

This draft document is being released to support the January 23, 2019, Advisory Committee on Reactor Safeguards Sub-Committee public meeting. The NRC staff is not requesting or accepting public comments on this draft document. This draft document has not been subject to Commission, NRC management, and legal reviews and approvals, and its contents should not be interpreted as official agency positions. Following the public meeting, the NRC staff plans to continue working on this document as well as other documents related to this rulemaking, and subsequently provide the documents to the Commission for approval in mid-2019.

FOR: The Commissioners

FROM: Margaret M. Doane  
Executive Director for Operations

SUBJECT: FINAL RULEMAKING: NON-POWER PRODUCTION OR UTILIZATION  
FACILITY LICENSE RENEWAL (RIN 3150-AI96, NRC-2011-0087)

PURPOSE:

To request Commission approval to publish the enclosed draft final rule that would amend the U.S. Nuclear Regulatory Commission's (NRC's) regulations that govern the license renewal process for certain production or utilization facilities, collectively referred to as non-power production or utilization facilities (NPUFs). This paper does not address any new commitments.

SUMMARY:

The NRC staff proposes to amend the NRC's regulations that govern the license renewal process for non-power reactors or other production or utilization facilities, licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) 50.21(a), 10 CFR 50.21(c), or 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities," that are not nuclear power reactors or production facilities as defined under paragraphs (1) and (2) of the definition of "production facility" in 10 CFR 50.2, "Definitions." The NRC staff collectively refers to these facilities as NPUFs.

The final rule would: (1) eliminate license terms for facilities, other than testing facilities, licensed under 10 CFR 50.21(a) or (c), (2) define the license renewal process for testing facilities and NPUFs licensed under 10 CFR 50.22, (3) require all NPUF licensees to submit to the NRC an updated final safety analysis report (FSAR) and subsequent FSAR updates at intervals not to exceed 5 years, and (4) provide an accident dose criterion of 1 Roentgen

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equivalent man (rem) (0.01 sievert (Sv)) total effective dose equivalent (TEDE) for NPUFs other than testing facilities. The final rule also includes additional changes, as described in the Discussion section.

#### BACKGROUND:

As discussed in Section I, "Background," of the enclosed final rule, the NRC currently licenses NPUFs under the authority granted in Sections 103 and 104 of the Atomic Energy Act of 1954, as amended (AEA). AEA Sections 104a and c (for facilities used for medical therapy and research and development activities) require that the Commission impose only the minimum amount of regulation needed to promote the common defense and security; protect public health and safety; and permit, under Section 104a, the widest possible amount of effective medical therapy and, under Section 104c, widespread and diverse research and development. The NRC regulates 36 NPUFs, of which 31 are currently operating. Two of the five nonoperating facilities have been issued construction permits, and the other three facilities 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 it does not specify license terms for facilities licensed under the authority of Section 104a or c. The regulation that implements this authority, 10 CFR 50.51, "Continuation of license," currently specifies that the NRC may grant an initial license under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," 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, 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, the staff found that some licensees had inconsistently maintained their licensing documentation, and 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. In April 2008, the Commission issued Staff Requirements Memorandum (SRM)-M080317B, "Staff Requirements—Briefing on State of NRC Technical Programs" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML080940439), 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" (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, in March 2009, the Commission issued SRM-SECY-08-0161, "Review of Research and Test Reactor License Renewal Applications" (ADAMS Accession No. ML090850159), 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 on the need for rulemaking and guidance development.

In August 2012, the NRC staff completed "Non-Power Reactor (NPR) License Renewal Rulemaking: Regulatory Basis Document" (ADAMS Accession No. ML12240A677).<sup>1</sup> 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; and other considerations and concluded that a rulemaking was warranted.

A public meeting took place on August 7, 2014 (ADAMS Accession No. ML15322A400), to discuss the regulatory basis and rulemaking options. The NRC staff held another public meeting 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 NRC staff considered the comments in developing the proposed rule.

