose criterion of 1 rem (0.01 Sv) TEDE is based on the Environmental Protection Agency's (EPA) Protection Action Guides (PAGs). The EPA PAGs are dose guidelines that support decisions during a radiological incident to take protective actions such as staying indoors or evacuating. The proposed rule stated that the 1 rem (0.01 Sv) TEDE accident dose criterion was based on the EPA PAGs published in EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents." In January 2017, the EPA published an update to its PAGs in EPA-400/R-17/001, "PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents." This update to the EPA PAGs does not change the basis for the 1 rem (0.01 Sv) TEDE accident dose criterion.

The PAG is defined as the projected dose to an individual from a release of radioactive material at which a specific protective action to reduce or avoid that dose is recommended. Three principles considered in the development of the EPA PAGs include: 1) prevent acute effects; 2) balance protection with other important factors and ensure that actions result in more benefit than harm; and 3) reduce risk of chronic effects. In the early phase (i.e., the beginning of the radiological incident, which may last hours to days), if the sum of the projected dose from external radiation exposure and the inhalation of radioactive material is 1 rem (0.01 Sv) to 5 rem (0.05 Sv), the EPA PAG recommends the protective action of sheltering-in-place or evacuation of the public to avoid inhalation of gases or particulates in an atmospheric plume and to minimize external radiation exposures. The EPA PAG Manual does not provide a protective action recommendation for the public when the projected dose to an individual from an incident is less than 1 rem (0.01 Sv). In light of this understanding of the early phase EPA PAG, the NRC's accident dose criterion of 1 rem (0.01 Sv) TEDE for NPUFs, other than testing facilities, provides reasonable assurance of adequate protection of the public from unnecessary exposure to radiation.

The NRC revised § 50.34(a)(1)(ii)(D)(2) of the proposed rule to replace "postulated accidental release of licensed material" with "postulated accident." This final rule requires applicants and licensees to evaluate the potential dose from postulated accidents to include the potential exposure from all radiological sources, such as direct or the scattered radiation from an unshielded source inside the **reactor buildingfacility**, in addition to potential exposure from a release of radioactive materials. This requirement is consistent with the evaluation methodology described in NUREG-1537, Part 1. Under this final rule, 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. Although the EPA PAGs were developed for radiological incidents that lead to the release or potential release of radioactive materials into the environment, the three principles considered in their development are not dependent on whether the dose received is due to exposure from a release of radioactive materials or from direct or scattered radiation.

To provide further clarification on the NRC's intent of the 1 rem (0.01 Sv) TEDE accident dose criterion for NPUFs, other than testing facilities, a footnote has been incorporated into the final rule text. The footnote clarifies that this 1 rem (0.01 Sv) TEDE accident dose criterion is not a dose limit, as explained in the preceding paragraphs.

In this final rule, the NRC moves proposed § 50.34(a)(1)(ii)(D)(2) to § 50.34(a)(1)(i) and leaves the rule language in § 50.34(a)(1)(ii)(D) unchanged. During the development of this final rule, the NRC recognized that the accident dose criterion more appropriately belongs in § 50.34(a)(1)(i) because the requirements in § 50.34(a)(1)(ii) apply to power reactor construction permit applicants, while the requirements in § 50.34(a)(1)(i) apply to all other construction permit applicants, such as NPUF applicants. Similarly, proposed § 50.34(a)(1)(ii)(D)(2) would have imposed a requirement on applications for renewed NPUF operating licenses, which more appropriately belongs in § 50.34(b). Therefore, the NRC moved the requirement to new § 50.34(b)(13) in this final rule to clarify that an application for an operating license or a renewed operating license for an NPUF must include in the FSAR a final evaluation of the applicable radiological consequences consistent with § 50.34(a)(1)(i).

Extends the applicability of § 50.59 to NPUFs regardless of their decommissioning status.

Before this final rule, § 50.59(b) of the Commission's regulations did not apply § 50.59 to NPUFs whose licenses were amended to reflect permanent cessation of operations and that no longer had fuel on site (e.g., they returned all of their fuel to the U.S. Department of Energy). The former language stated that § 50.59 applied to

licensees "whose license has been amended to allow possession of nuclear fuel, but not operation of the facility." Therefore, § 50.59 did not apply to NPUF licensees that no longer possessed nuclear fuel. For these licensees, the NRC has typically added license conditions identical to the provisions of § 50.59 to allow the licensee to make changes to its facility or changes in its procedures that would not otherwise require obtaining a license amendment pursuant to § 50.90. Because most NPUFs promptly return their fuel to the U.S. Department of Energy after permanent shutdown, in contrast to decommissioning power reactors, these licensees had to request the addition of the license conditions, which imposed an administrative burden on the licensees and the NRC. This final rule eliminates this burden by revising § 50.59(b) to extend the applicability of § 50.59 to NPUFs regardless of their decommissioning status.

 Clarifies an applicant's requirements for meeting the existing provisions of § 51.45.

The NRC is required to prepare either an environmental impact statement or environmental assessment, as appropriate, for all licensing actions pursuant to 10 CFR part 51, unless a categorical exclusion applies as provided in § 51.22. For most types of licenses, 10 CFR part 51 specifies that an applicant must submit environmental documentation in the form of an environmental report, or a supplement to a previously submitted environmental report, to assist the NRC's review and its compliance with the National Environmental Policy Act of 1969, as amended. However, before this final rule, the NRC did not have explicit requirements under 10 CFR part 51 with respect to the nature of the environmental documentation that must accompany applications for construction permits, initial licenses, and renewed licenses for NPUFs.

This final rule adds a new section to 10 CFR part 51 to clarify NPUF environmental reporting requirements. Section 51.56 clarifies an applicant's existing requirements for meeting the provisions of § 51.45. This change improves consistency throughout 10 CFR part 51 with respect to environmental report submissions required from applicants. The NRC also is making a conforming change to § 51.17 to reflect the approved information collection requirement of § 51.56.

9. Eliminates the requirement for NPUF licensees to submit financial qualification information with license renewal applications under § 50.33(f)(2).

This final rule eliminates license renewal financial qualification requirements for NPUFs. Before this final rule, § 50.33(f) required NPUF license applicants to provide information sufficient to demonstrate their financial qualifications to carry out the activities for which the license is sought. Because the regulatory requirements for the content of an application for a renewed NPUF license were the same as those for an original license, NPUF licensees that requested license renewal were required to submit an update to the same financial information that was required in an application for an initial license. In addition, the NRC found that the financial qualification information did not meaningfully contribute to the NRC's safety determination on the license renewal application. The elimination of NPUF license renewal financial qualification requirements reduces the burden associated with license renewal applications while still enabling the NRC to conduct its review of these applications.

