

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2, 50, and 51

[NRC-2011-0087]

RIN 3150-AI96

Non-Power Production or Utilization Facility License Renewal

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations that govern the license renewal process for non-power reactors, testing facilities, and other production or utilization facilities, licensed under the authority of Section 103, Section 104a, or Section 104c of the Atomic Energy Act of 1954, as amended (AEA), that are not nuclear power reactors. In this proposed rule, the NRC collectively refers to these facilities as non-power production or utilization facilities (NPUFs). The NRC is proposing to: eliminate license terms for licenses issued under the authority of Sections 104a or 104c of the AEA, other than for testing facilities; define the license renewal process for licenses issued to testing facilities or under the authority of Section 103 of the AEA; require all NPUF licensees to submit final safety analysis report (FSAR) updates to the NRC every 5 years; and provide an accident dose criterion of 1 rem (0.01 Sievert (Sv)) total effective dose equivalent (TEDE) for NPUFs other than testing facilities. The proposed rule also includes other changes, as described in Section III, "Discussion," of this document. The NRC is issuing concurrently draft Regulatory Guide (DG-2006), "Preparation of Updated Final Safety Analysis Reports for Non-power Production or Utilization Facilities," for review and comment. The NRC anticipates the proposed rule and associated draft implementing guidance would result in reduced burden on both licensees and the NRC, and would create a more responsive and efficient regulatory

framework that will continue to protect public health and safety, promote the common defense and security, and protect the environment. During the public comment period, the NRC plans to hold a public meeting to promote a full understanding of the proposed rule and facilitate the public's ability to submit comments on the proposed rule.

DATES: Submit comments by June 13, 2017. Submit comments specific to the information collections aspects of this proposed rule by May 1, 2017. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

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

- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.

- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Duane Hardesty, Office of Nuclear Reactor Regulation, telephone: 301-415-3724, e-mail: Duane.Hardesty@nrc.gov; and Robert Beall, Office of Nuclear Reactor Regulation, telephone: 301-415-3874, e-mail: Robert.Beall@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations related to the license renewal process for non-power reactors, testing facilities, and other production or utilization facilities, licensed under the authority of Section 103, Section 104a, or Section 104c of the Atomic Energy Act of 1954, as amended, that are not nuclear power reactors. In this proposed rule, the NRC collectively refers to these facilities as non-power production or utilization facilities (NPUFs). To establish a more efficient, effective, and focused regulatory framework, the NRC proposes revisions to parts 2, 50, and 51 of title 10 of the *Code of Federal Regulations* (10 CFR).

B. Major Provisions

In addition to administrative changes and clarifications, the proposed rule includes the following major changes:

- Creates a definition for “non-power production or utilization facility,” or “NPUF;”
- Eliminates license terms for facilities, other than testing facilities, licensed under 10 CFR 50.21(a) or (c);
 - Defines the license renewal process for testing facilities licensed under § 50.21(c) and NPUFs licensed under 10 CFR 50.22;
 - Requires all NPUF licensees to submit final safety analysis report updates to the NRC every 5 years;
 - Amends the current timely renewal provision under 10 CFR 2.109, allowing facilities to continue operating under an existing license past its expiration date if the facility submits a license renewal application at least 2 years (currently 30 days) before the current license expiration date;
 - Provides an accident dose criterion of 1 rem (0.01 Sievert) total effective dose equivalent for NPUFs other than testing facilities;
 - Extends the applicability of 10 CFR 50.59 to NPUFs regardless of their decommissioning status;
 - Clarifies an applicant’s requirements for meeting the existing provisions of 10 CFR 51.45 for submitting an environmental report; and
 - Eliminates the requirement for NPUFs to submit financial qualification information with license renewal applications under 10 CFR 50.33(f)(2).

C. Costs and Benefits

The NRC prepared a draft regulatory analysis to determine the expected quantitative costs and benefits of the proposed rule and the draft implementing guidance, as well as

qualitative factors to be considered in the NRC's rulemaking decision. The analysis concluded that the proposed rule would result in net savings to licensees and the NRC (i.e., be cost beneficial). The analysis examined the benefits and costs of the proposed rule requirements and the draft implementing guidance relative to the baseline for the current license renewal process (i.e., the no action alternative). Relative to the no action baseline, the NRC estimates that total net benefits to NPUFs (i.e., cost savings minus costs) would be \$3.8 million (\$1.5 million using a 7 percent discount rate and \$2.5 million using a 3 percent discount rate) over a 20-year period. The average NPUF would incur net benefits ranging from approximately \$54,000 to \$167,000 over a 20-year period. The NRC would incur total net benefits of \$9.4 million (\$3.8 million using a 7 percent discount rate and \$6.4 million using a 3 percent discount rate) over a 20-year period.

The draft regulatory analysis also considered, in a qualitative fashion, additional benefits of the proposed rule and the draft 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 draft regulatory analysis concluded that the proposed rule and the draft implementing guidance are justified because of the cost savings incurred by both licensees and the NRC while public health and safety is maintained. For a detailed discussion of the methodology and complete results, see Section VII, "Regulatory Analysis," of this document.

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

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 <http://www.regulations.gov> and search for Docket ID NRC-2011-0087.

- **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 search, select “[ADAMS Public Documents](#)” and then select “[Begin Web-based ADAMS Search](#).” For problems with ADAMS, please contact the NRC’s Public Document Room reference staff at 1-800-397-4209, 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 Section XVI, “[Availability of Documents](#),” of this document.

- **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.

B. Submitting Comments

Please include Docket ID NRC-2011-0087 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Sections 103 (for facilities used for commercial or industrial purposes) and 104a and c (for facilities used for medical therapy and useful for research and development activities, respectively) of the AEA establish the NRC's authority to license NPUFs. The section of the AEA that provides licensing authority for the NRC corresponds directly to the class of license issued to a facility (i.e., Section 104a of the AEA authorizes the issuance of a "class 104a" license). Sections 104a and c 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 NPUFs, of which 31 are currently operating. The other five facilities are in the process of decommissioning (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, and termination of the license). Most NPUFs are located at universities or colleges throughout the United States. The NRC regulates one operating testing facility.

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 of title 10 of the *Code of Federal Regulations* (10 CFR), but the AEA does not specify license terms for class 104a or c facilities, which are licensed under § 50.21(a) or (c). The regulation that implements this statutory authority, § 50.51(a), currently specifies that the NRC may grant an initial license for NPUFs for no longer than a 40-year license term. If the NRC initially issues a license for a shorter period, then it may renew the license by amendment for a maximum aggregate period not to exceed 40 years. An NPUF license is usually renewed for a term of 20 years. If the requested renewal would extend the

license beyond 40 years from the date of issuance, the original license may not be amended.

Rather, the NRC issues a superseding renewed license.

Any application for license renewal or a superseding renewed license 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 and should be augmented by the guidance of 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 to 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 an application in order to continue operations. Per 10 CFR 2.109(a), referred to as the "timely renewal provision," if, at least 30 days before the expiration of an existing license, the licensee files an application for a renewal or for a new license for the authorized activity, the existing license will not be deemed to have expired until the application has been finally determined.

B. Environmental Analysis

Part of the license renewal process involves the NRC's environmental analysis of the license renewal action. The National Environmental Policy Act of 1969, as amended (42 USC 4321 *et seq.*) (NEPA), requires all Federal agencies to evaluate the impacts of proposed major actions on the human environment. The NRC complies with NEPA through regulations in 10 CFR part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." The regulations in 10 CFR part 51 implement Section 102(2) of NEPA in a manner that is consistent with the NRC's domestic licensing and related regulatory authority under the AEA, the Energy Reorganization Act of 1974, as amended, and the Uranium Mill

Tailings Radiation Control Act of 1978. This reflects the Commission's announced policy as cited in § 51.10(a) to voluntarily take account of the 1978 Council on Environmental Quality final regulations for implementing NEPA, "National Environmental Policy Act—Regulations," subject to certain conditions. For various licensing actions specified under 10 CFR part 51, applicants are required to submit environmental documentation in the form of an environmental report, or a supplement to an environmental report, as applicable, as part of license applications. This documentation assists the NRC in performing its independent environmental review of the potential environmental impacts of the licensing action in support of meeting the NRC's obligations under NEPA and the NRC's regulations for implementing NEPA under 10 CFR part 51. For all licensing actions, as specified in 10 CFR part 51, the NRC must prepare either an environmental impact statement or an environmental assessment, as appropriate, pursuant to §§ 51.20 or 51.21.