On March 30, 2017, the NRC published a proposed rule, "Non-Power Production or Utilization Facility License Renewal," in Volume 82 of the *Federal Register* (FR), page 15643 (82 FR 15643). The proposed rule included provisions to eliminate license terms for licenses issued under the authority of Sections 104a or c of the AEA, other than for testing facility licenses; define the license renewal process for licenses issued to testing facilities or under the authority of Section 103 of the AEA except for power reactor licenses; require all NPUF licensees to submit an updated FSAR and subsequent FSAR updates to the NRC at intervals not to exceed 5 years; and provide an accident dose criterion of 1 rem (0.01 Sv) TEDE for NPUFs other than testing facilities. The NRC also asked the public to provide feedback on specific questions, including questions concerning the criteria, other than power level, to use when determining the applicability of requirements for low-risk commercial production or utilization facilities and low-risk testing facilities. The NRC provided a public comment period of 75 days to review and comment on the proposed rule and associated guidance. In response to publication of the proposed rule and draft regulatory guide, the NRC received 16 comment

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<sup>1</sup> 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 staff has changed the title of the rulemaking to the "Non-power Production or Utilization Facility License Renewal Rulemaking."

submissions. The NRC staff analyzed, summarized, and responded to the public comments received in order to formulate the final rule (ADAMS Accession No. ML18031A005).

## DISCUSSION:

The final rule will do the following:

- (1) Create a definition for “non-power production or utilization facility” and revise the definitions for “non-power reactor,” “research reactor,” and “testing facility.” The NRC staff is adding a specific definition for “non-power production or utilization facility” to 10 CFR 50.2 to establish a term that is flexible and captures all non-power facilities licensed under 10 CFR 50.22 or 10 CFR 50.21(a) or (c), such as medical radioisotope irradiation and processing facilities, research reactors, and testing facilities, none of which are production facilities as defined under paragraphs (1) and (2) of the definition of “production facility” in 10 CFR 50.2. The final rule will revise the definitions of “research reactor” and “testing facility” to reflect a risk-informed, performance-based approach that relies on postulated accident dose rather than the power level of the reactor to distinguish between research reactors and testing facilities. The final rule also will make conforming changes to the definition of “non-power reactor” and in other sections to refer to the new and revised definitions.

The changes to the definitions of “non-power reactor,” “research reactor,” and “testing facility” necessitate clarity in certain uses of these terms in existing NRC documentation, such as Commission papers (SECYs), Staff Requirements Memoranda (SRMs), and NRC guidance documents. Similar to the NRC’s regulations, NRC documents typically refer to most non-power entities licensed under 10 CFR Part 50 as non-power reactors, research reactors, and test reactors. Under this final rule, these entities will have new definitions and generically be more appropriately categorized as NPUFs. It is unnecessarily burdensome to identify and change all of the guidance document references at this time solely to add, correct, or standardize the terminology and definitions. Instead, the staff intends to make these changes in the normal course of required guidance updates, with the understanding that the definitions in the regulations establish the meaning of these terms in the guidance documents.

In SRM-SECY-06-0111, “Staff Recommendations Regarding Security at Research and Test Reactors,” dated June 30, 2006 (ADAMS Accession No. ML061810214, non-publicly available), the Commission directed the Office of Nuclear Reactor Regulation (NRR) to be “the lead for RTR [research and test reactor] responsibilities, including physical security for RTRs” and that the staff “should transfer these functions from the Office of Nuclear Security and Incident Response (NSIR) to NRR.” With the implementation of the term “non-power production or utilization facility,” and the fact that RTRs are a subset of NPUFs, the staff will extend physical security oversight by NRR to all NPUFs, including non-power production facilities such as SHINE Medical Technologies, Inc., the 31 currently operating research reactors and testing facilities, and any future NPUF. Furthermore, references to non-power reactors, research reactors, and test reactors in previous SECYs and SRMs will be read to mean, where appropriate, non-power production or utilization facilities, non-power reactors, research reactors, and testing facilities as defined in the final rule, to ensure the proper implementation of these SRMs.

- (2) Eliminate license terms for facilities licensed under 10 CFR 50.21(a) or (c), other than testing facilities. By issuing non-expiring licenses for facilities licensed under 10 CFR 50.21(a) or (c), other than testing facilities, the NRC will reduce the burden on qualifying NPUFs (i.e., currently operating research reactors) while continuing to protect public health and safety, promote the common defense and security, and protect the environment through regular, existing oversight activities and the addition of routine updated FSAR and subsequent FSAR update submittals. The final rule also will make conforming changes to 10 CFR 50.82(b) and (c), which use license expiration as a reference point. The NRC will issue orders following the publication of the final rule to remove license terms from each eligible license. In addition, the orders will establish when the respective licensee's initial updated FSAR will be due to the NRC.