This change is consistent with the current license renewal process for power reactors. On January 30, 2004, the NRC published in the *Federal Register* the final rule, "Financial Information Requirements for Applications to Renew or Extend the Term of an Operating License for a Power Reactor" (69 FR 4439). This final rule discontinued financial qualification reviews for power reactors at the license renewal stage except in very limited circumstances. The Commission stated that "[t]he NRC believes that its primary tool for evaluating and ensuring safe operations at nuclear power reactors is through its inspection and enforcement programs...." Further, the Commission stated that "[t]he NRC has not found a consistent correlation between licensees' poor financial

health and poor safety performance. If a licensee postpones inspections and repairs that are subject to NRC oversight, the NRC has the authority to shut down the reactor or take other appropriate action if there is a safety issue."

At NPUF sites, the NRC's inspection and enforcement programs serve as important tools for evaluating licensee performance and ensuring safe operations. The NRC periodically inspects each operating NPUF using a graded approach that prioritizes higher-power facilities. The NRC completes an annual inspection of NPUFs licensed to operate at power levels of 2 MW(t) or greater. For NPUFs operating under 2 MW(t), the inspection program is designed to be completed every two years, although inspector availability and licensee availability sometimes dictate that an inspection cycle is carried out in multiple inspections over the 2-year cycle. Inspections can include reviews of organizational structure, operator training and qualification, design and design control, radiation and environmental protection, maintenance and surveillance activities, transportation, material control and accounting, operational activities, review and audit functions, experiments, fuel handling, procedural controls, emergency preparedness, and security. The NRC also performs special and reactive inspections. In addition, the NRC manages the NPUF operator license examination program. The NRC also manages the review of NPUF emergency and security plans and develops and implements policy and guidance concerning the NPUF licensing program.

The same basis for the NRC's elimination of financial qualification requirements for power reactor licensees at the time of license renewal supports the NRC's elimination of NPUF financial qualification requirements at the time of license renewal. The NRC is not aware of any connection between an NPUF's financial qualifications at license renewal and safe operation of the facility. The NRC retains broad authority under the AEA and § 50.54(cc), § 50.54(f), and § 2.102 to request additional financial information from its licensees and applicants, as necessary, to protect public health and safety.

III. Opportunity for Public Participation

The NRC hosted two public meetings to engage with external stakeholders on the proposed rule and associated draft guidance document during the public comment period. A public meeting was held on May 24, 2017, to discuss the proposed rule. A public meeting on the implementation schedule of the final requirements was held on April 25, 2019. Summaries of both public meetings are available in ADAMS, as provideddescribed in the "Availability of Documents" section. The feedback from these public meetings informed the development of this final rule.

IV. Public Comment Analysis

The NRC prepared a summary and analysis of public comments received on the 2017 proposed rule and draft regulatory guide, as referenced in the "Availability of Documents" section. In response to the proposed rule and draft regulatory guide, the NRC received 16 comment submissions.

The public comment submittals are available from the Federal e-Rulemaking Web site at http://www.resulations.gov under Docket ID NRC-2011-0087. Responses to the public comments, including a summary of how the final rule text or guidance changed as a result of the public comments, can be found in the public comment analysis document.

For more information about the associated guidance document, see the "Availability of Guidance" section of this document.

V. Section-by-Section Analysis

The following paragraphs describe the specific changes within this final rule.

Section 2.109 Effect of timely renewal application.

In § 2.109, this final rule revises paragraph (a) to exclude NPUFs (including testing facilities) licensed under § 50.22 and testing facilities licensed under § 50.21(c) from the 30-day timely renewal provision. This final rule also adds paragraph (e) to require these same licensees to submit a license renewal application at least 2 years before license expiration to be considered timely.

Section 20.1905 Exemptions to labeling requirements.

In § 20.1905, this final rule revises paragraph (g) to standardize terminology by replacing the term "reactors" with the phrase "production or utilization facilities."

Section 26.3 Scope.

In § 26.3, this final rule revises paragraph (e) to standardize terminology by replacing the term "reactor" with the phrase "production or utilization facility."

Section 50.2 Definitions.

In § 50.2, this final rule adds a definition for *Non-power production or utilization facility* and revises the definitions for *Non-power reactor* and *Testing facility*.

Section 50.8 Information collection requirements: OMB approval.

In § 50.8, this final rule revises paragraph (b) to include new § 50.135 as an approved information collection requirement in 10 CFR part 50.

Section 50.33 Contents of applications; general information.

In § 50.33, this final rule revises paragraph (f)(2) to remove the phrase "for a power reactor" from the fourth sentence and to remove the fifth sentence, which required a non-power reactor applicant to submit with license renewal applications the same financial information that is required for initial license applications. It also redesignates the footnote to conform to the Office of the Federal Register's requirements.

Section 50.34 Contents of applications; technical information.

In § 50.34, this final rule revises paragraph (a)(1)(i) to include an accident dose criterion for applicants for construction permits for NPUFs not subject to 10 CFR part 100 and a new footnote 2. It also redesignates the footnotes to conform to the Office of the Federal Register's requirements. This final rule also adds paragraph (b)(13) to require an applicant for an operating or a renewed operating license for an NPUF to include in the FSAR a final evaluation of the applicable radiological consequences in § 50.34(a)(1)(i).

Section 50.36 Technical specifications.

In § 50.36, this final rule revises paragraph (c)(6) to standardize terminology by replacing the term "non-power reactor" with the phrase "non-power production or utilization."

Section 50.51 Continuation of license.

In § 50.51, this final rule revises paragraph (a) to add the conditional phrase "except as noted under § 50.51(c)." This final rule also adds new paragraph (c) to clarify that NPUFs licensed under § 50.21(a) or (c), other than testing facilities, after the effective date of this final rule, will have non-expiring license terms.

Section 50.59 Changes, tests, and experiments.

In § 50.59, this final rule revises paragraph (b) to extend applicability to NPUFs that have permanently ceased operations and that no longer have fuel on site.

Section 50.71 Maintenance of records, making of reports.

In § 50.71, this final rule revises paragraph (e) to include NPUFs in the requirement and makes a <u>verb</u> tense correction to footnote 1. This final rule also revises paragraph (e)(3)(I) and redesignates paragraph (4) as paragraph (4)(I) to clarify that these paragraphs <u>only</u> apply <u>only</u> to nuclear power reactors. New paragraphs (e)(3)(IV) and (e)(4)(II) are added to include the requirements for NPUFs. This final rule also revises paragraph (g) to standardize terminology by replacing the phrase "non-power reactor" with the phrase "non-power production or utilization facility."

Section 50.75 Reporting and recordkeeping for decommissioning planning.

In § 50.75, this final rule also revises paragraphs (d)(1), (e)(1)(iv), and (f)(4) to standardize terminology by replacing the phrase "non-power reactor" with the phrase "non-power production or utilization facility." This final rule also revises paragraph (f)(5) by replacing the phrase "non-power reactors" with the phrase "non-power production or utilization facilities."

Section 50.82 Termination of license.

In § 50.82, this final rule revises paragraph (b) to standardize terminology by replacing the term "reactor" with the phrase "production or utilization facility" and revises paragraph (b)(1) to include testing facilities licensed under § 50.21(c) and holders of a license issued under § 50.22. Paragraph (c) is revised by moving the phrase "that has

permanently ceased operation before the expiration of its license" to new paragraph (c)(2) to clarify when the collection period for shortfalls in funding will be determined for NPUFs and holders of licenses issued under § 50.21(b) or § 50.22, or testing facilities.