C. Ongoing Oversight Activities

In the period of time between license applications, NPUFs are required under § 50.59(d)(1) and (2) to maintain records of changes in the facility, changes in procedures, and tests and experiments. For changes, experiments, or tests not requiring a license amendment, § 50.59 requires licensees to maintain written evaluations that provide the bases of the determinations that the change, test, or experiment does not require a license amendment. Licensees currently submit a report to the NRC annually summarizing all changes, tests, and experiments, but are not required to submit updated FSARs other than at the time of license renewal.

In addition, 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 megawatts thermal (MWt) or greater. For NPUFs operating under 2 MWt, the NRC completes an inspection once every 2 years.

Inspections can include reviews of organizational structure, reactor operator qualifications, 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.

III. Discussion

The NRC is proposing to amend the NRC's regulations that govern the license renewal process for NPUFs. This proposed rulemaking would: 1) create a definition for "non-power production or utilization facility," or "NPUF;" 2) eliminate license terms for facilities, other than testing facilities, licensed under 10 CFR 50.21(a) or (c); 3) define the license renewal process for testing facilities licensed under § 50.21(c) and NPUFs licensed under 10 CFR 50.22; 4) require all NPUF licensees to submit FSAR updates to the NRC every 5 years; 5) amend the current timely renewal provision under 10 CFR 2.109, allowing facilities to continue operating under an existing license past its expiration date if the facility submits a license renewal application at least 2 years (currently 30 days) before the current license expiration date; 6) provide an accident dose criterion of 1 rem (0.01 Sv) TEDE for NPUFs other than testing facilities; 7) extend the applicability of 10 CFR 50.59 to NPUFs regardless of their decommissioning status; 8) clarify an applicant's requirements for meeting the existing provisions of 10 CFR 51.45; and 9) eliminate the requirement to submit financial qualification information with license renewal applications under 10 CFR 50.33(f)(2). This section describes the need for improvements in the current license renewal process and the changes the NRC proposes to make to the license renewal process to address these needs.

A. Need for Improvement in the License Renewal Process

In 2008, the NRC identified 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. This need for improvement in the reliability and efficiency of the process was primarily driven by four issues:

1. Historic NRC Staffing and Emergent Issues

Non-power production or utilization facilities were some of the first reactors licensed by the Atomic Energy Commission (AEC) and the first reactors to face license renewal. Most of these reactors were initially licensed in the late 1950s and 1960s for terms 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 conduct a technical review for license renewal equivalent to initial licensing. The licenses 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 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 restarted, the NRC issued a number of renewals in a short period of time primarily by relying on generic evaluations. These were 20-year renewals that expired starting in the late 1990s. Original 40-year licenses also started expiring in the late 1990s. These two groups of renewals coming due in a short period of time created a new surge of license renewal applications.

In response to the security initiatives identified following the terrorist attacks of September 11, 2001, the NRC redirected its staff from processing the license renewal applications that were received in the late 1990s to addressing security items. In addition, the NRC was focused on implementing 10 CFR 50.64 to convert NPUF licensees to the use of low-enriched uranium.

2. Limited Licensee Resources

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

3. Inconsistent Existing License Infrastructure

The NPUFs licensed under § 50.21(a) or (c) primarily comprise 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 basis 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 must issue RAIs 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 is the same as that for an original license.

In addition, in response to Commission direction in the Staff Requirements Memorandum (SRM) to 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.

NRC Response to These Issues

Once 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 process itself. The Commission issued SRM-M080317B, "Briefing on State of NRC Technical Programs" in April 2008, which directed the NRC staff to "examine the license renewal process for non-power reactors and identify and implement efficiencies to streamline this process while ensuring that adequate protection of public health and safety are maintained."

In October 2008, the NRC 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 NRC staff discussed stakeholder feedback on the current process, including ways it could be improved and the options the NRC staff was considering for improving the review process. The NRC staff provided a detailed description of five options for streamlining the NPUF license renewal process:

- The “alternate safety review approach” would limit the review of license renewal applications to changes to the facility since the previous license review occurred, compliance with the current regulations, and the inspection process.
- The “graded approach” 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.
- The “generic analysis approach” 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.
- The “generic siting analysis approach” 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 “extended license term approach” would permit extended or indefinite terms for NPUF licenses. The NRC 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 (RTRs)] are not significant. With surveillance, maintenance and repair, RTRs 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 SARs 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, which instructed the NRC staff to proceed with several actions. The Commission directed NRC staff to: 1) immediately implement 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 NRC 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 NRC 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 NRC 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 NRC staff responded to Commission direction by implementing short-term actions to address the license renewal application backlog and developing the "Interim Staff Guidance on 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 the streamlined review process presented in 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 the 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 MWt, 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 MWt 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 more timely manner.

In addition, the NRC 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 NRC staff proposed to develop a draft regulatory basis to support proceeding with 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 NRC staff to accelerate the rulemaking to establish a more efficient, effective, and focused regulatory framework.

In August 2012, the NRC staff completed the "Regulatory Basis to Support Proceeding with Rulemaking to Streamline and Enhance the Research and Test Reactor (RTR) License Renewal Process," hereafter referred to as the regulatory basis.¹

¹ At the time of publication of the regulatory basis, the rulemaking title was the "Non-Power Reactor (NPR) License Renewal Rulemaking." During the development of the proposed rule, the scope of the rulemaking expanded to include recent license applicants (e.g., medical radioisotope irradiation and processing facilities) that are not reactors. In order to encompass all affected entities, the NRC has changed the title of the rulemaking to the "Non-power Production or Utilization Facility License Renewal Rulemaking."

The regulatory basis analyzed the technical, legal, and policy issues; impacts on public health, safety, and security; impacts on licensees; impacts on the NRC; stakeholder feedback; as well as other considerations, and concluded that a rulemaking was warranted. In developing the regulatory basis for rulemaking, the NRC staff considered lessons learned as a result of implementation of the streamlined review process outlined in the ISG. 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. The participants provided comments and questions to the NRC that focused on the potential impacts of eliminating license terms, the scope of reviews under the new process, and how this new change in regulation would work compared to the current license renewal process. The NRC considered those comments in developing this proposed rule.

B. Proposed Changes

The proposed amendments are intended to enhance 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. This proposed rule would:

1. Create a definition for "non-power production or utilization facility," or "NPUF."

The proposed rule would address inconsistencies in definitions and terminology associated with NPUFs in §§ 50.2 and 50.22 and 10 CFR part 170.3, which result in challenges in determining the applicability of the regulations. In an October 2014 direct final rule, "Definition of a Utilization Facility," the NRC amended its regulations to add SHINE Medical Technologies, Inc.'s (SHINE) proposed accelerator-driven subcritical operating assemblies to the NRC's definition of a "utilization facility" in § 50.2. The existing definitions for non-power facilities (e.g., non-power reactor, research reactor, testing facility) do not adequately cover new entities like SHINE or other medical radioisotope irradiation and processing facilities. The NRC

is proposing to add a specific definition for “non-power production or utilization facility” to § 50.2 to establish a term that is flexible enough to capture all non-power facilities licensed under § 50.22 or § 50.21(a) or (c). This action will ensure clarity and consistency for the applicability of the associated regulations for NPUFs. The proposed rule also would make conforming changes in other sections to refer to this new definition.

2. Eliminate license terms for facilities, other than testing facilities, licensed under 10 CFR 50.21(a) or (c).

The AEA does not establish license terms for Section 104a or c facilities. These licenses, however, are subject to § 50.51(a), which states that a 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.” The NRC currently issues licenses under § 50.21(a) or (c) for a term of 20 years. The NRC intends to reduce the burden on licensees associated with license terms by requiring periodic submittals of updated FSARs instead of periodic license renewal applications.

Currently, license renewal offers both the NRC and the public the opportunity to re-evaluate the licensing basis of the NPUF. The purpose of the license renewal is to assess the likelihood of continued safe operation of the facility to ensure the safe use of radioactive materials for beneficial civilian purposes while protecting people and the environment and ensuring the common defense and security. For several reasons that are unique to NPUFs, the NRC believes that this objective can be achieved through other forms of regulatory oversight. The NRC can continue to protect public health and safety, promote the common defense and security, and protect the environment through regular, existing oversight activities and the proposed addition of requirements for periodic FSAR submittals. This approach also would be consistent with the NRC’s overall program to make licensing more efficient and effective and would implement and reflect lessons learned from decades of processing license renewal applications. The NRC has reached this conclusion based on the following three considerations.

