



## RULEMAKING ISSUE (Affirmation)

June 17, 2019

SECY-19-0062

FOR: The Commissioners

FROM: Margaret M. Doane  
Executive Director for Operations

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

PURPOSE:

In this paper, the staff requests 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).

SUMMARY:

The final rule would amend the NRC's regulations that govern the license renewal process for non-power reactors and certain other production or utilization facilities collectively referred to as NPUFs. These facilities are licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.21, "Class 104 licensees; for medical therapy and research and development facilities," paragraphs (a) and (c) or 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities." This category of facilities does not include 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."

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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 NPUFs (including testing facilities) licensed under 10 CFR 50.22 and testing facilities licensed under 10 CFR 50.21(c); (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 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:

The NRC licenses NPUFs under the authority granted in Sections 103 and 104 of the Atomic Energy Act of 1954, as amended (AEA). Section 103 of the AEA applies to commercial or industrial facilities, Section 104a of the AEA applies to facilities used for medical therapy, and Section 104c of the AEA applies to facilities useful in the conduct of research and development activities. Furthermore, Sections 104a and 104c of the AEA 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 research reactors or testing facilities currently licensed to operate. Two of the five remaining facilities have been issued construction permits (SHINE Medical Technologies, Inc. and Northwest Medical Isotopes, LLC), and the other three facilities are in the process of decommissioning. The NRC regulates one operating testing facility at the National Institute of Standards and Technology.

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 renewed by amendment. Rather, 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 provided inconsistent 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, 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), and directed the 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 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). The paper discussed stakeholder feedback on the current process and provided options for streamlining and improving the review process, including an option that would permit an extended, or possibly indefinite, license term.

In March 2009, the Commission issued SRM-SECY-08-0161, "Review of Research and Test Reactor License Renewal Applications" (ADAMS Accession No. ML090850159), in which it instructed the 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 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 staff completed the "Non-Power Reactor (NPR) License Renewal Rulemaking: Regulatory Basis Document" (ADAMS Accession No. ML12240A677).<sup>1</sup> The staff analyzed, in the regulatory basis, 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. The staff concluded that a rulemaking was warranted.

The NRC held a public meeting on August 7, 2014 (ADAMS Accession No. ML15322A400), to discuss the regulatory basis and rulemaking options, and a second 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. Participant comments and questions focused on the potential impact of eliminating license terms, the scope of review under the new process, and how the amended regulation would work compared to the existing license renewal process. The staff considered the comments when developing the proposed rule.

On March 30, 2017, the NRC published the proposed rule, "Non-Power Production or Utilization Facility License Renewal" (82 FR 15643). The NRC proposed to eliminate license terms for facilities used for medical therapy or research and development licensed under the authority of Sections 104a or c of the AEA, other than for testing facilities. Other proposed amendments addressed the license renewal process for licenses issued to testing facilities and licenses issued to non-power commercial or industrial facilities under the authority of Section 103 of the AEA. The proposed rule also included a provision to require all NPUF licensees to submit an updated FSAR and subsequent FSAR updates to the NRC at intervals not to exceed 5 years.

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<sup>1</sup> At the time of publication of the regulatory basis, the action was titled "Non-Power Reactor (NPR) License Renewal Rulemaking." During the development of the proposed rule, the scope of the rulemaking expanded to include licenses for certain facilities that are not reactors, based upon recent license applicants (e.g., for medical radioisotope irradiation and processing facilities). In order to encompass all affected entities, the staff retitled the rulemaking to "Non-power Production or Utilization Facility License Renewal."

The NRC also proposed an accident dose criterion of 1 rem (0.01 Sv) TEDE for NPUFs other than testing facilities. The NRC requested public feedback on specific questions, including questions concerning the criteria, other than power level, to use when determining the applicability of requirements for low-risk commercial production or utilization facilities and low-risk testing facilities. The proposed rule provided a public comment period of 75 days. The NRC received 16 comment submissions on the proposed rule and draft implementation guidance. The staff summarized and analyzed public comments and used this input to formulate the draft final rule.

#### DISCUSSION:

The final rule would 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 rule would add 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 (commercial or industrial facilities) or 10 CFR 50.21(a) or (c) (medical therapy or research and development facilities) that are not production facilities as defined under paragraphs (1) and (2) of the definition of "production facility" in 10 CFR 50.2. Examples of these facilities include medical radioisotope irradiation and processing facilities, research reactors, and testing facilities. The final rule would 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 would also make conforming changes to the definition of "non-power reactor" to refer to the new and revised definitions.