Section 50.135 Renewal of non-power production or utilization facility licenses issued under § 50.22 and testing facility licenses.

This final rule adds new § 50.135 to clearly define the license renewal process for NPUFs (including testing facilities) licensed under § 50.22 and testing facilities licensed under § 50.21(c).

Appendix C to Part 50—A Guide for the Financial Data and Related Information Required To Establish Financial Qualifications for Construction Permits and Combined Licenses.

In appendix C to part 50, this final rule revises paragraph III by replacing the reference to "medical and research reactors" with a reference to "non-power production or utilization facilities of a type described in § 50.21(a) or (c), other than testing facilities."

Appendix E to Part 50—Emergency Planning and Preparedness for Production and Utilization Facilities.

In appendix E to part 50, this final rule revises footnote 2 in paragraph I.3 to include the title of Regulatory Guide 2.6 and to replace the phrase "research and test reactor" with the phrase "non-power production or utilization facility."

Section 51.17 Information collection requirements; OMB approval.

In § 51.17, this final rule revises paragraph (b) to add new § 51.56 as an approved information collection requirement in 10 CFR part 51.

Section 51.45 Environmental report.

In § 51.45, this final rule revises paragraph (a) to add a cross reference to new § 51.56.

Section 51.56 Environmental report - non-power production or utilization facility.

This final rule adds new § 51.56 to clarify existing requirements for the submittal and content of environmental reports by applicants seeking a permit to construct, a license to operate, or a renewal of a license to operate, a non-power production or utilization facility.

Section 55.5 Communications.

In § 55.5, this final rule revises paragraph (b)(1) to remove the conditional phrase "except for test and research reactor facilities." It also revises paragraph (b)(3) to correct a division title and to clarify the applicability of this paragraph to utilization facilities licensed under 10 CFR part 50 that are not power reactors.

Section 55.40 Implementation.

In § 55.40, this final rule revises paragraph (d) to replace the phrase "test and research reactors" with the phrase "non-power reactors."

Section 55.53 Conditions of licenses.

In § 55.53, this final rule revises paragraphs (e) and (f)(2) to replace the phrase "test and research reactors" with the phrase "non-power reactors." It also revises paragraphs (j) and (k) to clarify that these paragraphs apply to utilization facilities licensed under 10 CFR part 50 that are not power reactors.

Section 55.59 Requalification.

In § 55.59, this final rule revises paragraph (c)(7) to clarify that this paragraph applies to utilization facilities licensed under 10 CFR part 50 that are not power reactors.

Section 55.61 Modification and revocation of licenses.

In § 55.61, this final rule revises paragraph (b)(5) to clarify that this paragraph applies to utilization facilities licensed under 10 CFR part 50 that are not power reactors.

Section 73.2 Definitions.

In § 73.2, this final rule adds the definition of *Non-power reactor* as it is defined in § 50.2.

Section 73.21 Protection of safeguards information: performance requirements.

In § 73.21, this final rule revises paragraph (a)(1)(ii) to replace the phrase "research and test reactors" with the phrase "non-power reactors."

Section 73.23 Protection of safeguards information—modified handling: specific requirements.

In § 73.23, this final rule replaces the phrase "research and test reactors" with the phrase "non-power reactors."

Section 73.60 Additional requirements for physical protection at non-power

reactors.

In § 73.60, this final rule revises all instances of "nonpower" to read "non-power."

Section 140.3 Definitions.

In § 140.3, this final rule removes the definition of *Testing reactor* and adds the definition of *Testing facility* as it is defined in § 50.2.

Section 140.11 Amounts of financial protection for certain reactors.

In § 140.11, this final rule revises paragraph (a)(3) to standardize terminology by replacing the term "reactor" with the term "facility."

Section 170.3 Definitions.

In § 170.3, this final rule revises the definition of *Research reactor* and revises the definition of *Testing facility* to align with the definition in § 50.2.

Section 171.5 Definitions.

In § 171.5, this final rule revises the definitions of Research reactor and Testing facility to align with the definitions in § 170.3 and § 50.2, respectively.

Section 171.15 Annual fees: Reactor licenses and independent spent fuel storage licenses.

In § 171.15, this final rule revises paragraphs (a) and (f) to standardize the terminology by replacing the phrase "test reactor" with the phrase "testing facility" and makes other conforming changes.

§ 171.17 Proration.

In § 171.17, this final rule revises paragraph (a)(1) to specify "research reactors" and "testing facilities" by removing the more generic "non-power reactors" phrase.

VI. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule does not have a significant economic impact on a substantial number of small entities. This final rule affects only the licensing and operation of NPUFs. In general, the companies, universities, and government agencies that own and operate these facilities do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810). One of the 31 NPUFs currently licensed to operate may be considered a small entity. Additional information is provided in Section 4 of the regulatory analysis, which is available as indicated in the "Availability of Documents" section of this document.

VII. Regulatory Analysis

The NRC has prepared a final regulatory analysis on this regulation and the implementation guidance. The analysis examines the costs and benefits of the alternatives considered by the NRC. The regulatory analysis is available as indicated in the "Availability of Documents" section of this document.

VIII. Backfitting and Issue Finality

The NRC's backfitting provisions for reactors facilities licensed under part 50 are found in § 50.109. The regulatory basis for § 50.100 was expressed solely in terms of nuclear power reactors. The NRC's Advanced Notice of Proposed Rulemaking, Policy Statement, Proposed Rules, and Final Rules for amendments to § 50.109 in the 1980s involved addressed only commercial nuclear power reactors. As a result, the NRC has historically not applied § 50.109 to research reactors, testing facilities, and other nonpower facilities licensed under 10 CFR part 50 (e.g., "Final Rule; Clarification of Physical Protection Requirements at Fixed Sites"). He While a 2012 final rule concerning nonpower reactors, the NRC stated, that "T[t]he NRC has determined that the backfit provisions in § 50.109 do not apply to test, research, or training reactors because the rulemaking record for § 50.109 indicates that the Commission intended to apply this provision to only power reactors, and NRC practice has been consistent with this rulemaking record" ("Final Rule; Requirements for Fingerprint-Based Criminal History Records Checks for Individuals Seeking Unescorted Access to Non-Power Reactors"), that rule merely had the effect of making existing requirements imposed by NRC orders generically applicable and included no backfits. Further, the orders imposing those requirements were based on a non-discretionary Congressional mandate included in Section 652 of the Energy Policy Act of 2005. Given the sparse regulatory record on the backfitting of non-commercial NPUFs, it is appropriate to examine the issue now. The Commission clarifies that such facilities fall within the scope of the backfit rule.