First, 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, as compared to power reactors, therefore presenting 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.

Twenty-seven² of the 31 currently licensed facilities' cores are submerged in a tank or pool of water. These volumes of water, ranging from 5,000 to more than 100,000 gallons, provide a built-in heat sink for decay heat. Twenty-five of these 27 licensed facilities are not required to have emergency core cooling systems (ECCS) because analysis has shown that air cooling is sufficient to remove decay heat if the water was not present. These NPUFs do not have significant decay heat, even after extended maximum licensed power operation, to be a risk for overheating, failure of a fission product barrier, or posing a threat to public health and safety, even under a loss of coolant accident where water levels drop below the core. Additionally, many of the facilities monitor for leaks in the form of routine inspections, track and trend water inventory, and perform surveillances on installed pool level instrumentation and sensors. Licensees perform analyses for radioisotope identification of primary and, if applicable, secondary coolant by sampling the water periodically. Many facilities sample weekly for gross radioactive material content, which is also used to establish trends to quickly identify fuel or heat exchanger failure. Most of these licensees analyze, in their FSARs, pool 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

² The three Aerojet-General Nucleonics (AGN) 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.

effluent concentration limits specified in Appendix B to 10 CFR part 20, and thus are not radiologically significant.

Only two of the NPUFs licensed under § 50.21(a) or (c), other than the one testing facility, are required by their safety analyses to have an ECCS. For these NPUFs,³ the ECCS is only needed to direct flow into the top of the tank or pool to provide cooling for a limited period of time after reactor shutdown. This period of time is dependent 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 even without the ECCS. Additionally, performance of the ECCS is ensured through required surveillance and testing on the system at these facilities. Operation of the facility is not permitted if the ECCS has not been verified operational prior to reactor startup or if the system is deemed non-operational during reactor operation. In the unlikely event that the ECCS is not available after an operational history that would require ECCS, core damage will not occur if the core is uncovered as long as a small amount of cooling flow is directed to the core, which is available from multiple sources.

Second, these facilities' simple design and operation yield a limited scope of aging-related concerns. The NRC has found no significant aging issues that need evaluation at the time of license renewal because the NRC currently imposes aging-related surveillance requirements on NPUFs via technical specifications, as needed. Aging related issues are 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 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

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

NUREG-1537, Parts 1 and 2, the NRC has determined that for NPUFs, there are two main areas related to aging that need surveillance because of potential safety concerns: 1) fuel cladding and 2) instrumentation and control features.

With regard to fuel cladding, the NRC currently requires NPUFs to perform periodic fuel inspections. Through years of operational experience, the NRC has found that fuel failures either do not occur or 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 would address concerns over aging-related issues during a non-expiring license term.

Third, the design bases of these facilities evolve slowly over time. The NRC receives approximately five license amendment requests from all NPUF licensees combined each year. Further, on average, each of these licensees reports only five § 50.59 evaluations per year for changes to its facility that do not require prior NRC approval. Lastly, changes to regulations that would impact the licensing bases of power reactor facility operations rarely apply to NPUFs.

Given these technical considerations, the elimination of license terms for NPUFs licensed under § 50.21(a) or (c), other than testing facilities, combined with the proposed

addition of requirements for periodic FSAR submittals, should have a positive effect on safety. Ending license renewal for these licensees would allow agency resources to be shifted to enhance oversight of these facilities through increased interactions with licensees related to ongoing oversight activities, such as conducting routine inspection activities and reviewing annual reports and updated FSARs. The NRC would enhance ongoing safe operations of licensed facilities, regardless of license duration, by requiring facilities to submit FSAR updates every 5 years (see discussion on proposed § 50.71(e) in Section III.B.4, “Require all NPUF licensees to submit FSAR updates to the NRC every 5 years,” of this document). Recurring FSAR reviews by the NRC would provide for maintenance of the facility’s licensing basis and provide reasonable assurance that a facility will continue to operate without undue risk to public health and safety or to the environment and without compromising the facility’s security posture. 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 in § 2.202 to modify, suspend, or revoke a license. In addition, the public would remain informed about facility operations through the publicly available FSAR submittals and would continue to have opportunities for participation through licensing actions and the § 2.206 petition process. By eliminating license terms and replacing them with required periodic FSAR update submittals coupled with existing oversight processes, the NRC would reduce the burden on facilities licensed under § 50.21(a) or (c), other than testing facilities, which is consistent with the AEA and supports the NRC’s efforts to make licensing more efficient and effective.

As described in Section V, “Section-by-Section Analysis,” of this document, the proposed rule language does not specifically address the timing of initial FSAR updates for existing NPUF licensees. The NRC intends to issue orders following the publication of the final rule to define how the proposed revisions would impact current licensees. The NRC considered incorporating these requirements into its regulations but determined that orders would be a more efficient and effective approach. This is because: 1) invoking the initial FSAR submittal

requirements for currently operating NPUFs would be a one-time requirement that would result in obsolete rule text after implementation; 2) a regulatory requirement would have compelled licensees to request and NRC to issue a license amendment to remove existing license terms; and 3) to facilitate licensee and NRC workload management, the initial FSAR submittals need to be staggered, and issuing orders allows the agency to assign licensees an appropriate implementation schedule to achieve this goal.

Specifically, the orders would remove license terms from each license as of the effective date of the final rule. The facilities would be grouped by whether they have undergone license renewal using NUREG-1537, Part 2 and the ISG. In addition, the orders would dictate when the licensee's initial FSAR update would be due to the NRC. The NRC would issue these orders for the purposes of staggering initial and ongoing FSAR updates. For that purpose, licensees would be placed in three groups based on the following:

1) Group 1 licensees would each be required to submit an updated FSAR 1 year following the effective date of the final rule. This group would consist of licensees that completed the license renewal process using the ISG. The NRC would require these licensees to submit an updated FSAR first because, with a recent license renewal, the FSARs should require minimal updates.

2) Group 2 licensees would each be required to submit an updated FSAR 2 years following the effective date of the final rule. This group would consist of licenses that last completed license renewal prior to the issuance of the ISG (i.e., license renewal was reviewed per NUREG-1537, Part 2). The NRC would allow these licensees more time to submit an updated FSAR than Group 1 licensees because more time has passed since Group 2's most recent license renewals, so additional time may be needed to update their FSARs.

3) Group 3 would consist of the remaining NPUF licensees, each of which would need to submit a license renewal application consistent with the format and content guidance in NUREG-1537, Part 1. The NRC would review the application using NUREG-1537, Part 2, and

the ISG, as appropriate. If the NRC were to conclude that a licensee meets the standard for issuing a renewed license, then the licensee would receive a non-expiring renewed license.

The proposed rule also would make conforming changes to requirements for facilities that are decommissioning by revising § 50.82(b) and (c). These provisions address license termination applications and collection periods for shortfalls in decommissioning funding for NPUFs. The proposed rule would clarify that NPUFs licensed under § 50.22 and testing facilities licensed under § 50.21(c) are the only NPUFs with license terms, which the NRC uses to determine when an application for license termination is needed. The NPUFs licensed under § 50.21(a) or (c) would need to submit an application for license termination within 2 years following permanent cessation of operations, as is currently required.

3. Define the license renewal process for testing facilities and NPUFs licensed under 10 CFR 50.22.

For NPUF licenses issued under § 50.22 and testing facilities licensed under § 50.21(c), the NRC proposes a set of regulations explicitly defining the license renewal process in proposed § 50.135 that would consolidate in one section existing regulatory requirements (i.e., requirements regarding written communications, application filing, application contents, and the issuance of renewed licenses) for current and future licensees. The proposed rule would not impose new regulations on these facilities. The NRC also would make a conforming change to § 50.8 to reflect the approved information collection requirement of proposed § 50.135.

Section 103 of the AEA establishes a license term of no more than 40 years for § 50.22 facilities. Although the AEA does not establish a fixed license term for testing facilities, these facilities are currently subject to additional license renewal requirements (e.g., siting subject to 10 CFR part 100, Advisory Committee on Reactor Safeguards [ACRS] review and environmental impact statements) due to higher power levels or other safety-significant design features as compared to other class 104a or c licensees. Therefore, the NRC is proposing that

licensees under § 50.22 and testing facilities licensed under § 50.21(c) would continue to prepare a complete license renewal application.