The changes to the definitions of "non-power reactor," "research reactor," and "testing facility" could create confusion in the uses of these terms in existing NRC documentation, such as Commission papers, 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, or test reactors. Under this final rule, these entities will have new definitions and generically be categorized as NPUFs. It is unnecessarily burdensome to identify and change all existing 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 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 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 intends to extend physical security oversight conducted by NRR to all NPUFs, including non-power production facilities such as SHINE Medical Technologies, Inc., the 31 research reactors and testing facilities currently licensed to operate, and any future NPUF. Furthermore, references to

non-power reactors, research reactors, and test reactors in previous Commission papers and SRMs will mean, where appropriate, NPUFs, 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 would reduce the burden on qualifying NPUFs (i.e., research reactors currently licensed to operate), while continuing to protect public health and safety, promote the common defense and security, and protect the environment. This would be achieved through regular, existing oversight activities and the additional requirement for routine updated FSAR and subsequent FSAR update submittals. The final rule would also make conforming changes to 10 CFR 50.82(b) and (c) where license expiration is currently used as a reference point.

The NRC would issue orders following the publication of the final rule to remove license terms from each eligible license. In addition, the orders would establish a date for 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 currently are subject to additional regulatory controls by means of public hearings, Advisory Committee on Reactor Safeguards (ACRS) review, and environmental review, which do not necessarily apply to research reactors. Compared to a research reactor, testing facilities have the potential for higher radiological consequences of accidents, or higher radiological risks associated with their design, operation, or use, which warrant classification as a testing facility and the associated regulatory controls. For these reasons, the final rule would maintain the requirement for testing facilities to be subject to license renewal, regardless of whether they are commercial facilities licensed under 10 CFR 50.22 or facilities used for research and development licensed under 10 CFR 50.21(c).

- (3) Define the license renewal process for NPUFs (including testing facilities) licensed under 10 CFR 50.22 and testing facilities licensed under 10 CFR 50.21(c). The final rule would define a license renewal process specific to all commercial or industrial NPUFs (including testing facilities) with licenses issued under 10 CFR 50.22 and testing facilities with licenses issued under 10 CFR 50.21(c). This process would be defined in 10 CFR 50.135, "Renewal of non-power production or utilization facility licenses issued under § 50.22 and testing facility licenses." This new section would consolidate existing requirements for current and future licensees (i.e., requirements for written communications, application filing, application content, and the issuance of renewed licenses).
- (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, each NPUF licensee would be required to submit a complete updated FSAR. This document would serve as the baseline for future changes. By requiring periodic submittals of subsequent FSAR updates, the NRC anticipates that licensees will document changes in their licensing bases as they occur. This practice would maintain continuity of knowledge about the licensing basis both for the licensee and the NRC, and support for understanding the changes in the licensing basis and the effects of these changes on the facility would be

significantly improved. Maintaining up-to-date FSARs is important because it enables licensees to manage their facilities in accordance with the licensing bases, including changes to the licensing bases, and enables licensees to properly train personnel in accordance with up-to-date licensing bases. Maintaining up-to-date FSARs also enables 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 an NPUF subject to license renewal to continue operating under an existing license past its expiration date if the licensee submits a license renewal application at least 2 years before the current license expiration date. If an NPUF subject to license renewal (i.e., a commercial or industrial NPUF (including a testing facility) licensed under 10 CFR 50.22 or a testing facility licensed under 10 CFR 50.21(c)) 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 that are not testing facilities is the dose limit to a member of the public in 10 CFR Part 20, "Standards for Protection Against Radiation." Testing facilities, in contrast, are subject to 10 CFR Part 100, "Reactor Site Criteria." The staff has determined that the public dose limit of 0.1 rem (0.001 Sv) TEDE in 10 CFR Part 20 is unduly restrictive when applied as an accident dose criterion for NPUFs that are not testing facilities.<sup>2</sup> The final rule would 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 would revise 10 CFR 50.59(b). Currently, 10 CFR 50.59 does not apply to an NPUF licensee if its license has been amended to cease operations and the licensee no longer has fuel at the site (e.g., has returned the fuel to the U.S. Department of Energy). Under these circumstances, the NRC has typically added license conditions identical to the provisions 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." Extending the applicability of 10 CFR 50.59 would reduce administrative burden on the licensees and the NRC, while still ensuring public health and safety.
- (8) Clarify an applicant's requirements for meeting the existing provisions of 10 CFR 51.45, "Environmental report." The final rule would 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