Although the AEA does not establish a fixed license term for testing facilities, these facilities are currently subject to additional mandatory regulatory requirements (e.g., public hearings, Advisory Committee on Reactor Safeguards (ACRS) review, and preparation of environmental impact statements) to which research reactors are not necessarily subject. Testing facilities have higher potential radiological consequences of accidents, or a design, operation, or use and associated risk that warrants classification as a testing facility. For these reasons, this final rule maintains the requirement for testing facilities to be subject to license renewal.

- (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 10 CFR 50.22 and testing facilities in 10 CFR 50.135, "Renewal of non-power production or utilization facility licenses issued under § 50.22 and testing facility licenses," the NRC will consolidate existing requirements for current and future licensees (i.e., requirements for written communications, application filing, application contents, and the issuance of renewed licenses) in one section.
- (4) Require all NPUF licensees to submit an updated FSAR and subsequent FSAR updates to the NRC at intervals not to exceed 5 years. Within 5 years of the issuance of the final rule or the date of issuance of an operating license, licensees will be required to submit an updated FSAR that is a complete updated document that can then serve as the baseline for future changes. By requiring periodic submittals of subsequent FSAR updates, the NRC anticipates that licensees will document changes in licensing bases as they occur, which will maintain the continuity of knowledge both for the licensee and the NRC and the understanding of changes and effects of changes on the facility. Maintaining up-to-date FSARs is important for licensees to manage their facilities safely, including changes in the licensing bases and training of personnel, and for the NRC to effectively fulfill its statutory obligations and regulatory responsibilities.
- (5) Amend the current timely renewal provision under 10 CFR 2.109, "Effect of timely renewal application," to allow NPUFs licensed under 10 CFR 50.22 and testing facilities licensed under 10 CFR 50.21(c) or 10 CFR 50.22 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. If an NPUF subject to license renewal (i.e., licensed under 10 CFR 50.22, or a testing facility) files a sufficient application for license renewal at least 2 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 NRC has made a final determination regarding the application. The final rule will ensure that the NRC has adequate time to review the

- sufficiency of the 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) TEDE for NPUFs other than testing facilities. Currently, the accident dose criterion for NPUFs other than testing facilities is the dose limit to a member of the public in 10 CFR Part 20, “Standards for Protection Against Radiation.” The NRC staff has determined that the public dose limit of 0.1 rem (0.001 Sv) TEDE is unduly restrictive to be applied as an accident dose criterion for NPUFs, other than those NPUF licensees subject to 10 CFR Part 100, “Reactor Site Criteria.”<sup>2</sup> The final rule will amend 10 CFR 50.34, “Contents of applications; technical information,” to add an accident dose criterion for NPUF licensees not subject to 10 CFR Part 100.
  - (7) Extend the applicability of 10 CFR 50.59, “Changes, tests, and experiments,” to NPUF licensees regardless of their decommissioning status. The final rule will revise the wording of 10 CFR 50.59(b), which currently does not apply 10 CFR 50.59 to NPUF licensees whose licenses have been amended to cease operations and that no longer have fuel at their site (e.g., have returned all of their fuel to the U.S. Department of Energy). For such a licensee, the NRC must add license conditions identical to those of 10 CFR 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 10 CFR 50.90, “Application for amendment of license, construction permit, or early site permit.” The regulatory change will 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 will clarify an applicant’s requirements for meeting the existing provisions of 10 CFR 51.45 and improve consistency throughout 10 CFR Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,” with respect to environmental report submissions required from applicants for licensing actions. The final rule will assist the NRC to effectively and efficiently meet its environmental review requirements consistent with the National Environmental Policy Act of 1969 (NEPA) and the NRC’s regulations for implementing NEPA.
  - (9) Eliminate the requirement for NPUF licensees to submit financial qualification information with license renewal applications under 10 CFR 50.33(f)(2). The NRC’s basis for reducing financial qualification requirements for power reactor licensees, that there is not a consistent correlation between licensees’ poor financial health and poor safety performance, can be applied similarly as a basis for eliminating NPUF license renewal financial qualification requirements. The NRC’s NPUF inspection and enforcement programs will remain in place to evaluate licensee safety performance.