The Commission has historically subjected commercial part 50 power reactors licensed under Section 103 or 104b of the AEA to the same public health and safety and common defense and security requirements. These commercial entities have always been considered within the scope of the Backfit Rule. In contrast, the NRC has not expressly addressed the scope of the Backfit Rule for non-commercial, non-power facilities licensed under Section 104a or 104c. Instead, these entities have been covered by the explicit statutory instruction to undertake only the "minimum necessary" regulation that exist in the AEA. Therefore, historically, most part 50 licensees have either been covered by the backfit rule or the similar, if not stronger, protection against unnecessary regulatory requirements in Section 104. However, this structure has created an inconsistency in which commercial NPUF facilities licensed under section 103 are covered by neither the backfit rule nor Section 104. The Commission is aware of no technical or legal basis for this regulatory anomaly. Therefore, the Commission concludes that industrial or commercial NPUFs licensed under Section 103 of the AEA are within the scope of the Backfit Rule.⁵

The term "non-power production or utilization facility," as defined in § 50.2 in this final rule, includes only licensees that have been excluded from the scope of § 50.109. Because NPUFs do not fall within the scope of § 50.109<u>Nevertheless</u>, the NRC did not apply the backfitting provisions of § 50.109 to this final rule. For NPUFs that are holding construction permits and are or will be applying for an operating license under Section 103 of the AEA, the amendments to the NRC's regulations encompassed by this final rule do not impact the rights conferred upon them by their construction permits. For those NPUFs, this final rule does not constitute backfitting as defined in § 50.109. Therefore, the backfitting provisions of § 50.109 do not apply to this final rule.

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. The NRC is meeting this standard by removing license renewal requirements for many entities licensed under Section 104 of the AEA, defining the license renewal process for testing facilities licensed under Section 104 of the AEA,

⁶ The Commission has, however, on occasion, determined not to apply the backfit rule to specific rulemakings for non-power reactors. See, for example, Staff Requirements – Affirmation/Discussion and Vote, 2:00 P.M., Thursday, February 6, 1986, Commissioners' Conference Room, D.C. Office (Open to Public Attendance) (SRM-M860206), affirming the SECY-86-17, Final Rule, "Limitation on the Use of Highly Enriched Uranium (HEU) in Research and Test Reactors," but conditioning the requirement for such reactors to convert their fuel to low enriched uranium on the certification of available Federal Government funding.

and eliminating the requirement for NPUF licensees to submit financial qualification information at the time of license renewal.

IX. Cumulative Effects of Regulation

Cumulative Effects of Regulation (CER) consists of the challenges licensees may face in addressing the implementation of new regulatory positions, programs, and requirements (e.g., rulemaking, guidance, generic letters, backfits, inspections). The CER may manifest in several ways, including the total burden imposed on licensees by the NRC from simultaneous or consecutive regulatory actions that can adversely affect the licensee's capability to implement those requirements, while continuing to operate or construct its facility in a safe and secure manner.

The goals of the NRC's CER effort were met throughout the development of this final rule. The NRC engaged external stakeholders at public meetings and by soliciting public comments on the proposed rule and associated draft guidance document. A public meeting was held on May 24, 2017 to discuss the proposed rule. A public meeting on implementation was held on April 25, 2019. Summaries of both public meetings are available in ADAMS, as provided in the "Availability of Documents" section of this document. The feedback from the April 25, 2019 public meeting informed the NRC's final rule implementation schedule.

Based upon input from the public and affected licensees, the NRC has specified that this final rule will take effect 30 days from the date of publication of this document. However, for For the purposes of implementing the requirements of § 50.71(e), the NRC will be issuing orders to certain holders of operating licenses, as described in Section II.4 of this document.

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X. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31883).

XI. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104-113, requires agencies to use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such standards is inconsistent with applicable law or is otherwise impractical. The NRC is amending its requirements for the license renewal process for certain production or utilization facilities. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XII. Environmental Assessment and Final Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this final rule will not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The provision to eliminate license terms for NPUFs, other than testing facilities, licensed under § 50.21(a) or (c) will result in no additional radiological or non-radiological impacts because of the minimal accident consequences of these facilities, existing surveillance and reporting by licensees, and NRC oversight. In addition, the implementation of this final rule will not affect the environmental review requirements for new facilities and facilities applying for license renewal. The NRC concludes that this final rule will not cause any additional radiological or non-radiological impacts on the human environment.

The NRC requested the views of the States on the environmental assessment for this rule. No States filed comments regarding the environmental assessment for this rule.

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. The environmental assessment is available as indicated under the "Availability of Documents" section.

XIII. Paperwork Reduction Act

This final rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.). The collections of information were approved by the Office of Management and Budget (OMB), approval numbers 3150-0011 and 3150-0021.

The new burden to the public for the information collections is estimated to average 51 hours per response for information collection requirements contained in 10 CFR part 50 and 0 hours per response for information collection requirements contained in 10 CFR part 51, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collections. The information collections are being conducted to create a more efficient licensing process that continues to protect public health, safety, and the environment. Information will be used by the NRC to ensure that licensing bases remain up-to-date and that adequate protection of public health and safety is maintained. Responses to these collections of information are mandatory under § 50.71(e) and § 51.56. Confidential and proprietary information submitted to the NRC is protected in accordance with NRC regulations at § 9.17(a) and § 2.390(b).

You may submit comments on any aspect of the information collections, including suggestions for reducing the burden, by the following methods:

- Federal rulemaking Web Site: Go to <u>http://www.regulations.gov</u> and search for Docket ID NRC-2011-0087.
- Mail comments to: Information Services Branch, Office of the Chief Information Officer, Mail Stop: T-6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or to or to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0011, 3150-0151), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e-mail: <u>oira submission@omb.eop.gov</u>.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XIV. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (5 U.S.C. 801-808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

XV. Criminal Penalties

For the purposes of Section 223 of the AEA, the NRC is issuing this final rule that amends 10 CFR 50.34, 50.36, 50.59, 50.71, 50.75, 50.82, 55.40, 55.53, 55.59, 73.21, 73.23, 73.57, 73.60, and 140.11 and creates § 50.135 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of these provisions would be subject to criminal enforcement.

XVI. Availability of Guidance

The NRC is issuing RG 2.7, Revision 0, "Preparation of Updated Final Safety Analysis Reports for Non-Power Production or Utilization Facilities," for the implementation of the requirements in § 50.71(e) of this final rule. The guidance is available in ADAMS under Accession No. ML18031A007. You can access information and public comment submissions related to the guidance at the federal rulemaking Web Site, www.regulations.gov, by searching on Docket ID NRC-2011-0087.

