

NOTE: The NRC is making this preliminary Commission paper publicly available to support the March 3, 2016, public meeting with the Advisory Committee on Reactor Safeguards. The NRC is not requesting public comments on this preliminary draft proposed rule at this time. When the notice of issuance of the proposed rule is published in the *Federal Register*, stakeholders will have an opportunity to comment on the proposed rule. The NRC will respond to any such comments when it issues the final rule.

FOR: The Commissioners

FROM: Victor M. McCree
Executive Director for Operations

SUBJECT: PROPOSED RULEMAKING: NON-POWER PRODUCTION OR
UTILIZATION FACILITY LICENSE RENEWAL (RIN 3150-AI96)

PURPOSE:

To obtain Commission approval to publish for public comment a proposed rule that would amend the U.S. Nuclear Regulatory Commission's (NRC's) 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, "Commercial Licenses," or Section 104a or 104c, "Medical Therapy and Research and Development," of the Atomic Energy Act of 1954, as amended (AEA), that are not nuclear power reactors. This paper does not address any new commitments or resource implications.

SUMMARY:

The NRC staff is proposing to amend the NRC's 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 AEA, that are not nuclear power reactors. The NRC staff collectively refers to these facilities as non-power production or utilization facilities (NPUFs).

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The proposed rule would: 1) eliminate license terms for facilities, other than testing facilities, licensed under paragraph (a) or (c) of section 21 of part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), "Class 104 licenses; for medical therapy and research and development facilities;" 2) define the license renewal process for testing facilities and NPUFs licensed under 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities;" 3) require all NPUF licensees to submit routine final safety analysis report (FSAR) updates to the NRC every five years; and 4) provide an accident dose criterion of 1 rem (0.01 Sv) total effective dose equivalent for NPUFs other than testing facilities. The proposed rule also includes other changes, as described in the Discussion section.

BACKGROUND:

As discussed in section II, "Background," of the enclosed proposed rule, the NRC currently licenses NPUFs under the authority granted in Sections 103 and 104 of the AEA. Sections 104a and c (for facilities used for medical therapy and research and development activities) of the AEA require that the Commission impose only the minimum amount of regulation needed to promote common defense and security, protect the health and safety of the public, and permit the widest possible amount of effective medical therapy and research and development. The NRC regulates 36 NPUFs, of which 31 are currently operating. The remaining five are in the process of decommissioning.

The AEA dictates an initial license term of no more than 40 years for facilities licensed under the authority of Section 103, but does not specify license terms for facilities licensed under the authority of Section 104a or c. The authority granted by the statute is reflected in paragraph (a) of 10 CFR 50.51, "Continuation of license," which currently specifies that the NRC may grant an initial license for no longer than a 40-year license term. If the license initially is issued for a shorter period, then it may be renewed 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, and the NRC must issue a renewed license that supersedes the initial license.

Beginning in late 2001, as a result of the NRC's response to the events of September 11, 2001, the NRC deferred work on a number of NPUF license renewal applications. When the NRC resumed reviewing applications, staff found that licensing documentation had been inconsistently maintained by some licensees, and that not all licensees were staffed to address the scope of the license renewal review or respond to NRC requests for additional information. As a result, delays ensued in the NRC staff's reviews of license renewal applications, the number of unprocessed renewals increased, and the NRC accrued a significant backlog of license renewal applications. The Commission and other stakeholders expressed concerns about the backlog of NPUF license renewal applications and questioned the burdensome nature and efficiency of the renewal process. The Commission issued SRM-M080317B, "Briefing on State of NRC Technical Programs" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML080940439), 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 of license renewal applications for NPUFs in SECY-08-0161, "Review of Research and Test Reactor License Renewal Applications" (ADAMS Accession No. ML082550140). 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 SECY paper considered several options for streamlining the license renewal process, including an option that would permit an extended, or possibly indefinite, license term.

In response to NRC staff recommendations, the Commission issued SRM-SECY-08-0161, "Review of Research and Test Reactor License Renewal Applications" (ADAMS Accession No. ML090850159), in March 2009, which instructed the NRC staff to proceed with several actions. The Commission directed the 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 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. 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 completed a regulatory basis document, "Regulatory Basis to Support Proceeding with Rulemaking to Streamline and Enhance the Research and Test Reactor (RTR) License Renewal Process" (ADAMS Accession No. ML12240A677) in August 2012.¹ 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.

A public meeting was held on August 7, 2014 (ADAMS Accession No. ML15322A400), to discuss the regulatory basis and rulemaking options. Another public meeting was held on October 7, 2015 (ADAMS Accession No. ML15307A110), to afford stakeholders the opportunity to provide feedback and comment on preliminary proposed rule concepts. The participants provided comments and questions to the NRC staff 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 existing license renewal process. The comments were considered in developing this proposed rule.