Section II, “Discussion,” of Enclosure 1 provides a more complete description of the scope of the final rule.

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<sup>2</sup> The NRC Atomic Safety and Licensing Appeal Board has suggested 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)).

## Process to Change License Type for Non-power Reactors

Based on the draft final rule's revised definitions of "testing facility" and "non-power reactor" in 10 CFR Part 50, including the criteria for a research reactor, some existing licensees may seek to convert their license types (e.g., from a testing facility to a research reactor to reduce their regulatory burden). The draft final rule does not include any specific changes to regulations to define a process for converting license types because the staff expects very few licensees will request such a change. Even so, the staff will add a section to this paper to describe the administrative process that will be used to change a non-power reactor license from one type to another.

## Significant Changes from the Proposed Rule to the Final Rule

The staff made significant changes in the draft final rule as a result of public comments and other considerations. The draft final rule differs from the proposed rule as follows:

- The NRC received public comments on the proposed definition of "non-power production or utilization facility." In reviewing the comments, the NRC identified that the proposed definition for "non-power production or utilization facility" was too broad for defining production facilities that are NPUFs. Previously, the definition excluded fuel reprocessing plants, but it did not address a needed exclusion for a production facility designed or used primarily for the formation of plutonium or uranium-233 or designed or used for the separation of the isotopes of plutonium. Accordingly, the final rule revises the definition for "non-power production or utilization facility" to exclude all production facilities as defined under paragraphs (1) and (2) of the definition of "production facility" in 10 CFR 50.2.
- The NRC also received a public comment on the definitions of "testing facility" in 10 CFR 50.2 and "research reactor" in 10 CFR 171.11(b)(2). The commenter recommended that the NRC revise the definitions of "testing facility" and "research reactor" by removing "the arbitrary 10MW(t) threshold, and apply instead a risk-based approach to its regulation of a testing facility." The NRC staff agreed that the use of a postulated accident dose is a more risk-informed, performance-based approach than the use of the reactor power level to distinguish between types of NPUFs, such as research reactors and testing facilities. As a result of this public comment, the NRC revised the definitions of "testing facility" in 10 CFR Parts 50, 140, 170, and 171, and "research reactor" in 10 CFR Parts 170 and 171, to reflect this risk-informed approach. The final rule also revises the definition of "non-power reactor" and makes conforming changes to the definitions of "research reactor" and "testing facility."
- The NRC staff also made conforming changes to the definitions of "testing facility," "research reactor," and "non-power reactor" wherever these definitions appear throughout 10 CFR Chapter I. Currently, the regulations refer to many types of facilities that are categorized as NPUFs in the final rule, such as non-power reactor, research reactor, training reactor, testing reactor, testing facility, and critical assembly. The NRC staff reviewed each instance of these various terms in 10 CFR Chapter I. Where appropriate, the NRC staff added, corrected, or standardized the terminology and definitions (e.g., replacing the term "test reactor" with "testing facility" in 10 CFR 171.15, "Annual fees: Reactor licenses and independent spent fuel storage licenses"). Additionally, the final rule standardizes the terminology in other parts of the regulations,

where appropriate, to modify the intended scope of regulations by citing “research and test reactors” to be either “non-power reactors” or “non-power production or utilization facilities.”