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

Related Regulatory Functions,” with respect to environmental report submissions required from applicants for licensing actions. The final rule would assist the NRC in effectively and efficiently meeting 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 an NPUF licensee to submit financial qualification information with a license renewal application under 10 CFR 50.33(f)(2). For power reactor licensees, the NRC has already eliminated requirements to provide financial qualification information with a license renewal application, as there is not a consistent correlation between a licensee’s financial health and safety performance. The same basis justifies the staff’s proposal to eliminate the NPUF license renewal financial qualification information requirements. The NRC’s NPUF inspection and enforcement programs will remain in place to evaluate licensee safety performance. The Commission retains broad authority under the AEA and NRC regulations at 10 CFR 2.102, “Administrative review of application,” 10 CFR 50.54(f), and 10 CFR 50.54(cc) to request additional financial information from its licensees and applicants as necessary to protect public health and safety.

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

The staff made various changes as a result of public comments and other considerations, as follows:

- The NRC received public comments on the proposed definition of “non-power production or utilization facility.” In reviewing the comments, the staff determined that the proposed definition for “non-power production or utilization facility” was too broad for defining production facilities that are NPUFs. As proposed, the definition excluded fuel reprocessing plants, but did not exclude production facilities designed or used primarily for the formation of plutonium or uranium-233 or designed or used for the separation of the isotopes of plutonium. Accordingly, the definition in the final rule for “non-power production or utilization facility” would exclude all production facilities as defined under paragraphs (1) and (2) of the definition of “production facility” in 10 CFR 50.2.
- The NRC received a 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 10 MW(t) threshold, and apply, instead, a risk-based approach to its regulation of a testing facility.” The 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. As a result of this comment, the final rule would reflect this approach in revised definitions of “testing facility” and “research reactor.”<sup>3</sup> The final rule would also revise the definition of “non-power reactor” and make conforming changes to the definitions of “research reactor” and “testing facility.”

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<sup>3</sup> The definition of “testing facility” appears in 10 CFR Part 50; 10 CFR Part 140, “Financial Protection Requirements and Indemnity Agreements”; 10 CFR Part 170, “Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended”; and 10 CFR Part 171, “Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC.” The definition of “research reactor” appears in 10 CFR Parts 170 and 171.

- The staff 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 staff reviewed each instance of these various terms in 10 CFR Chapter I. Where appropriate, the 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 would standardize the terminology in other parts of the regulations, where appropriate, to modify the intended scope of regulations by changing “research and test reactors” to either “non-power reactors” or “non-power production or utilization facilities.”

However, the final rule would not change the definitions of “research reactor” in the specific exemptions for Federally-owned and State-owned research reactors in 10 CFR 170.11(a)(9) or 10 CFR 171.11(b)(2). Those definitions rely, in part, on reactor power level distinctions. The definition in 10 CFR 171.11(b)(2) is based on the language of the Omnibus Budget Reconciliation Act of 1990, as amended (OBRA-90).<sup>4</sup> Further, a substantively similar definition of “research reactor” was included in the provisions of the Nuclear Energy Innovation and Modernization Act (NEIMA) that relate to the NRC’s fee recovery structure.<sup>5</sup> Changing the definition of “research reactor” in 10 CFR 171.11(b)(2) would therefore be inconsistent with OBRA-90 and NEIMA. The definition of “research reactor” in 10 CFR 170.11(a)(9) is not based on OBRA-90, but the basis for that exemption from fees parallels the basis for the exemption from annual fees in 10 CFR 171.11(b)(2). Changing the definition of “research reactor” in 10 CFR 170.11(a)(9) would be a substantive change beyond the scope of the final rule.