DISCUSSION:

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) which are not reactors. In order to encompass all affected entities, the NRC staff has changed the title of the rulemaking to the "Non-power Production or Utilization Facility License Renewal Rulemaking."

The proposed rulemaking would:

1. Create a definition for “non-power production or utilization facility,” or “NPUF.” The NRC is proposing to add a specific definition for “non-power production or utilization facility” to 10 CFR 50.2, “Definitions,” to establish a term that is flexible and captures all non-power facilities licensed under § 50.22 or § 50.21(a) or (c), including medical radioisotope irradiation and processing facilities, and research and test reactors. 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). By issuing non-expiring licenses for facilities (other than testing facilities) licensed under § 50.21(a) or (c), the NRC would reduce the burden on qualifying NPUFs (i.e., currently operating research reactors) while continuing to protect public health and safety, promote common defense and security, and protect the environment through regular, existing oversight activities, and the proposed addition of routine FSAR updates. The proposed rule also would make conforming changes to paragraphs (b) and (c) of 10 CFR 50.82, “Termination of license,” where license expiration is used as a reference point. The NRC staff proposes to issue orders following the publication of the final rule to remove license terms from each license. In addition, the orders would establish when the respective licensee’s initial FSAR update would be due to the NRC.
3. Define the license renewal process for testing facilities and NPUFs licensed under 10 CFR 50.22. By defining a license renewal process specific to NPUFs with licenses issued under § 50.22, and testing facilities, in proposed § 50.135, the NRC would consolidate existing requirements for current and future licensees (i.e., requirements regarding written communications, application filing, application contents, and the issuance of renewed licenses) in one section.
4. Require all NPUF licensees to submit routine FSAR updates to the NRC every five years. By requiring periodic updates to the FSAR, the NRC anticipates that licensees would document changes in licensing bases as they occur, which would maintain the continuity of knowledge both for the licensee and the NRC staff and the understanding of changes and effects of changes on the facility. An updated FSAR is important for the NRC’s inspection program and for effective licensee operator training and examinations. The updated FSAR submittal also would enhance the NRC’s continuous oversight of a facility during operation, while imposing a minimal amount of regulation needed to promote common defense and security, protect the health and safety of the public, and permit widespread and diverse research and development.
5. Amend the current timely renewal provision under 10 CFR 2.109, “Effect of timely renewal application,” to allow facilities to continue operating under an existing license past its expiration date if the facility submits a license renewal application at least two years (currently 30 days) before the current license expiration date. Under the proposed rule, if an NPUF subject to license renewal (i.e., licensed under § 50.22 or a testing facility) files a sufficient application for license renewal at least two years (rather than the current 30 days) before the expiration of the existing license, then the existing license will not be deemed to have expired until the application has been finally determined by the NRC. The proposed revision would ensure that the NRC staff has adequate time to

review the sufficiency of a license renewal application while the facility continues to operate under the terms of its current license.

6. Provide an accident dose criterion of 1 rem (0.01 Sv) total effective dose equivalent for NPUFs other than testing facilities. Currently, the NRC applies the standards in 10 CFR part 20, "Standards for Protection Against Radiation," to NPUFs, other than testing facilities, as the accident dose criteria. More specific dose criteria in accident analyses for NPUFs, other than those NPUFs subject to 10 CFR part 100, are needed. Because of an NPUF's low potential radiological risk to the environment and the public, the part 20 public dose limits are unnecessarily restrictive as applied to accident consequences, such as the maximum hypothetical accidents considered in NPUF license renewal applications.² The NRC is proposing to amend its regulations in 10 CFR 50.34, "Contents of applications; technical information," to add accident dose criteria for NPUFs not subject to part 100.
7. Extend the applicability of 10 CFR 50.59, "Changes, tests, and experiments," to NPUFs regardless of their decommissioning status. The proposed rule would revise the wording of § 50.59(b) which currently does not apply to NPUFs whose licenses have been amended to cease operations and no longer have fuel (e.g., have returned all of their fuel to the U.S. Department of Energy). For a licensee that has fuel removed from its site, the NRC is required to add license conditions identical to those of § 50.59 to allow the licensee to make changes to its facility or procedures that would not otherwise require obtaining a license amendment pursuant to § 50.90. The proposed regulatory change would reduce administrative burden on the licensees and the NRC..
8. Clarify an applicant's requirements for meeting the existing provisions of 10 CFR 51.45, "Environmental report." This change would clarify an applicant's requirements for meeting the existing provisions of § 51.45 and improve consistency within and throughout 10 CFR part 51 with respect to environmental report submissions required by applicants for licensing actions. The proposed regulatory requirements would help to ensure that the NRC effectively and efficiently meets its environmental review requirements consistent with the National Environmental Policy Act (NEPA) and the NRC's regulations for implementing NEPA.
9. Eliminate the requirement for NPUFs to submit financial qualification information with license renewal applications under paragraph (f)(2) of 10 CFR 50.33, "Contents of applications; general information." The basis on which the NRC has relied to reduce or eliminate financial qualification requirements on power reactor licensees, supported by the NRC's NPUF inspection and enforcement programs, can similarly be applied as a basis for eliminating NPUF license renewal financial qualification requirements.