The NRC is proposing to make renewed operating licenses for these facilities effective 30 days after the date of issuance, replacing the previous operating license. The 30 days is intended to allow the facility to make any necessary and conforming changes to the facility processes and procedures to the extent that they are required by the applicable conditions of the renewed license. If administrative or judicial appeal affects the renewed license, then the previous operating license would be reinstated unless its term has expired and the facility has failed to submit a license renewal application in a timely manner according to proposed § 50.135(c)(2).

4. Require all NPUF licensees to submit FSAR updates to the NRC every 5 years.

Under the current license renewal process, the NRC found that licensees were not always able to provide documentation describing the details of their licensing basis, including their design basis calculations, in license renewal applications. Some licensees had difficulty documenting the necessary updates to licensing bases when they were called upon to do so between initial licensing and license renewal. Consequently, the license renewal application review process was overly burdensome for both licensees and the NRC because the NRC had incomplete information regarding changes to design and operational characteristics of the facility. From a safety perspective, an updated FSAR is important for the NRC's inspection program and for effective licensee operator training and examination.

The proposed rule would require all NPUF licensees to submit FSAR updates to the NRC every 5 years. By requiring periodic submittals of FSAR updates, the NRC anticipates that licensees will document changes in licensing bases as they occur, which would maintain the continuity of knowledge both for the licensee and the NRC and the understanding of changes and effects of changes on the facility. The NRC anticipates that these changes would result in minimal additional burden on licensees and the NRC, largely because licensees are currently

required by § 50.59 to keep FSARs up to date. The proposed rule would impose a new requirement for licensees to submit an updated FSAR to the NRC according to proposed § 50.71(e).

The proposed rule also would correct an existing grammatical error in footnote 1 to § 50.71(e). Currently the footnote states, “Effects of changes includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate.” The proposed rule would change “includes” to “include” so that the plural subject is followed by a plural verb.

5. Amend the current timely renewal provision under 10 CFR 2.109, allowing facilities to continue operating under an existing license past its expiration date if the facility 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, the current provision in § 2.109 allows 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 has accepted license renewal applications and addressed their deficiencies through the license renewal process, largely through submitting RAIs to the licensee to supplement the application. This approach increases the burden of the license renewal process on both licensees and the NRC.

To address this issue, the NRC is proposing revisions to the timely renewal provision for NPUFs 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, revisions to § 2.109 would amend the current timely renewal provision, allowing NPUFs licensed under § 50.22 and testing facilities licensed under § 50.21(c) to continue operating under an existing license past its expiration date if the facility submits a sufficient

license renewal application at least 2 years before the current license expiration date. In such cases, the existing license would not be deemed to have expired until the application has been finally determined by the NRC, as indicated in § 2.109. The proposed revision would ensure that the NRC has adequate time to review the sufficiency of license renewal applications while the facility continues to operate under the terms of its current license. The NRC also is proposing to eliminate this provision for facilities, other than testing facilities, licensed under § 50.21(a) or (c), as these facilities will no longer have license expiration dates.

6. Provide 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 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, no acute radiation-related harm will result to any member of the public. Currently, the accident dose criterion for NPUFs other than testing facilities is 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.

Since January 1, 1994, for NPUF licensees (other than testing facilities) applying for initial or renewed licenses, the NRC applies the accident dose criterion by comparing the results from the initial or renewed license applicant's accident analyses with the standards in 10 CFR part 20. Prior to that date, the NRC had generally found acceptable accident doses that were less than 0.5 rem (0.005 Sv) whole body and 3 rem (0.03 Sv) thyroid for members of the

public. On January 1, 1994, the NRC amended 10 CFR part 20 to lower the dose limit to a member of the public to 0.1 rem (0.001 Sv) TEDE.

The NRC has determined that the public dose limit of 0.1 rem (0.001 Sv) TEDE is unduly restrictive to be applied as accident dose criteria for NPUFs, other than those NPUFs subject to 10 CFR part 100.⁴ However, the NRC considers the accident dose criteria in 10 CFR part 100 (25 rem whole body and 300 rem to the thyroid) applicable to accident consequences for power reactors, which have greater potential consequences resulting from an accident, to be too high for NPUFs other than testing facilities. For these reasons, the NRC is proposing to amend its regulations in § 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), which were published in EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents." The EPA PAGs are dose guidelines to support decisions that trigger protective actions such as staying indoors or evacuating to protect the public during a radiological incident. 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 nuclear incident, which may last hours to days), the EPA PAG that 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

⁴ The NRC Atomic Safety and Licensing Appeal Board stated 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)).

exposures, is 1 rem (0.01 Sv) to 5 rem (0.05 Sv). So, if the projected dose to an individual from an incident is less than 1 rem (0.01 Sv), then no protective action for the public is recommended. In light of this understanding of the early phase EPA PAG, the NRC's proposed accident dose criterion of 1 rem (0.01 Sv) TEDE for NPUFs, other than testing facilities would provide reasonable assurance of adequate protection of the public from unnecessary exposure to radiation.

7. Extend the applicability of 10 CFR 50.59 to NPUFs regardless of their decommissioning status.

Section 50.59(b) of the Commission's regulations does not apply § 50.59 to NPUFs whose licenses have been amended to reflect permanent cessation of operations and that no longer have fuel on site (e.g., they have returned all of their fuel to the U.S. Department of Energy [DOE]). The current language states that § 50.59 is applicable to licensees "whose license has been amended to allow possession of nuclear fuel, but not operation of the facility." Therefore, § 50.59 is no longer applicable to NPUF licensees that no longer possess nuclear fuel. For these licensees, the NRC adds license conditions identical to those of § 50.59 to allow the licensee to make changes in 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 DOE after permanent shutdown, in contrast to decommissioning power reactors, these licensees must request the addition of the license conditions. This imposes an administrative burden on the licensees and the NRC. This burden would be eliminated with the proposed regulatory change to revise the wording of § 50.59(b) to extend the applicability of § 50.59 to NPUFs regardless of their decommissioning status.

8. Clarify an applicant's requirements for meeting the existing provisions of 10 CFR 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.

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. However, the NRC does not currently have explicit requirements under 10 CFR part 51 with respect to the nature of the environmental documentation that must accompany applications for initial licenses and renewed licenses for NPUFs. This fact was recently highlighted in association with the NRC's review of a construction permit application for a new NPUF to be licensed under the authority of Section 103 of the AEA.

The proposed rule would add a new section to 10 CFR part 51 to clarify NPUF environmental reporting requirements. Proposed § 51.56 would clarify an applicant's existing requirements for meeting the provisions of § 51.45. This change would improve consistency throughout 10 CFR part 51 with respect to environmental report submissions required from applicants for licensing actions. The NRC also would make a conforming change to 10 CFR 51.17 to reflect the approved information collection requirement of proposed 10 CFR 51.56.

9. Eliminate the requirement for NPUFs to submit financial qualification information with license renewal applications under 10 CFR 50.33(f)(2).

The proposed rule would eliminate license renewal financial qualification requirements for NPUFs. Currently, § 50.33(f) requires 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 are the same as those for an original license, NPUF licensees requesting license renewal must submit the same financial information that is required in an application for an initial license. In addition, the NRC has found that the financial qualification information does not have a significant impact on the NRC's 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 obtain the information necessary to conduct its review of license renewal applications.

Similar to the current proposal for NPUFs, the 2004 rulemaking, “Financial Information Requirements for Applications to Renew or Extend the Term of an Operating License for a Power Reactor,” 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 performs routine NPUF program inspections and 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. These programs provide, in part, the NRC’s safety oversight of these licensees.

The elimination of financial qualification requirements for power reactor licensees at the time of license renewal supports the NRC’s basis for eliminating 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. Moreover, because NPUFs have significantly smaller fission product inventory and potential for radiological consequences than do power reactors, the NPUF financial qualification reviews appear to be of less value in ensuring safety than reviews previously required of power reactors.