XVII. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS Accession No. / Web link FEDERAL REGISTER CITATION
NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content"	ML042430055
NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria"	ML042430048
Interim Staff Guidance-2009-001, "Interim Staff Guidance on the Streamlined Review Process for License Renewal for Research Reactors"	ML092240244
Non-Power Reactor License Renewal: Preliminary Draft Regulatory Basis; Request for Comment	77 FR 38742; June 29, 2012
Non-Power Reactor (NPR) License Renewal Rulemaking: Regulatory Basis Document	ML12240A677
Federal Register Notice: Final Regulatory Basis for Rulemaking to Streamline Non- Power Reactor License Renewal; Notice of Availability of Documents	ML12250A658
SECY-08-0161, "Review of Research and Test Reactor License Renewal Applications"	ML082550140
SRM-SECY-08-0161, "Review of Research and Test Reactor License Renewal Applications"	ML090850159
SRM-M080317B, "Briefing on State of NRC Technical Programs"	ML080940439
SECY-09-0095, "Long-Term Plan for Enhancing the Research and Test Reactor License Renewal Process and Status of the Development and Use of the Interim Staff Guidance"	ML092150717
SRM-SECY-91-061, "Separation of Non- Reactor and Non-Power Reactor Licensing Activities from Power Reactor Licensing Activities in 10 CFR Part 50"	ML010050021
SRM-M090811, "Briefing on Research and Test Reactor (RTR) Challenges"	ML092380046
Draft Regulatory Guide DG-2006, "Preparation of Updated Final Safety Analysis Reports for Non-Power Production or Utilization Facilities"	ML17068A041
Proposed Rule: Draft Regulatory and Backfit Analysis	ML17068A038
Proposed Rule: Draft OMB Supporting Statement	ML17068A077

Proposed Rule: Draft Environmental Assessment	ML17068A035
SECY-16-0048, "Proposed Rulemaking: Non- Power Production or Utilization Facility License Renewal (RIN 3150-AI96)"	ML16019A048
Regulatory Guide 2.7, "Preparation of Updated Final Safety Analysis Reports for Non-Power Production or Utilization Facilities"	ML18031A007
Final Rule: Regulatory Analysis for Non-power Production or Utilization Facility License Renewal	ML18031A003
EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents"	https://www.epa.gov/sites/production files/2016-03/documents/pags.pdf
EPA-400/R-17/001, "PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents"	https://www.epa.gov/sites/production files/2017- 01/documents/epa_pag_manual_fina _revisions_01-11- 2017_cover_disclaimer_8.pdf
Summary of August 7, 2014, Public Meeting to Discuss the Rulemaking for Streamlining Non-power Reactor License Renewal	ML15322A400
Summary of October 7, 2015, Public Meeting to Discuss the Rulemaking for Streamlining Non-Power Reactor License Renewal	ML15307A002
Federal Register Notice: Final Rule; Standards for Protection Against Radiation	56 FR 23360; May 21, 1991
Federal Register Notice: Proposed Rule; Non-Power Production or Utilization Facility License Renewal	82 FR 15643; March 30, 2017
SRM-SECY-16-0048, "Staff Requirements— Proposed Rulemaking: Non-Power Production or Utilization Facility License Renewal (RIN 3150-AI96)"	ML17045A543
Final Rule: OMB Supporting Statement	ML18031A006
Final Rule: Environmental Assessment	ML18031A004
Federal Register Notice: Final Rule; Financial Information Requirements for Applications to Renew or Extend the Term of an Operating License for a Power Reactor	69 FR 4439; January 30, 2004
Summary of May 24, 2017, Public Meeting to Discuss the Proposed Non-Power Production or Utilization Facility License Renewal Rule	ML17170A066
Nuclear Energy Innovation and Modernization Act (Pub. L. 115-439), enacted January 14, 2019	https://www.congress.gov/115/bills/st 12/BILLS-115s512enr.pdf
Summary of April 25, 2019, Public Meeting to Discuss the Implementation Schedule for the Non-Power Production or Utilization Facility License Renewal Final Rule	ML19133A080
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NRC Response to Public Comment Non-Power Production or Utilization Facility License Renewal	ML18031A005
SECY-19-09X0062, "Final Rule: Non-Power Production or Utilization Facility License Renewal (RIN 3150-Al96, NRC-2011-0087)"	MLXXXXXXXXXIII_18031A000
SRM-SECY-19-00XX0062, "Final Rule: Non- Power Production or Utilization Facility License Renewal (RIN 3150-AI96)"	MLXXXXXXXXXX
Federal Register Notice: Final Rule; 10 CFR Part 50 – Licensing of Production and Utilization Facilities	33 FR 9704; July 4, 1968
Federal Register Notice: Final Rule; Elimination of Review of Financial Qualifications of Electric Utilities in Licensing Hearings for Nuclear Power Plants	47 FR 13750; March 31, 1982
Federal Register Notice: Final Rule; Elimination of Review of Financial Qualifications of Electric Utilities in Operating License Reviews and Hearings for Nuclear Power Plants	49 FR 35747; September 12, 1984
Federal Register Notice: Final Rule; National Environmental Policy Act—Regulations	43 FR 55978; November 29, 1978
Advanced Notice of Proposed Rulemaking; Revision of Backfitting Process for Power Reactors	48 FR 44217; September 28, 1983
Policy Statement; Revision of Backfitting Process for Power Reactors	48 FR 44173; September 28, 1983
Federal Register Notice: Proposed Rule; Revision of Backfitting Process for Power Reactors	49 FR 47034; November 30, 1984
Federal Register Notice: Final Rule; Revision of Backfitting Process for Power Reactors	50 FR 38097; September 20, 1985
Federal Register Notice: Final Rule; Financial Information Requirements for Applications to Renew or Extend the Term of an Operating License for a Power Reactor	69 FR 4439; January 30, 2004
Federal Register Notice: Proposed Rule; Revision of Backfitting Process for Power Reactors	52 FR 34223; September 10, 1987
Federal Register Notice: Final Rule; Revision of Backfitting Process for Power Reactors	53 FR 20603; June 6, 1988
Federal Register Notice: Final Rule; Limiting the Use of Highly Enriched Uranium in Domestically Licensed Research and Test Reactors	51 FR 6514; February 25, 1986
Federal Register Notice: Final Rule; Clarification of Physical Protection Requirements at Fixed Sites	58 FR 13699; March 15, 1993

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Commented [A2]: Staff should insert the accession number for this SRM when issued.

See.

Federal Register Notice: Final Rule; Requirements for Fingerprint-Based Criminal History Record Checks for Individuals Seeking Unescorted Access to Non-Power Reactors	77 FR 27561, 27572; May 11, 2012
Plain Language in Government Writing	63 FR 31885; June 10, 1998

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified Information, Confidential business information; Freedom of information, Environmental protection, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 20

Byproduct material, Criminal penalties, Hazardous waste, Licensed material, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 26

Administrative practice and procedure, Alcohol abuse, Alcohol testing, Appeals, Chemical testing, Drug abuse, Drug testing, Employee assistance programs, Fitness for duty, Management actions, Nuclear power plants and reactors, Privacy, Protection of information, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 50

Administrative practice and procedure, Antitrust, Classified information, Criminal penalties, Education, Fire prevention, Fire protection, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalties, Radiation

protection, Reactor siting criteria, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statements, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 55

Criminal penalties, Manpower training programs, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements.