A more complete description of the scope of the proposed rulemaking is provided in section III, "Discussion," of the enclosed FRN.

² The NRC Atomic Safety and Licensing Appeal Board has suggested that the standards in part 20 are unduly restrictive as accident dose criteria for research reactors.

Cumulative Effects of Regulation

The NRC staff is following its cumulative effects of regulation process by engaging with external stakeholders throughout this rulemaking and related regulatory activities. During the development of the regulatory basis for the rulemaking, the NRC staff provided the public an opportunity to comment on the draft regulatory basis, "Draft Regulatory Basis for Rulemaking to Streamline Non-Power Reactor License Renewal; Notice of Availability and Solicitation of Public Comments" (published June 29, 2012; ADAMS Accession No. ML12167A383). The NRC staff also held three public meetings that supported the development of the draft regulatory basis document. These meetings were held on September 13, 2011; December 19, 2011; and June 20, 2012.

During the development of the proposed rule language, the NRC staff held public meetings with stakeholders on August 7, 2014 and October 7, 2015 and will be issuing the draft guidance with the proposed rule to support a more informed external stakeholder feedback.

BACKFITTING CONSIDERATIONS:

The NRC's backfitting provisions for reactors are found in 10 CFR 50.109, "Backfitting." The regulatory basis for § 50.109 was expressed solely in terms of nuclear power reactors. For example, the NRC's advance 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" [(48 FR 44217; September 28, 1983), (48 FR 44173; September 28, 1983), (49 FR 47034; November 30, 1984), and (50 FR 38097; September 20, 1985), respectively]. As a result, the NRC has not applied § 50.109 to research reactors, testing facilities, and other non-power facilities licensed under part 50 (e.g., "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)). 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," (77 FR 27561; May 11, 2012)).

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 "NPUF" 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 to NPUFs, the NRC staff 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. This statutory requirement is comparable to the NRC's performance of regulatory analyses because the NRC must consider all costs and benefits of a proposed action before deciding whether to take the action. So, despite not having "minimum amount of regulation" protection, NPUFs licensed under the authority of Section 103 of the AEA receive similar protection as class 104 NPUFs because both classes of licensees fall within the scope of the NRC's regulatory analyses.

RESOURCES:

The NPUF proposed and final rule would require resources in fiscal years 2016 and 2017 in the Operating Reactors Business Line. Detailed resource estimates can be found in Enclosure 4.

RECOMMENDATIONS:

The NRC staff recommends that the Commission approve the enclosed proposed rule notice (Enclosure 1) for publication in the *Federal Register*.

Note the following:

1. The NRC staff has prepared a regulatory analysis for this rulemaking (Enclosure 2).
2. The NRC staff will publish a draft Regulatory Guide (Enclosure 3) for comment concurrent with the publication of the proposed rule.
3. The NRC staff will inform the appropriate congressional committees.
4. The Office of Public Affairs will issue a press release when the NRC publishes the proposed rule in the *Federal Register*.
5. A rulemaking plan was not created because the proposed rulemaking predated the NRC staff's recommendations in SECY-15-0129, "Commission Involvement in the Early Stages of Rulemaking," dated October 19, 2015 (ADAMS Accession No. ML15267A716). The Commission approved NRC staff work on the rulemaking by issuing SRM-M090811, "Staff Requirements Memorandum – Briefing on Research and Test Reactor (RTR) Challenges" (ML092380046).

COORDINATION:

The Office of the General Counsel has no legal objection to this SECY paper and rulemaking package.

Coordination with Advisory Committee on Reactor Safeguards

The NRC staff has met with the Advisory Committee on Reactor Safeguards (ACRS) on March 3, 2016. The ACRS provided a letter dated XXXXX.

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Enclosures:

1. Proposed Rule *Federal Register* Notice
2. Regulatory Analysis
3. Draft Regulatory Guide
4. Resources for the NPUF Rulemaking Activities