IV. Specific Requests for Comments

The NRC is seeking public comment on the proposed rule. We are particularly interested in comments and supporting rationale from the public on the following:

- As discussed in Section III, “Discussion,” of this document, the NRC is proposing that license terms for NPUFs, other than testing facilities, licensed under 10 CFR 50.21(a) or (c) would be removed from existing licenses via order. Are there any unintended consequences associated with removing license terms in this manner? Provide the basis for your answer.
- Proposed § 50.71 would require all NPUFs to submit an update to the FSAR originally submitted with the facility’s license application every 5 years. The NRC staff plans to specify the first submittal date in orders issued to each facility. Should the NRC specify the date by which each facility or category of facility must submit its first updated FSAR in the rule language instead of using site-specific orders? Are there any unintended consequences of establishing the first submittal dates through orders? Please provide the basis for your answer.
- Proposed § 50.135 outlines the license renewal process for facilities licensed under § 50.22 and testing facilities licensed under § 50.21(c). Should any elements of the process be removed from or added to the NRC proposal? Please provide specific examples.
- The NPUFs licensed under § 50.22 are those facilities that are used for industrial or commercial purposes. For example, a facility used primarily for the production and sale of radioisotopes other than for use in research and development would be considered a commercial production or utilization facility and therefore would be licensed under § 50.22. Currently, license applications for such NPUFs pass through additional steps in the licensing process (e.g., mandatory public hearings). These additional steps are required even though many such facilities have the same inherent low risk profile as low-power NPUFs licensed under

§ 50.21(a) or (c) which are not required to proceed through these additional steps. Are these additional steps necessary for all NPUFs licensed under § 50.22, or would it be more efficient and effective to differentiate low-power NPUFs licensed under § 50.22 from high-power NPUFs licensed under § 50.22? Elaborate on requirements that could be tailored for low-power, low-risk NPUFs licensed under § 50.22, including recommended criteria (e.g., power level or other measure) for establishing reduced requirements.

- As discussed in Section III, "Discussion," of this document, the NRC is proposing that license terms would not expire for NPUFs, other than testing facilities, licensed under § 50.21(a) or (c), whereas testing facilities would continue to have fixed license terms that would require periodic license renewal. While the AEA does not establish a fixed license term for testing facilities, these facilities are currently subject to additional regulatory requirements due to higher power levels (e.g., mandatory public hearings, ACRS review, and preparation of environmental impact statements). Is a fixed license term necessary for testing facilities licensed under § 50.21(c) or would it be more efficient and effective to also grant testing facilities non-expiring licenses? Provide the basis for revising NRC requirements to account for the higher risk of testing facilities licensed under § 50.21(c) relative to other NPUFs licensed under § 50.21(a) or (c), including recommended criteria for establishing eligibility for a non-expiring license.

- For NPUFs licensed under § 50.22 and testing facilities licensed under § 50.21(c), does the revision to the timely renewal provision from 30 days to 2 years provide an undue burden on licensees? If so, in addition to your response, please provide information supporting an alternate provision for timely renewal.

- The NRC is considering requiring each NPUF licensee, other than testing facilities, to demonstrate in its accident analysis that an individual located in the unrestricted area following the onset of a postulated accidental release of licensed material, including consideration of experiments, would not receive a dose in excess of 1 rem (0.01 Sv) TEDE for the duration of the

accident. Is the accident dose criterion 1 rem (0.01 Sv) TEDE in proposed § 50.34(a)(1)(ii)(D)(2) appropriate for NPUFs, other than testing facilities? If not, what accident dose criterion is appropriate? Please provide the basis for your answer.

V. Section-by-Section Analysis

The following paragraphs describe the specific changes proposed by this rulemaking.

Proposed § 2.109 Effect of Timely Renewal Application

The NRC is proposing to revise 10 CFR 2.109(a) to exclude NPUFs from the 30-day timely renewal provision because 30 days does not provide the NRC with adequate time to assess license renewal applications.

In addition to this exception from the 30-day timely renewal provision, the NRC is proposing to add a new subparagraph defining a new timely renewal provision for NPUFs with license terms (i.e., facilities licensed under 10 CFR 50.22 and testing facilities licensed under § 50.21(c)). The NRC is proposing to add paragraph (e) to § 2.109 to require an NPUF with a license term to submit a license renewal application at least 2 years prior to license expiration. This will permit adequate time for the NRC to determine the acceptability of the application before expiration of the license term.

Proposed § 50.2 Definitions

The proposed rule would add a definition to § 50.2 for a “non-power production or utilization facility,” or “NPUF.” An NPUF would be defined as a non-power reactor, testing facility, or other production or utilization facility, licensed under the authority of Section 103, Section 104a, or Section 104c of the AEA that is not a nuclear power reactor or fuel reprocessing plant.

Proposed § 50.8 Information Collection Requirements: OMB Approval

The NRC is proposing to revise § 50.8(b) to include proposed § 50.135 as an approved information collection requirement in 10 CFR part 50. This is a conforming change to existing regulations to account for the new information collection requirement.

Proposed § 50.33 Contents of Applications; General Information

The NRC is proposing to revise § 50.33(f)(2) to remove the requirement for NPUFs to submit with license renewal applications the same financial information that is required for initial license applications. These NPUFs (i.e., facilities licensed under § 50.22 and testing facilities) would not be required to submit any financial information with license renewal applications.

Proposed § 50.34 Contents of Applications; Technical Information

The NRC is proposing to revise § 50.34(a)(1)(ii)(D) to clarify the section's applicability to NPUFs licensed under § 50.22 or § 50.21(a) or (c). Paragraph (a)(1)(ii)(D) would be modified to create § 50.34(a)(1)(ii)(D)(1) and (2) to clearly distinguish these requirements between applicants for power reactor construction permits and applicants for NPUF construction permits. Section 50.34(a)(1)(ii)(D)(1) would describe the requirements applicable to power reactor construction permit applicants. The proposed rule would not change the existing requirements for these applicants.

Proposed § 50.34(a)(1)(ii)(D)(2) would specify an accident dose criterion for NPUFs, other than testing facilities subject to 10 CFR part 100. The proposed regulation would set an accident dose criterion of 1 rem (0.01 Sv) TEDE for NPUFs other than testing facilities.

Proposed § 50.51 Continuation of License

The NRC is proposing to revise § 50.51(a) to exempt from license terms NPUFs, other than testing facilities, licensed under § 50.21(a) or (c). Testing facilities and NPUFs licensed under § 50.22 would continue to have fixed license terms and undergo license renewal as described in proposed § 50.135. The NRC is proposing to add § 50.51(c) to clarify that NPUFs, other than testing facilities, licensed under § 50.21(a) or (c) after the effective date of the final rule, would have non-expiring license terms. The implementing change to applicable existing NPUF licensees would be instituted by order to remove license terms.

Proposed § 50.59 Changes, Tests and Experiments

The NRC is proposing to revise paragraph (b) of § 50.59 to extend the section's applicability to NPUFs that have permanently ceased operations and that no longer have fuel on site (e.g., have returned all of their fuel to the DOE).

Proposed § 50.71 Maintenance of Records, Making of Reports

The NRC is proposing to revise paragraph (e) of § 50.71 to require NPUFs to submit an update to the FSAR originally submitted with the facility's license application, as is currently required for nuclear power reactor licensees and applicants for a combined license under 10 CFR part 52. Updates should reflect the changes and effects of changes to the facility's design basis and licensing basis, including any information documented in annual reports, § 50.59 evaluations, license amendments, and other submittals to the NRC since the previous FSAR update submittal. The NRC also is proposing to revise footnote 1 in paragraph (e) of § 50.71 to change the word "includes" to "include" to correct an existing grammatical error.

In addition to extending the applicability of the requirements specified in § 50.71(e), the proposed rule would establish supporting requirements in § 50.71(e)(3) and (e)(4). The NRC is proposing to revise paragraph (e)(3)(i) of § 50.71 to make explicit the applicability of the FSAR

requirements therein to only power reactor licensees. This change would not modify the underlying requirements in § 50.71 that currently apply to power reactor licensees.

The NRC also would add § 50.71(e)(3)(iv) to set forth FSAR requirements similar to those in proposed § 50.71(e)(3)(i) specifically for NPUFs. The NRC is proposing to require NPUFs licensed after the effective date of the final rule to submit initial FSAR revisions within 5 years of the date of issuance of the operating license. Each revision would reflect all changes made to the FSAR up to a maximum of 6 months prior to the date of filing the revision.