- The staff modified the language in 10 CFR 50.135 to make renewed operating licenses effective immediately upon the date of issuance, replacing the previous operating license. The immediate effectiveness of the renewed license is a change from the proposed rule, which would have made the renewed license effective 30 days after issuance. An applicant for the renewed license can propose a schedule for implementation of the renewed license to the extent that the applicant needs additional time to make any necessary and conforming changes to the facility processes and procedures required by the applicable conditions of the renewed license. The NRC will review and, upon approval, make the implementation schedule a condition of the renewed license. The final rule provides a substantially similar result as the proposed rule and gives licensees potentially greater flexibility in the timing of their implementation of the renewed license.
- The staff modified the language in 10 CFR 50.135(e)(2) because the proposed rule could have unnecessarily restricted the license term for a renewed NPUF license to less than 40 years. Section 103 of the AEA allows for license terms of up to 40 years. The final rule will maintain this allowance.
- The staff modified the language in 10 CFR 2.109(a) because the proposed rule would have eliminated the timely renewal provision for facilities, other than testing facilities, licensed under 10 CFR 50.21(a) or (c), as these facilities will no longer have license expiration dates. However, the final rule includes the timely renewal provision for facilities, other than testing facilities, licensed under 10 CFR 50.21(a) or (c) because at least one of these facilities may submit a license renewal application after the final rule is published.
- The staff moved 10 CFR 50.34(a)(1)(ii)(D)(2) to 10 CFR 50.34(a)(1)(i) and new 10 CFR 50.34(b)(13). During the development of the final rule, the staff recognized that the accident dose criterion more appropriately belongs in 10 CFR 50.34(a)(1)(i) because the requirements in 10 CFR 50.34(a)(1)(ii) apply to power reactor construction permit applicants, while the requirements in 10 CFR 50.34(a)(1)(i) apply to all other construction permit applicants, such as NPUF applicants. Similarly, proposed 10 CFR 50.34(a)(1)(ii)(D)(2) would have imposed a requirement on applications for renewed NPUF operating licenses, which more appropriately belongs in 10 CFR 50.34(b). Therefore, the NRC staff also added 10 CFR 50.34(b)(13) to clarify that an application for an operating license or a renewed operating license for an NPUF include a final evaluation of the applicable radiological consequences in 10 CFR 50.34(a)(1)(i).

### Regulatory Analysis

The staff prepared a regulatory analysis to determine anticipated quantitative costs and benefits of the draft final rule. In particular, the regulatory analysis evaluates the costs and benefits associated with new and revised requirements. Relative to the no action baseline, the NRC estimates that total net benefits to NPUFs (i.e., cost savings minus costs) will be \$5.5 million (\$2.6 million using a 7-percent discount rate and \$3.9 million using a 3-percent discount rate)



over a 20-year period. The NRC will incur total net benefits of \$12 million (\$5.9 million using a 7-percent discount rate and \$8.6 million using a 3-percent discount rate) over a 20-year period. The net benefit estimates are higher for the final rule relative to the proposed rule for the following three reasons:

- (1) The NRC issued construction permits to SHINE Medical Technologies, Inc., on February 29, 2016 (ADAMS Accession No. ML16041A471), and Northwest Medical Isotopes on May 9, 2018 (ADAMS Accession No. ML18037A468). The scope of the proposed rule's regulatory analysis did not include these construction permit holders. The final rule's regulatory analysis accounts for the rule's impact on these two construction permit holders.
- (2) Since 2017, the NRC completed reviews of additional license renewal applications. The final rule's regulatory analysis accounts for the additional data on the costs associated with the license renewal process.
- (3) The NRC staff adjusted assumptions related to the timing and level of effort associated with the submittal of updated FSARs and subsequent FSAR updates.

### 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. When the NRC issued the proposed rule, the agency provided a 75-day period to review and comment on the proposed rule. The NRC also issued the draft guidance for public comment at the same time as the March 2017 proposed rule. The NRC staff engaged external stakeholders at public meetings and by soliciting public comments on the proposed rule and associated draft guidance document. A public meeting took place on May 24, 2017, to discuss the proposed rule (see the meeting summary at ADAMS Accession No. ML17170A066). A public meeting on the implementation schedule of the draft final rule took place on February XX, 2019 (see the meeting summary at ADAMS Accession No. MLXXXXXXXXXX). The feedback from these public meetings informed the NRC staff's recommended schedule for implementation of the final rule.

A fundamental means of addressing the cumulative effects of the regulation, as discussed in SRM-SECY-11-0032, "Staff Requirements—SECY-11-0032—Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," dated October 11, 2011 (ADAMS Accession No. ML112840466), is to issue the final guidance with the final rule and thus support effective implementation. The staff has prepared Regulatory Guide 2.7, Revision 0, "Preparation of Updated Final Safety Analysis Reports for Non-Power Production or Utilization Facilities" (ADAMS Accession No. ML18031A007), and will publish the regulatory guide simultaneously with the final rule.