10 CFR Part 73

Criminal penalties, Exports, Hazardous materials transportation, Incorporation by reference, Imports, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 140

Criminal penalties, Extraordinary nuclear occurrence, Insurance, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors. Penalties, Reporting and recordkeeping requirements.

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Byproduct material, Holders of certificates, registrations, approvals, Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the AEA, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 2, 20, 26, 50, 51, 55, 73, 140, 170, and 171:

PART 2 -- AGENCY RULES OF PRACTICE AND PROCEDURE

1. The authority citation for part 2 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 29, 53, 62, 63, 81, 102, 103, 104, 105, 161, 181, 182, 183, 184, 186, 189, 191, 234 (42 U.S.C. 2039, 2073, 2092, 2093, 2111, 2132, 2133, 2134, 2135, 2201, 2231, 2232, 2233, 2234, 2236, 2239, 2241, 2282); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); Nuclear Waste Policy Act of 1982, secs. 114(f), 134, 135, 141 (42 U.S.C. 10134(f), 10154, 10155, 10161); Administrative Procedure Act (5 U.S.C. 552, 553, 554, 557, 558); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note. Section 2.205(j) also issued under 28 U.S.C. 2461 note.

2. In § 2.109, revise paragraph (a) and add paragraph (e) to read as follows:

§ 2.109 Effect of timely renewal application.

(a) Except for the renewal of an operating license for a nuclear power plant under § 50.21(b) or § 50.22, a non-power production or utilization facility under § 50.22, a testing facility under § 50.21(c), an early site permit under subpart A of part 52 of this chapter, a manufacturing license under subpart F of part 52 of this chapter, or a combined license under subpart C of part 52 of this chapter, if at least 30 days before the expiration of an existing license authorizing any activity of a continuing nature, the licensee files an application for a renewal or for a new license for the activity so authorized, the existing license will not be deemed to have expired until the application has been finally determined.

.

(e) If the licensee of a non-power production or utilization facility licensed under 10 CFR 50.22, or a testing facility, files a sufficient application for renewal at least 2 years before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

PART 20 -- STANDARDS FOR PROTECTION AGAINST RADIATION

3. The authority citation for part 20 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 53, 63, 65, 81, 103, 104, 161, 170H, 182, 186, 223, 234, 274, 1701 (42 U.S.C. 2014, 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2210h, 2232, 2236, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Low-Level Radioactive Waste Policy Amendments Act of 1985, sec. 2 (42 U.S.C. 2021b); 44 U.S.C. 3504 note.

§ 20.1905 [Amended]

4. In § 20.1905(g), remove the word "reactors" and add in its place the phrase

"production or utilization facilities".

PART 26 - FITNESS FOR DUTY PROGRAMS

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

Authority: Atomic Energy Act of 1954, secs. 53, 103, 104, 107, 161, 223, 234, 1701 (42 U.S.C. 2073, 2133, 2134, 2137, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

§ 26.3 [Amended]

6. In § 26.3(e), remove the word "reactor" and add in its place the phrase

"production or utilization facility".

PART 50 -- DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION

FACILITIES

7. The authority citation for part 50 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 102, 103, 104, 105, 108, 122, 147, 149, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Sec. 109, Pub. L. 96–295, 94 Stat. 783.

8. In § 50.2, add in alphabetical order the definition for Non-power production or utilization facility, and revise the definitions for Non-power reactor and Testing facility to read as follows:

§ 50.2 Definitions.

Non-power production or utilization facility means a production or utilization facility, licensed under § 50.21(a), § 50.21(c), or § 50.22, as applicable, that is not a nuclear power reactor or a production facility as defined under paragraphs (1) and (2) of the definition of *Production facility* in § 50.2.

Non-power reactor means:

(1) A testing facility; or

(2) A research reactor, which is a non-power production or utilization facility that is a nuclear reactor licensed under § 50.21(c):

(i) For which a safety assessment demonstrates accident radiation doses

consistent with § 50.34(a)(1)(i); and

(ii) That is not a testing facility; or

(3) A commercial or industrial reactor, which is a non-power production or utilization facility that is a nuclear reactor licensed under § 50.22:

(i) For which a safety assessment demonstrates accident radiation doses

consistent with § 50.34(a)(1)(i); and

(ii) That is not a testing facility.

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Testing facility means a non-power production or utilization facility that is a nuclear reactor licensed under § 50.21(c) or § 50.22 for which:

(1) Analyzed accident radiation doses are in excess of the dose criterion for

facilities not subject to 10 CFR part 100 set forth in § 50.34(a)(1)(i); or

(2) The Commission determines that the design, operation, or use and the

associated risk warrant classification as a testing facility.

a (a) a) a)

§ 50.8 [Amended]

9. In § 50.8(b), add the number "50.135," in numerical order.

§ 50.33 [Amended]

10. In § 50.33:

a. Remove the phrase "for a power reactor" from the fourth sentence and remove

the last sentence in paragraph (f)(2); and

b. Redesignate footnotes 4 and 5 as footnotes 1 and 2.

11. In § 50.34:

a. Redesignate footnote 5 as footnote 1;

b. Revise paragraph (a)(1)(i);

c. Redesignate footnotes 6 and 7 as footnotes 3 and 4;

d. Remove footnotes 8 and 9;

f. Redesignate footnotes 10 and 11 as footnotes 5 and 6; and

g. Add paragraph (b)(13).

The revision and addition read as follows:

§ 50.34 Contents of applications; technical information.

(a) * * * *

(I) A description and safety assessment of the site on which the facility is to be located, with appropriate attention to features affecting facility design. Special attention should be directed to the site evaluation factors identified in part 100 of this chapter. The assessment must contain an analysis and evaluation of the major structures, systems and components of the facility which bear significantly on the acceptability of the site under the site evaluation factors identified in part 100 of this chapter, assuming that the facility will be operated at the ultimate power level which is contemplated by the applicant. For non-power production or utilization facilities not subject to 10 CFR part 100, the assessment must provide an evaluation of the applicable radiological consequences that demonstrates with reasonable assurance that any individual located in the unrestricted area following the onset of a postulated accident, including consideration of experiments, would not receive a radiation dose in excess of 1 rem (0.01 Sv) TEDE for the duration of the accident. With respect to operation at the projected initial power level, the applicant is required to submit information prescribed in paragraphs (a)(2) through (a)(8) of this section, as well as the information required by this paragraph, in support of the application for a construction permit, or a design approval.

. . .

(b) * *

(13) Non-power production or utilization facility applicants who apply for an initial or renewed operating license shall provide a final evaluation of the applicable radiological consequences in § 50.34(a)(1)(i). ² The 1 rem accident dose criterion for non-power production or utilization facilities is not a dose limit; it informs the analysis of postulated accidents and the development of safety measures so that in the unlikely event of an accident, the NRC has reasonable assurance that no acute radiation-related harm will result to any member of the public.

§ 50.36 [Amended]

 In § 50.36(c)(6), remove the phrase "non-power reactor" and add in its place the phrase "non-power production or utilization".