The NRC is proposing to restructure and revise paragraph (e)(4) of § 50.71. New paragraph (e)(4)(i) would make explicit that the FSAR update requirements therein apply to nuclear power reactor licensees only. This administrative change would not modify the underlying requirements of existing § 50.71(e)(4) that currently apply to power reactor licensees. In addition, the NRC would add § 50.71(e)(4)(ii) to establish similar FSAR update requirements for NPUFs. Specifically, the NRC is proposing to require NPUF licensees to file subsequent FSAR updates at intervals not to exceed 5 years. Each update must reflect all changes made to the FSAR up to a maximum of 6 months prior to the date of filing the update. The orders described under Section III.B, “Proposed Changes,” of this document would also establish the requirement for currently licensed NPUFs to submit recurring FSAR updates on a 5-year periodicity.

Proposed § 50.82 Termination of License

The NRC is proposing to revise paragraph (b) of § 50.82 to replace the term “non-power reactor licensees” with “non-power production or utilization facility licensees” in order to ensure that all NPUFs are subject to the relevant termination and decommissioning regulations.

The NRC is proposing to revise paragraph (b)(1) of § 50.82 to clarify that only NPUFs holding a license issued under § 50.22 and testing facilities licensed under § 50.21(c) would need to submit an application for license termination.

The NRC is proposing to revise paragraph (c) of § 50.82 to clarify when the collection period for shortfalls in funding would be determined. Currently, § 50.82(c) refers to a facility ceasing operation before the expiration of its license. Under the proposed rule, licenses for NPUFs, other than testing facilities, licensed under § 50.21(a) or (c) would not expire. Therefore, for NPUFs, other than testing facilities, licensed under § 50.21(a) or (c), the NRC proposes to revise § 50.82(c) to remove references to the expiration of the license. The requirements for all other licensees (i.e., the holders of a license issued under § 50.22 – including power reactor licenses – and testing facilities) have been renumbered, but the underlying requirements remain unchanged.

Proposed § 50.135 License Renewal for Non-Power Production or Utilization Facilities Licensed Under § 50.22 and Testing Facility Licensees

The NRC is proposing to add § 50.135 to 10 CFR part 50 to clearly define the license renewal process for NPUFs licensed under § 50.22 and testing facilities licensed under § 50.21(c). This section would consolidate existing regulatory requirements related to the NPUF license renewal process in one section and would not modify the underlying requirements that currently apply to NPUFs seeking license renewal.

Proposed § 50.135(a) would specify the section's applicability to NPUFs licensed under § 50.22 and testing facilities licensed under § 50.21(c).

Proposed § 50.135(b) would require that all applications, correspondence, reports, and other written communications be filed in accordance with § 50.4.

Proposed § 50.135(c)(1) would require license renewal applications be prepared in accordance with subpart A of 10 CFR part 2 and all applicable sections of 10 CFR part 50. Proposed § 50.135(c)(2) would allow licensees to submit applications for license renewal up to 10 years before the expiration of the current operating license.

Proposed § 50.135(d)(1) would require licensees to provide the information specified in §§ 50.33, 50.34, and 50.36, as applicable, in license renewal applications. Proposed § 50.135(d)(2) would require applications to include conforming changes to the standard indemnity agreement under 10 CFR part 140. Proposed § 50.135(d)(3) would require licensees to submit a supplement to the environmental report with the license renewal application, consistent with the requirements of proposed § 51.56.

Proposed § 50.135(e) would specify the terms of renewed operating licenses. Proposed paragraph (e)(1) would require that the renewed license would be for the same facility class as the previous license. Proposed paragraph (e)(2) would establish the terms of a renewed license. Renewed licenses would be issued for a fixed period of time, which would be the sum of the remaining amount of time on the current operating license plus the additional amount of time beyond the current operating license expiration (not to exceed 30 years) that the licensee requests in its renewal application. Terms would not exceed 40 years in total. Proposed paragraph (e)(3) would make a renewed license effective 30 days after the date of issuance, replacing the previous operating license. Proposed paragraph (e)(4) would specify that a renewed license may be subsequently renewed following the requirements in § 50.135 and elsewhere in 10 CFR part 50.

Proposed § 51.17 Information Collection Requirements; OMB Approval

The NRC is proposing to revise § 51.17(b) to include proposed § 51.56 as an approved information collection requirement in 10 CFR part 51. This is a conforming change to existing regulations to account for the new information collection requirement.

Proposed § 51.45 Environmental Report

The NRC is proposing to revise § 51.45(a) to add a cross reference to proposed new § 51.56. This is a conforming change to existing regulations to clarify the environmental report requirements for NPUFs.

Proposed § 51.56 Environmental Report – Non-Power Production or Utilization Facility Licenses

The NRC is proposing to add a new section, § 51.56, to clarify existing requirements for the submittal and content of environmental reports by applicants seeking a permit to construct, or a license to operate, an NPUF, or to renew an existing license as otherwise prescribed by § 50.135 of this proposed rule. This section would clarify existing regulatory requirements related to environmental reports and would not modify the underlying requirements that currently apply to NPUFs.

VI. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if adopted, have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation of NPUFs. 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).

VII. Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation and the draft implementing guidance. The analysis examines the costs and benefits of the alternatives considered by the NRC. The NRC requests public comment on the draft regulatory analysis.

The draft regulatory analysis is available as indicated in Section XVI, "Availability of Documents," of this document. Comments on the draft regulatory analysis may be submitted to the NRC as indicated under the ADDRESSES caption of this document.

VIII. Backfitting

The NRC's backfitting provisions for reactors are found in 10 CFR 50.109. The regulatory basis for § 50.109 was expressed solely in terms of nuclear power reactors. For example, the NRC's Advanced Notice of Proposed Rulemaking, Policy Statement, Proposed Rule, and Final Rule for § 50.109 each had the same title: "Revision of Backfitting Process for Power Reactors." As a result, the NRC has not applied § 50.109 to research reactors, testing facilities, and other non-power facilities licensed under 10 CFR part 50 (e.g., "Final Rule; Limiting the Use of Highly Enriched Uranium in Domestically Licensed Research and Test Reactors"; "Final Rule; Clarification of Physical Protection Requirements at Fixed Sites"). In a 2012 final rule concerning non-power reactors, the NRC stated, "The 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").

Under proposed § 50.2, "NPUFs" would include non-power reactors, testing facilities, or other non-power production or utilization facilities licensed in accordance with §§ 50.21(a) or (c) (Section 104a or c of the AEA) or § 50.22 (Section 103 of the AEA). Because the term "NPUFs" would include licensees that are excluded from the scope of § 50.109, NPUFs would not fall within the scope of § 50.109. Because § 50.109 does not apply to NPUFs, and this proposed rule would apply exclusively to NPUFs, the NRC did not apply § 50.109 to this proposed rule.

Although NPUF licensees are not protected by § 50.109, 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.

IX. Cumulative Effects of Regulation

The NRC is following its Cumulative Effects of Regulation (CER) process by engaging extensively with external stakeholders throughout this rulemaking and related regulatory activities. Public involvement has included: 1) a request for comment on a preliminary draft regulatory basis document on June 29, 2012, and 2) three public meetings (held on September 13, 2011; December 19, 2011; and March 27, 2012) that supported the development of the draft regulatory basis document. During the development of the proposed rule language, the NRC held two public meetings with stakeholders on August 7, 2014 and October 7, 2015 and will be issuing the draft implementing guidance with the proposed rule to support more informed external stakeholder feedback. Section XIV, "Availability of Guidance," of this document describes how the public can access the draft implementing guidance for which the NRC seeks external stakeholder feedback.

Finally, the NRC is requesting CER feedback on the following questions:

1. In light of any current or projected CER challenges, does the proposed rule's effective date provide sufficient time to implement the new proposed requirements, including changes to programs, procedures, and facilities?

2. If CER challenges currently exist or are expected, what should be done to address them? For example, if more time is required for implementation of the new requirements, what period of time is sufficient?

3. Do other (NRC or other agency) regulatory actions (e.g., orders, generic communications, license amendment requests, inspection findings of a generic nature) influence the implementation of the proposed rule's requirements?

4. Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule's purpose and objectives? If so, what are the unintended consequences, and how should they be addressed?

5. Please comment on the NRC's cost and benefit estimates in the draft regulatory analysis that supports the proposed rule. The draft regulatory analysis is available as indicated in Section XVI, "Availability of Documents," of this document.