- The NRC’s proposed rule would have made a renewed license effective 30 days after its issuance. The staff modified the language in proposed 10 CFR 50.135 to make renewed operating licenses effective, and thereby replace the previous operating license, immediately upon the date of 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 would review this proposal and, if approved, make the implementation schedule a condition of the renewed license. The final rule provides a substantially similar result as the proposed rule, but would give a licensee 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 would maintain this allowance.
- The proposed rule would have eliminated the timely renewal provision in 10 CFR 2.109(a) for medical therapy or research and development facilities, other than

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<sup>4</sup> Pub. L. No. 101-508, section 6101(c)(4).

<sup>5</sup> Pub. L. No. 115-439, section 102(b)(3)(D)(i).



testing facilities, licensed under 10 CFR 50.21(a) or (c), because these facilities will no longer have license expiration dates. The NRC reinstated the provision in the final rule to enable its use for the remaining license renewal applications that may be submitted after the final rule is published. The staff anticipates that there is one research reactor that would use this provision.

- The staff moved 10 CFR 50.34(a)(1)(ii)(D)(2) to 10 CFR 50.34(a)(1)(i) and added 10 CFR 50.34(b)(13). During the development of the draft 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 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 must include a final evaluation of the applicable radiological consequences in 10 CFR 50.34(a)(1)(i).

#### Nuclear Energy Innovation and Modernization Act

In section 106 of NEIMA, Congress changed the framework by which the NRC determines whether a utilization facility is licensed under section 103 or 104c of the AEA. The new law amended section 104c of the AEA in two ways. First, it removed the words "and which are not facilities of the type specified in subsection 104 b." This deletion would require revising 10 CFR 50.21(c) to remove the reference to 10 CFR 50.21(b). Second, NEIMA included cost recovery requirements to determine whether a utilization facility is licensed for research and development purposes or industrial or commercial purposes. Before January 14, 2019, the AEA did not limit how these utilization facilities recovered money from commercial activities. The current 10 CFR 50.22 considers the amount of money a production or utilization facility spends on commercial activities. Under the current 10 CFR 50.22, a production or utilization facility is licensed for industrial or commercial purposes under section 103 of the AEA if more than 50 percent of the annual cost of owning and operating the facility is devoted to commercial activities. If less than 50 percent of the annual cost of owning and operating the facility is devoted to commercial activities, then the facility is licensed under section 104c of the AEA.

Section 106 of NEIMA changed section 104c of the AEA to focus on how the facility's costs are recovered. Specifically, the NRC is now authorized to issue a license under section 104c of the AEA to a utilization facility that recovers up to 75 percent of the annual costs to the licensee of owning and operating the facility through commercial activities or recovers up to 50 percent of annual costs through sales of energy to others.

To implement this revised licensing authority, the NRC will apply the new cost recovery requirements in section 104c of the AEA to research reactors that are currently in the license renewal process and any future applicable new or renewed license applicants. The changes made to section 104c of the AEA by NEIMA did not address the applicability of the cost recovery requirements for current utilization facilities that are not in the license renewal process and will not undergo license renewal as a result of this final rule (i.e., they will have non-expiring licenses), but to which the new authority otherwise applies. The NRC could apply the new cost recovery requirements to these licensees or continue to apply the current requirements in 10 CFR 50.22 to these licensees. At this time, the NRC staff does not have sufficient information

to make a recommendation regarding whether to apply the cost recovery requirements to these licensees. The staff intends to seek input from the public and regulated community to inform its recommendation to the Commission. Addressing this issue will likely warrant a standalone rulemaking to, at a minimum, conform 10 CFR 50.22 to NEIMA. The staff will provide the Commission with recommendations by April 1, 2020.

### Regulatory Analysis

The staff prepared a regulatory analysis to evaluate the costs and benefits of the draft final rule. In particular, the regulatory analysis quantifies 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) would be \$5.5 million (\$3.9 million using a 3-percent discount rate or \$2.6 million using a 7-percent discount rate) over a 20-year period. The NRC would receive total net benefits of \$12 million (\$8.6 million using a 3-percent discount rate or \$5.9 million using a 7-percent discount rate) over a 20-year period. The net benefit estimates are higher for the draft 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, LLC on May 9, 2018 (ADAMS Accession No. ML18037A468). The proposed rule's regulatory analysis did not address these construction permit holders. The final rule's regulatory analysis accounts for the rule's effects on these two construction permit holders.
- (2) Since the 2017 publication of the proposed rule, the NRC completed reviews of additional license renewal applications. The cost data associated with these actions is more current, and thus more likely represents actual costs than the data in the proposed rule's regulatory analysis. The final rule's regulatory analysis incorporates this recent cost data.
- (3) The staff adjusted assumptions related to the timing and level of effort associated with the submittal of updated FSARs and subsequent FSAR updates as a result of public comments and updated estimates for the level of effort required by the licensee.