13. In § 50.51, in the first sentence of paragraph (a) remove the word "Each" and add in its place the phrase "Except as noted in § 50.51(c), each" and add paragraph (c) to read as follows:

§ 50.51 Continuation of license.

.

(c) Each non-power production or utilization facility license issued under § 50.21(a) or (c), other than a testing facility license, after [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], will be issued with no fixed license term.

14. In § 50.59, revise paragraph (b) to read as follows:

§ 50.59 Changes, tests, and experiments.

.

(b) This section applies to each holder of an operating license issued under this part or a combined license issued under part 52 of this chapter, including the holder of a license authorizing the operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under § 50.82(a)(1) or

§ 50.110, a reactor licensee whose license has been amended to allow possession of nuclear fuel but not operation of the facility, or a non-power production or utilization facility that has permanently ceased operations.

15. In § 50.71;

a. In the first sentence of paragraph (e), add the phrase ", or non-power production or utilization facility," after the word "reactor", and in footnote 1, remove the word "includes" and add in its place the word "include";

b. In paragraph (e)(3)(i), remove the article "A" at the beginning and add in its place the phrase "For nuclear power reactor licensees, a" and add paragraph (e)(3)(iv);

c. Redesignate paragraph (e)(4) as paragraph (e)(4)(i) and remove the word "Subsequent" and add in its place the phrase "For nuclear power licensees, subsequent"; add paragraph (e)(4)(ii); and

d. In paragraph (g), remove the phrase "non-power reactor" and add in its place the phrase "non-power production or utilization facility".

The additions and revisions read as follows:

§ 50.71 Maintenance of records, making of reports.

- . . .
- (e)* *
- (3)* * *

(iv) Holders of non-power production or utilization facility licenses issued after

INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL

REGISTER], shall file a revision of the original FSAR containing those original pages

that are still applicable plus new replacement pages within 5 years of the date of issuance of the operating license. The revision must bring the FSAR up to date as of a maximum of 6 months prior to the date of filing the revision.

. . .

(4)* *

(ii) Non-power production or utilization facility licensees shall file an FSAR update no more than 5 years from the date of the submittal of the updated FSAR required by § 50.71(e)(3)(iv) or by order and shall file subsequent updates no more than 5 years from the date of the previous submittal. Each submittal must reflect all changes made to the FSAR up to a maximum of 6 months prior to the date of filing the submittal.

* * * * *

16. In § 50.75:

a. Revise paragraph (d)(1);

b. In paragraphs (e)(1)(iv) and (f)(4), remove the phrase "non-power reactor" and add in its place the phrase "non-power production or utilization facility"; and

c. In paragraph (f)(5), remove the phrase "power and non-power reactors" and add in its place the phrase "power reactors and non-power production or utilization facilities".

The revision reads as follows:

§ 50.75 Reporting and recordkeeping for decommissioning planning.

(d)(1) Each applicant for or holder of an operating license for a non-power production or utilization facility shall submit a decommissioning report as required by § 50.33(k) of this part.

17. In § 50.82, revise paragraphs (b) introductory text, (b)(1), and (c) to read as follows:

§ 50.82 Termination of license.

* * * *

(b) For non-power production or utilization facility licensees-

(1) A licensee that permanently ceases operations must make application for license termination within 2 years following permanent cessation of operations, and for testing facilities licensed under § 50.21(c) or facilities licensed under § 50.22, in no case later than 1 year prior to expiration of the operating license. Each application for termination of a license must be accompanied or preceded by a proposed decommissioning plan. The contents of the decommissioning plan are specified in paragraph (b)(4) of this section.

* * * *

(c) The collection period for any shortfall of funds will be determined, upon application by the licensee, on a case-by-case basis taking into account the specific financial situation of each holder of the following licenses:

(1) A non-power production or utilization facility licensed under § 50.21(a) or (c), other than a testing facility, that has permanently ceased operations.

(2) A facility licensed under § 50.21(b) or § 50.22, or a testing facility, that has permanently ceased operation before the expiration of its license.

18. Add § 50.135 to read as follows:

§ 50.135 Renewal of non-power production or utilization facility licenses issued under § 50.22 and testing facility licenses.

(a) Applicability. The requirements in this section apply to applicants for renewed non-power production or utilization facility operating licenses issued under § 50.22 and to applicants for renewed testing facility operating licenses issued under § 50.21(c).

(b) Written communications. All applications, correspondence, reports, and other written communications must be filed in accordance with applicable portions of § 50.4.

(c) Filing of application.

(1) The filing of an application for a renewed license must be in accordance with subpart A of 10 CFR part 2 and all applicable sections of this part.

(2) An application for a renewed license may not be submitted to the Commission earlier than 10 years before the expiration of the operating license currently in effect.

(d) Contents of application.

(1) Each application must include the information specified in §§ 50.33, 50.34,

and 50.36, as applicable.

(2) Each application must include conforming changes to the standard indemnity agreement, under 10 CFR part 140 to account for the expiration term of the proposed renewed license.

(3) Each application must include a supplement to the environmental report that complies with the requirements of 10 CFR 51.56.

(e) Issuance of a renewed license.

(1) A renewed license will be of the class for which the operating license currently in effect was issued.

(2) A renewed license will be issued for a fixed period of time. The term of any renewed license may not exceed 40 years.

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(3) A renewed license will become effective immediately upon its issuance, thereby superseding the operating license previously in effect. If a renewed license is subsequently set aside upon further administrative or judicial appeal, the operating license previously in effect will be reinstated unless its term has expired and the renewal application was not filed in a timely manner in accordance with 10 CFR 2.109.

(4) A renewed license may be subsequently renewed in accordance with all applicable requirements.

Appendix C to Part 50 [Amended]

19. In paragraph III of appendix C to part 50, remove the phrase "for medical and research reactors" and add in its place the phrase "for non-power production or utilization facilities of a type described in § 50.21(a) or (c), other than testing facilities".

20. In paragraph I.3 to appendix E to part 50, revise footnote 2 to read as follows:

APPENDIX E TO PART 50—EMERGENCY PLANNING AND PREPAREDNESS FOR PRODUCTION AND UTILIZATION FACILITIES

² Regulatory Guide 2.6, "Emergency Planning for Research and Test Reactors and Other Non-Power Production and Utilization Facilities," may be used as guidance for the acceptability of non-power production or utilization facility emergency response plans.

PART 51 -- ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS 21. The authority citation for part 51 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 193 (42 U.S.C. 2201, 2243); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); National Environmental Policy Act of 1969 (42 U.S.C. 4332, 4334, 4335); Nuclear Waste Policy Act of 1982, secs. 144(f), 121, 135, 141, 148 (42 U.S.C. 10134(f), 10141, 10155, 10161, 10168); 44 U.S.C. 3504 note.