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. The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

XI. Environmental Assessment and Proposed Finding of No Significant Environmental Impact

The Commission has determined under NEPA and the Commission's regulations in subpart A of 10 CFR part 51, that this rule, if adopted, would not be a major Federal action

significantly affecting the quality of the human environment. Consequently, an environmental impact statement is not required. The basis of this determination reads as follows: The proposed rule to eliminate license terms for NPUFs, other than testing facilities, licensed under § 50.21(a) or (c) would result in no additional radiological or non-radiological impacts because of existing surveillance and oversight and the minimal consequences of MHAs for these facilities. In addition, the implementation of the proposed rulemaking would not affect the NEPA environmental review requirements of new facilities and facilities applying for license renewal. The NRC concludes that this proposed rule would not cause any additional radiological or non-radiological impacts on the human environment.

The determination of this environmental assessment (EA) is that there will be no significant effect on the quality of the human environment from this action. Public stakeholders should note, however, that comments on any aspect of the EA may be submitted to the NRC. The EA is available as indicated in Section XVI, "Availability of Documents," of this document.

The NRC has sent a copy of the EA and this proposed rule to every State Liaison Officer and has requested comments.

XII. Paperwork Reduction Act

This proposed rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This proposed rule has been submitted to the Office of Management and Budget (OMB) for approval of the information collections.

Type of submission, new or revision: Revision.

The title of the information collection: 10 CFR Part 50, Non-power Production or Utilization Facility License Renewal, Proposed Rule.

The form number if applicable: Not applicable.

How often the collection is required or requested: Once and annually.

Who will be required or asked to respond: NPUF licensees.

An estimate of the number of annual responses: 58 (27 reporting responses + 31 recordkeepers).

The estimated number of annual respondents: 31.

An estimate of the total number of hours needed annually to comply with the information collection requirement or request: 1,551.

Abstract: The proposed rule would result in incremental changes in recordkeeping and reporting burden relative to existing rules by eliminating license terms for class 104a or c NPUFs, other than testing facilities, and defining the license renewal process for class 103 NPUFs and testing facilities; and requiring the periodic submittal of updates to the FSAR. The NRC anticipates that, overall, the proposed rule would result in reduced burden on licensees and the NRC, and would create a more responsive and efficient licensing process that would continue to protect public health and safety, promote the common defense and security, and protect the environment.

Currently, NPUF licensees are not required to submit to the NRC updated FSARs. During the recent round of license renewals, the NRC found that some FSARs submitted with license renewal applications often did not reflect a facility's current licensing basis. The lack of ongoing FSAR updates added burden to the license renewal process for NPUF licensees and the NRC in order to re-establish each facility's licensing basis. Periodic submittals of updates to FSARs would create a mechanism for incorporating design and operational changes into the licensing basis as they occur. As a result, NPUFs would routinely update their licensing bases and the NRC would be made aware of changes to the licensing bases more frequently.

The NRC has determined that the proposed information collection requirements are necessary to ensure that: 1) licensee procedures are up-to-date and are consistent with the NRC's requirements, 2) licensing bases are not lost over time, and 3) the NRC is made aware of changes to facilities more frequently.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden of the proposed information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the OMB clearance package and proposed rule is available in ADAMS under Accession No. ML17068A077 or may be viewed free of charge at the NRC's PDR, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, MD 20852. You may obtain

information and comment submissions related to the OMB clearance package by searching on <http://www.regulations.gov> under Docket ID NRC-2011-0087.

You may submit comments on any aspect of these proposed information collection(s), including suggestions for reducing the burden and on the previously stated issues, by the following methods:

- **Federal rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2011-0087.
- **Mail comments to:** Information Services Branch, Office of the Chief Information Officer, Mail Stop: T-2 F43, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or to Aaron Szabo, Desk Officer, Office of Information and Regulatory Affairs (3150-AI96), NEOB-10202, Office of Management and Budget, Washington, DC 20503; telephone: 202-395-3621, e-mail: oir_submission@omb.eop.gov.

Submit comments by May 1, 2017. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

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.

XIII. Criminal Penalties

For the purposes of Section 223 of the AEA, the NRC is issuing this proposed rule that would amend 10 CFR 2.109, 50.2, 50.33, 50.34, 50.51, 50.59, 50.71, 50.82, and 51.45 and create 10 CFR 50.135 and 51.56 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

XIV. Availability of Guidance

The NRC is issuing DG-2006, "Preparation of Updated Final Safety Analysis Reports for Non-power Production or Utilization Facilities," in accordance with 10 CFR 50.71(e), for the implementation of the proposed requirements in this rulemaking. The DG is available as indicated in Section XVI, "Availability of Documents," of this document. You may obtain information and comment submissions related to the DG by searching on <http://www.regulations.gov> under Docket ID NRC-2011-0087.

The draft implementing guidance defines multiple terms found in 10 CFR part 50 and other documents relevant to the preparation of FSARs, including aging; aging management; change; design bases; effects of changes; facility; FSAR (as updated); historical information; licensing basis; NPUFs; obsolete information, and safety related items. The NRC recognizes that changes to facilities may be necessary during the course of operations due to facilities' dynamic designs and operations; however, licensees must justify and implement any changes to the design basis and licensing basis in accordance with NRC regulations. The updated FSAR provides the NRC with the most current design and licensing bases for a licensee and provides the general public with a description of the facility and its operation. Section 50.34 and NUREG-1537, Part 1 provide the scope and format of an updated FSAR. Content should include changes to the facility or its operations resulting from new or amended regulatory requirements as well as changes and the effects of changes to the facility, its procedures, or

experiments. The NRC Facility Project Manager reserves the right to conduct an inspection related to changes reported in the updated FSAR.

You may submit comments on the DG by the following methods:

- **Federal rulemaking Web site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2011-0087. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov.
- **Mail comments to:** Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: OWFN-12-H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

XV. Public Meeting

The NRC will conduct a public meeting on the proposed rule for the purpose of describing the proposed rule to the public and answering questions from the public to assist the public in providing informed comments on the proposed rule during the comment period.

The NRC will publish a notice of the location, time, and agenda of the meeting on the NRC's public meeting Web site at least 10 calendar days before the meeting. In addition, the NRC will post the meeting notice on Regulations.gov under NRC-2011-0087. Stakeholders should monitor the NRC's public meeting Web site for information about the public meeting at: <http://www.nrc.gov/public-involve/public-meetings/index.cfm>.

XVI. Availability of Documents

The documents identified in the following table are available to interested persons as indicated.

Document	ADAMS Accession No. / Web link / FEDERAL REGISTER CITATION
SECY-16-0048, "Proposed Rulemaking: Non-Power Production or Utilization Facility License Renewal"	ML16019A048
SRM-SECY-16-0048, "Proposed Rulemaking: Non-Power Production or Utilization Facility License Renewal"	ML17045A543
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 on Streamlined Review Process for License Renewal for Research Reactors	ML091420066
Non-Power Reactor License Renewal: Preliminary Draft Regulatory Basis; Request for Comment	77 FR 38742; June 29, 2012
Regulatory Basis to Support Proceeding with Rulemaking to Streamline and Enhance the Research and Test Reactor (RTR) License Renewal Process	ML12240A677
<i>Federal Register</i> 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
Draft Regulatory and Backfit Analysis	ML17068A038

EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents"	http://www2.epa.gov/sites/production/files/2014-11/documents/00000173.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
Summary of September 13, 2011 Public Meeting to Discuss Streamlining Non-Power Reactor License Renewal	ML112710285
Summary of December 19, 2011 Public Meeting to Discuss the Regulatory Basis for Streamlining Non-Power Reactor License Renewal and Emergency Preparedness	ML113630166
Summary of March 27, 2012 Public Meeting: Briefing on License Renewal for Research and Test Reactors	ML120930333
Draft OMB Supporting Statement	ML17068A077
Draft Environmental Assessment	ML17068A035
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
Final Rule; 10 CFR Part 50 – Licensing of Production and Utilization Facilities	33 FR 9704; July 4, 1968
Final Rule; Elimination of Review of Financial Qualifications of Electric Utilities in Licensing Hearings for Nuclear Power Plants	47 FR 13750; March 31, 1982
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
Final Regulations; National Environmental Policy Act—Regulations	43 FR 55978; November 29, 1978
Direct Final Rule; Definition of a Utilization Facility	79 FR 62329; October 17, 2014
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
Proposed Rule; Revision of Backfitting Process for Power Reactors	49 FR 47034; November 30, 1984
Final Rule; Revision of Backfitting Process for Power Reactors	50 FR 38097; September 20, 1985
Final Rule; Limiting the Use of Highly Enriched Uranium in Domestically Licensed Research and Test Reactors	51 FR 6514; March 27, 1986
Final Rule; Clarification of Physical Protection Requirements at Fixed Sites	58 FR 13699; March 15, 1993

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

Throughout the development of this rule, the NRC may post documents related to this rule, including public comments, on the Federal rulemaking Web site at <http://www.regulations.gov> under Docket ID NRC-2011-0087. The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe:

- 1) Navigate to the docket folder (NRC-2011-0087);
- 2) click the “Sign up for E-mail Alerts” link;
- and 3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

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 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.