### Backfitting Considerations

The NRC's backfitting provisions for reactors are found in 10 CFR 50.109, "Backfitting." The regulatory basis for 10 CFR 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 10 CFR 50.109 each had the same title: "Revision of Backfitting Process for Power Reactors." As a result, the NRC has not applied 10 CFR 50.109 to research reactors, testing facilities, and other non-power facilities licensed under 10 CFR Part 50 (e.g., "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 10 CFR 50.2, the NRC defines “non-power production or utilization facilities” to include non-power reactors or other production or utilization facilities licensed under 10 CFR 50.21(a) or (c) (Section 104a or c of the AEA) or 10 CFR 50.22 (Section 103 of the AEA) that are not nuclear power reactors or production facilities as defined under paragraphs (1) and (2) of the definition of “production facility” in 10 CFR 50.2. Because the term “non-power production or utilization facility” includes licensees that are excluded from the scope of 10 CFR 50.109, NPUFs do not fall within the scope of 10 CFR 50.109. Because 10 CFR 50.109 does not apply to NPUFs, and this final rule applies exclusively to NPUFs, the NRC did not apply 10 CFR 50.109 to this final rule.

Although 10 CFR 50.109 does not apply to NPUF licensees, 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 public health and safety, and permit the conduct of widespread and diverse research and development and the widest amount of effective medical therapy possible. The draft final rule would meet this standard by removing license renewal requirements for many entities licensed under Section 104 of the AEA, defining the license renewal process for testing facilities licensed under Section 104 of the AEA, and eliminating the requirement for testing facilities to submit financial qualification information at the time of license renewal.

#### RECOMMENDATIONS:

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

Note the following:

- The NRC staff has prepared a regulatory analysis for this rulemaking (Enclosure 2).
- The NRC staff will publish a regulatory guide simultaneously with the publication of the final rule.
- The NRC staff will inform the appropriate Congressional committees.
- The NRC Office of Public Affairs will consider issuing a press release when the NRC publishes the final rule in the *Federal Register*.
- This final rule will have no significant impact on small entities. Only one<sup>3</sup> out of 36 NPUFs has been classified as a “small entity” which is not a substantial number of small entities.

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<sup>3</sup> “Aerotest Fee Waiver Response To Request Dated July 16, 2018” (ADAMS Accession No. ML18268A345).

RESOURCES:

The NPUF rulemaking is budgeted in the Operating Reactors Business Line. There is no need to change the budgeted resources as a result of this paper.

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 met with the ACRS on February 7, 2019. The ACRS provided a letter dated YYYYYX, 2019, ....

Margaret M. Doane  
Executive Director  
for Operations

Enclosures:

1. Draft Final Rule *Federal Register* Notice
2. Regulatory Analysis
3. Environmental Assessment

**SUBJECT: FINAL RULE— NON-POWER PRODUCTION OR UTILIZATION FACILITY  
 LICENSE RENEWAL (RIN 3150-AI96, NRC-2011-0087) DATED: XXX YY, 2019**

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 SECY: ML18031A001  
 FRN: ML18031A002  
 RA: ML18031A003  
 EA: ML18031A004

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<b>OFFICE</b>	NMSS/DRM/RRPB: PM	QTE*	NMSS/DRM/RRPB: RS	NMSS/DRM/RRPB: BC*
<b>NAME</b>	RBeall	KAzariah-Kribbs	GLappert	MKhanna
<b>DATE</b>	11/28/2018	12/03/2018	01/07/2019	
<b>OFFICE</b>	NRR/DLP/PRLB: BC	RES/DE/ RGGIB: BC*	NMSS/DRM/RASB: BC*	NRR/DLP/PFPB: BC*
<b>NAME</b>	AAdams	TBoyce	CBladey	ABowers
<b>DATE</b>				
<b>OFFICE</b>	NMSS/DRM: D*	RES/DE: D*	NRO/DLSE: D*	NRR/DLP: D*
<b>NAME</b>	PHolahan	BThomas	RTaylor	LLund
<b>DATE</b>				
<b>OFFICE</b>	NRR/DRA: D*	NRR/DMLR: D*	OCIO/CSD/FPIB: TL*	OGC (NLO)*
<b>NAME</b>	MFranovich	GWilson	DCullison	HBenowitz
<b>DATE</b>				
<b>OFFICE</b>	NRR: D*	EDO		
<b>NAME</b>	HNieh	MDoane		
<b>DATE</b>				

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