§ 51.17 [Amended]

22. In § 51.17(b), add the number "51.56," in numerical order.

§ 51.45 [Amended]

23. In § 51.45(a), add the number "51.56," in numerical order.

24. Add § 51.56 to read as follows:

§ 51.56 Environmental report—non-power production or utilization facility. Each applicant for a non-power production or utilization construction permit or facility license, or renewal of a non-power production or utilization facility license issued pursuant to § 50.21(a) or (c) or § 50.22 of this chapter shall submit a separate document, entitled "Applicant's Environmental Report" or "Supplement to Applicant's Environmental Report," as appropriate, with its application to: ATTN: Document Control Desk, Director, Office of Nuclear Reactor Regulation. The environmental report or supplement shall contain the information specified in § 51.45. If the application is for a renewal of a license for which the applicant has previously submitted an environmental report, the supplement, to the extent applicable, shall include an analysis of any environmental impacts resulting from operational experience or a change in operations, and an analysis of any environmental impacts that may result from proposed decommissioning activities. The supplement may incorporate by reference the previously submitted environmental report, or portions thereof.

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PART 55 -- OPERATORS' LICENSES

25. The authority citation for part 55 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 107, 161, 181, 182, 183, 186, 187, 223, 234 (42 U.S.C. 2137, 2201, 2231, 2232, 2233, 2236, 2237, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); 44 U.S.C. 3504 note.

§ 55.5 [Amended]

26. In § 55.5:

a. In paragraph (b)(1) remove the phrase "Except for test and research reactor

facilities, the" and add in its place the word "The"; and

b. In paragraph (b)(3) remove the phrase "a test and research reactor or nonpower reactor facility licensed under 10 CFR part 50" and add in its place "a utilization facility licensed under part 50 of this chapter that is not a power reactor", and remove the phrase "Division of Policy and Rulemaking" and add in its place the phrase "Division of Licensing-ProjectsAdvanced Reactors and Non-Power Production and Utilization

Facilities"

§ 55.40 [Amended]

27. In § 55.40(d), remove the phrase "all test and research reactors" and add in its place the phrase "all non-power reactors"

§ 55.53 [Amended]

28. In § 55.53:

a. In paragraphs (e) and (f)(2), remove the phrase "test and research reactors"

and add in its place the phrase "non-power reactors"; and

b. In paragraphs (j) and (k), remove the phrase "non-power reactors" and add in its place the phrase "utilization facilities licensed under 10 CFR part 50 that are not

power reactors", and also in paragraph (k) remove the term "non-power" at the end of the paragraph.

§ 55.59 [Amended]

29. In § 55.59(c)(7), in the paragraph heading remove the phrase "research and test reactor facilities" and add in its place the phrase "utilization facilities licensed under 10 CFR part 50 that are not power reactors", and in the paragraph remove the phrase "research reactor or test reactor facility" and add in its place "utilization facility licensed under 10 CFR part 50 that is not a power reactor".

§ 55.61 [Amended]

30. In § 55.61(b)(5), remove the phrase "non-power reactors" and add in its place the phrase "utilization facilities licensed under 10 CFR part 50 that are not power reactors".

PART 73 -- PHYSICAL PROTECTION OF PLANTS AND MATERIALS

31. The authority citation for part 73 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 147, 149, 161, 170D, 170E, 170H, 170I, 223, 229, 234, 1701 (42 U.S.C. 2073, 2167, 2169, 2201, 2210d, 2210e, 2210h, 2210i, 2273, 2278a, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note. Section 73.37(b)(2) also issued under Sec. 301, Public Law 96-295, 94 Stat. 789 (42 U.S.C. 5841 note).

32. In § 73.2, add in alphabetical order the definition for Non-power reactor.

§ 73.2 Definitions.

Non-power reactor is defined at 10 CFR 50.2.

§ 73.21 [Amended]

33. In § 73.21(a)(1)(ii), remove the phrase "Research and test reactors" and add in its place the phrase "non-power reactors".

§ 73.23 [Amended]

34. In § 73.23, remove the phrase "research and test reactors" and add in its place the phrase "non-power reactors".

§ 73.60 [Amended]

35. In § 73.60, wherever it may appear, remove the word "nonpower" and add in its place the word "non-power".

PART 140 - FINANCIAL PROTECTION REQUIREMENTS AND INDEMNITY

AGREEMENTS

36. The authority citation for part 140 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 170, 223, 234 (42 U.S.C. 2201, 2210, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

37. In § 140.3, remove the definition for Testing reactor and revise the definition

for Testing facility to read as follows;

§ 140.3 Definitions.

. . . .

Testing facility is defined at 10 CFR 50.2.

§ 140.11 [Amended]

38. In § 140.11(a)(3), remove the phrase "testing reactor" and add in its place the phrase "testing facility".

PART 170 -- FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

39. The authority citation for part 170 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w) (42 U.S.C. 2014, 2201(w)); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2214; 31 U.S.C. 901, 902, 9701; 44 U.S.C. 3504 note.

40. In § 170.3, revise the definitions for Research reactor and Testing facility to read as follows:

§ 170.3 Definitions.

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Research reactor means a non-power production or utilization facility, as defined

in 10 CFR 50.2, that is a nuclear reactor licensed under 10 CFR 50.21(c):

(i) For which a safety assessment demonstrates accident radiation doses

consistent with 10 CFR 50.34(a)(1)(i); and

(ii) That is not a testing facility. *

Testing facility is defined at 10 CFR 50.2.

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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

41. The authority citation for part 171 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w), 223, 234 (42 U.S.C. 2014, 2201(w), 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2214; 44 U.S.C. 3504 note.

42. In § 171.5, revise the definitions for Research reactor and Testing facility to

read as follows:

§ 171.5 Definitions.

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Research reactor is defined at 10 CFR 170.3.

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> Testing facility is defined at 10 CFR 50.2. .

. ÷ 43. In § 171.15, revise paragraphs (a) and (f) to read as follows:

§ 171.15 Annual fees: Reactor licenses and independent spent fuel storage licenses.

(a) Each person holding an operating license for a power reactor, testing facility, or research reactor; each person holding a combined license under part 52 of this chapter after the Commission has made the finding under 10 CFR 52.103(g); each person holding a part 50 or part 52 power reactor license that is in decommissioning or possession only status, except those that have no spent fuel onsite; and each person holding a part 72 license who does not hold a part 50 or part 52 license and provides notification in accordance with 10 CFR 72.80(g), shall pay the annual fee for each license held during the Federal fiscal year in which the fee is due. This paragraph does not apply to testing facilities or research reactors exempted under § 171.11(b).

(f) The FY 2019 annual fees for licensees authorized to operate a research reactor or testing facility licensed under 10 CFR part 50, unless the reactor is exempted from fees under § 171.11(b), are as follows:

Research reactor	\$82,400
Testing facility	\$82,400

§ 171.17 [Amended]

44. In § 171.17(a)(1), remove the phrase "non-power reactors" and add in its place the phrase "research reactors, testing facilities".

Dated at Rockville, Maryland, this xxth day of Xxxxx, 20XX.

For the Nuclear Regulatory Commission.

CONTACT DRM/RASB FOR DIGITAL SIGNATURE

Annette L. Vietti-Cook, Secretary of the Commission.