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 proposing to adopt the following amendments to 10 CFR parts 2, 50, and 51:

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 10 CFR 50.21(b) or 50.22, a non-power production or utilization facility, 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 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 50 -- DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

3. 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.

4. In § 50.2, add, in alphabetical order, the definition for *non-power production or utilization facility* to read as follows:

§ 50.2 Definitions.

* * * * *

Non-power production or utilization facility means a non-power reactor, testing facility, or other production or utilization facility, licensed under § 50.21(a), § 50.21(c), or § 50.22, that is not a nuclear power reactor or fuel reprocessing plant.

* * * * *

5. In § 50.8, revise paragraph (b) to read as follows:

§ 50.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 50.30, 50.33, 50.34, 50.34a, 50.35, 50.36, 50.36a, 50.36b, 50.44, 50.46, 50.47, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.60, 50.61, 50.61a, 50.62, 50.63, 50.64, 50.65, 50.66, 50.68, 50.69, 50.70, 50.71, 50.72, 50.74, 50.75, 50.80, 50.82, 50.90, 50.91, 50.120, 50.135, 50.150, and appendices A, B, E, G, H, I, J, K, M, N, O, Q, R, and S to this part.

* * * * *

6. In § 50.33, revise paragraph (f)(2) to read as follows:

§ 50.33 Contents of applications; general information.

* * * * *

(f) * * *

(2) If the application is for an operating license, the applicant shall submit information that demonstrates the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. The applicant shall submit estimates for total annual operating costs for each of the first 5 years of operation of the facility. The applicant shall also indicate the source(s) of funds to cover these costs. An applicant seeking to renew or extend the term of an operating license need not submit the financial information that is required in an application for an initial license.

* * * * *

7. In § 50.34, revise paragraph (a)(1)(ii)(D) to read as follows:

§ 50.34 Contents of applications; technical information.

(a) * * *

(1) * * *

(ii) * * *

(D) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to design features intended to mitigate the radiological consequences of accidents.

(1) In performing this assessment for a nuclear power reactor, an applicant shall assume a fission product release⁶ from the core into the containment assuming that the facility is

⁶ The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. The evaluation must determine that:

(i) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem⁷ total effective dose equivalent (TEDE).

(ii) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE.

(2) All holders of operating licenses issued to non-power production or utilization facilities, and applicants for renewed licenses for non-power production or utilization facilities under § 50.135 of this chapter not subject to 10 CFR part 100, shall provide an evaluation of the applicable radiological consequences in the facility safety analysis report that demonstrates with reasonable assurance that any individual located in the unrestricted area following the onset of a postulated accidental release of licensed material, 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.

* * * * *

⁷ A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, in order to assure that such designs provide assurance of low risk of public exposure to radiation, in the event of such accidents.

8. In § 50.51, revise paragraph (a) and add paragraph (c) to read as follows:

§ 50.51 Continuation of license.

(a) Except as noted in § 50.51(c), 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. Where the operation of a facility is involved, the Commission will issue the license for the term requested by the applicant or for the estimated useful life of the facility if the Commission determines that the estimated useful life is less than the term requested. Where construction of a facility is involved, the Commission may specify in the construction permit the period for which the license will be issued if approved pursuant to § 50.56. Licenses may be renewed by the Commission upon the expiration of the period. Renewal of operating licenses for nuclear power plants is governed by 10 CFR part 54. Application for termination of license is to be made pursuant to § 50.82.

* * * * *

(c) Each non-power production or utilization facility license, other than a testing facility license, issued under § 50.21(a) or (c) after **[EFFECTIVE DATE OF FINAL RULE]** will be issued with no fixed license term.

9. 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 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, or 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.

* * * * *

10. In § 50.71, revise paragraph (e) introductory text and paragraph (e)(3)(i), add new paragraph (e)(3)(iv), and revise paragraph (e)(4) to read as follows:

§ 50.71 Maintenance of records, making of reports.

* * * * *

(e) Each person licensed to operate a nuclear power reactor, or non-power production or utilization facility, under the provisions of § 50.21 or § 50.22, and each applicant for a combined license under part 52 of this chapter, shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the license, to assure that the information included in the report contains the latest information developed. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the applicant or licensee or prepared by the applicant or licensee pursuant to Commission requirement since the submittal of the original FSAR, or as appropriate, the last update to the FSAR under this section. The submittal shall include the effects¹ of all changes made in the facility or procedures as described in the FSAR; all safety analyses and evaluations performed by the applicant or licensee either in support of approved license amendments or in support of conclusions that changes did not

¹ Effects of changes include appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate.

require a license amendment in accordance with § 50.59(c)(2) or, in the case of a license that references a certified design, in accordance with § 52.98(c) of this chapter; and all analyses of new safety issues performed by or on behalf of the applicant or licensee at Commission request. The updated information shall be appropriately located within the update to the FSAR.

* * * * *

(3)(i) For nuclear power reactor licensees, a revision of the original FSAR containing those original pages that are still applicable plus new replacement pages shall be filed within 24 months of either July 22, 1980, or the date of issuance of the operating license, whichever is later, and shall bring the FSAR up to date as of a maximum of 6 months prior to the date of filing the revision.

* * * * *

(iv) For non-power production or utilization facility licenses issued after **[EFFECTIVE DATE OF FINAL RULE]**, a revision of the original FSAR must be filed 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)(i) For nuclear power reactor licensees, subsequent revisions must be filed annually or 6 months after each refueling outage provided the interval between successive updates does not exceed 24 months. The revisions must reflect all changes up to a maximum of 6 months prior to the date of filing. For nuclear power reactor facilities that have submitted the certifications required by § 50.82(a)(1), subsequent revisions must be filed every 24 months.

(ii) Non-power production or utilization facility licensees shall file subsequent FSAR updates at intervals not to exceed 5 years. Each update must reflect all changes made to the FSAR up to a maximum of 6 months prior to the date of filing the update.

* * * * *

11. In § 50.82, revise paragraph (b) introductory text and paragraphs (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 holders of a license issued 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 license issued under § 50.21(a) or § 50.21(c), other than a testing facility, that has permanently ceased operations.

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

12. Add new § 50.135 to read as follows:

§ 50.135 License renewal for non-power production or utilization facilities licenses issued under § 50.22 and testing facility licensees.

(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 provide 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) Contents of application--environmental information. 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, which is the sum of the additional amount of time beyond the expiration of the operating license (not to exceed 30 years) that is requested in a renewal application plus the remaining number of years on the operating license currently in effect. The term of any renewed license may not exceed 40 years.

(3) A renewed license will become effective 30 days after 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.

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

PART 51 -- ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

13. 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.

14. In § 51.17, revise paragraph (b) to read as follows:

§ 51.17 Information collection requirements; OMB approval.

* * * * *

(b) The approved information collection requirements in this part appear in §§ 51.6, 51.16, 51.41, 51.45, 51.49, 51.50, 51.51, 51.52, 51.53, 51.54, 51.55, 51.56, 51.58, 51.60, 51.61, 51.62, 51.66, 51.68, and 51.69.

15. In § 51.45, revise paragraph (a) to read as follows:

§ 51.45 Environmental report.

(a) General. As required by §§ 51.50, 51.53, 51.54, 51.55, 51.56, 51.60, 51.61, 51.62, or 51.68, as appropriate, each applicant or petitioner for rulemaking shall submit with its application or petition for rulemaking one signed original of a separate document entitled "Applicant's" or "Petitioner's Environmental Report," as appropriate. An applicant or petitioner for rulemaking may submit a supplement to an environmental report at any time.

* * * * *

16. Add new § 51.56 to read as follows:

§ 51.56 Environmental report—non-power production or utilization facility licenses.

Each applicant for a non-power production or utilization facility license or other form of permission, or renewal of a non-power production or utilization facility license or other form of permission 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 or other form of permission 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.

Dated at Rockville, Maryland, this 23rd day of March, 2017.

For the Nuclear Regulatory Commission.

/RA/

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