### Cumulative Effects of Regulation

The staff followed 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 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 for the final rule took place on April 25, 2019 (see the meeting summary at ADAMS Accession No. ML19133A080). The staff answered questions about the proposed implementation schedule at this public meeting.

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 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. The NRC's advanced notice of proposed rulemaking, policy statement, proposed rules, and final rules for amendments to 10 CFR 50.109 in the 1980s involved only nuclear 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)).

The term "non-power production or utilization facility," as would be defined in 10 CFR 50.2 in the final rule, includes only licensees that have been excluded from the scope of 10 CFR 50.109. Therefore, the staff has concluded that NPUFs do not fall within the scope of 10 CFR 50.109 and has not applied the backfitting provisions of 10 CFR 50.109 to this final rule. For those NPUFs licensed under the authority of Section 104 of the AEA, however, 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 final rule would meet this standard by applying a more risk informed, performance-based approach for license renewal requirements. The staff was also directed to establish a more efficient, effective and focused regulatory framework for NPUF license renewals. As a result, the final rule would remove license renewal requirements for many entities licensed under Section 104 of the AEA, consolidate in one section the license renewal requirements for testing facilities licensed under Section 104 of the AEA, and eliminate the requirement for NPUF licensees to submit financial qualification information at the time of license renewal.

### Potential Requests to Change License Type for Non-power Reactors

The final rule would revise definitions of "testing facility" and "non-power reactor" in 10 CFR Part 50, including the criteria for classifying a facility as a research reactor. As a result, some current licensees may seek to convert their license types. For example, a testing facility might, based on the dose criterion in the final rule, seek to change its license type to a research reactor to reduce regulatory and financial burdens. A research reactor licensee could, for business purposes, propose to modify its facility such that it would need to be licensed as a testing facility. In either case, transitioning from one non-power reactor license type to another type presents an unprecedented situation for a facility that is already licensed and operating.

From a technical and safety perspective, the staff will approve a conversion from one type of non-power reactor license to another type if the licensee's request demonstrates that the

facility's conversion and operation as the new type of non-power reactor meets applicable NRC regulations. The staff will establish an appropriate review process if it anticipates a request to convert from one license type to another.

COMMITMENT:

The staff will provide the Commission with a paper on a standalone rulemaking to, at a minimum, conform 10 CFR 50.22 to NEIMA by April 1, 2020.

RECOMMENDATIONS:

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

In addition:

- The staff has prepared a regulatory analysis for this final rule (Enclosure 2).
- The staff has prepared an environmental assessment for this final rule (Enclosure 3).
- The staff will publish a regulatory guide with the publication of the final rule.
- The staff will inform the appropriate Congressional committees.
- The Office of Public Affairs will consider issuing a press release when the NRC publishes the final rule in the *Federal Register*.
- This final rule would not have a significant economic impact on a substantial number of small entities. One of the 31 NPUFs currently licensed to operate (Aerotest Radiography and Research Reactor) may be considered a "small entity" as discussed further in Section 4 of the regulatory analysis (Enclosure 2).

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 rulemaking package.

The staff met with the Office of the Advisory Committee on Reactor Safeguards (ACRS) on February 6, 2019. The ACRS provided a letter dated February 28, 2019 (ADAMS Accession No. ML19057A390), that recommended publication of the final rule with no changes to the content of the rule.

A handwritten signature in cursive script that reads "Margaret M. Doane".

Margaret M. Doane  
Executive Director  
for Operations

Enclosures:

1. Final Rule
2. Regulatory Analysis
3. Environmental Assessment

**SUBJECT: FINAL RULE— NON-POWER PRODUCTION OR UTILIZATION FACILITY  
LICENSE RENEWAL (RIN 3150-AI96, NRC-2011-0087) DATED: JUNE 17, 2019**

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Pkg: ML18031A000  
SECY: ML18031A001  
FRN: ML18031A002  
RA: ML18031A003  
EA: ML18031A004

\* via e-mail

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<b>DATE</b>	6/4/2019	6/17/19		

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