



NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC-2024-0189]

Commercial Non-Power Production or Utilization Facilities

AGENCY: Nuclear Regulatory Commission.

ACTION: Notification of interpretation; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an interpretation of its regulations to include non-power production or utilization facilities (NPUFs) licensed under section 103 of the Atomic Energy Act of 1954, as amended (AEA), within the scope of the NRC's backfitting regulations and to exclude non-commercial NPUFs licensed under section 104 of the AEA from the scope of the NRC's backfitting regulations. The interpretation is effective immediately with a 30-day post-promulgation comment period.

DATES: This interpretation is effective **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Submit comments by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration of only comments received by this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- **Federal Rulemaking website:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2024-0189. Address questions about NRC dockets to Helen Chang; telephone: 301-415-3228; email: Helen.Chang@nrc.gov. For technical questions contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Email comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic email reply confirming receipt, then contact us at 301-415-1677.
- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. eastern time, Federal workdays; telephone: 301-415-1677.

You can read a plain language description of this interpretation at <https://www.regulations.gov/docket/NRC-2024-0189>. For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Christopher Prescott, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-001; telephone: 301-287-9452; email: Christopher.Prescott@nrc.gov. For technical questions contact Jeff Rady, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-001; telephone: 301-415-3724; email: Jeff.Rady@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2024-0189 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and

search for Docket ID NRC-2024-0189.

- **NRC's Agencywide Documents Access and Management System**

(ADAMS): You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin ADAMS Public Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.

- **NRC's PDR:** The NRC Public Document Room (PDR), where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the **Federal Rulemaking Website** (<https://www.regulations.gov>). Please include Docket ID NRC-2024-0189 in your comment submission.

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

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

submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

An NPUF is defined in section 50.2, “Definitions,” in part 50, “Domestic Licensing of Production and Utilization Facilities,” of title 10 of the *Code of Federal Regulations* (10 CFR) as a production or utilization facility, licensed under paragraph (a) or (c) of 10 CFR 50.21, “Class 104 licenses; for medical therapy and research and development facilities,” or 10 CFR 50.22, “Class 103 licenses; for commercial and industrial facilities,” as applicable, that is not a nuclear power reactor or a production facility as defined under paragraphs (1) and (2) of the definition of “production facility” in 10 CFR 50.2. The NRC’s regulatory history and practice has excluded NPUFs licensed under section 104 of the AEA (i.e., research reactors and testing facilities) from the scope of 10 CFR 50.109, “Backfitting” (the Backfit Rule). The NRC has always considered nuclear power reactors licensed under section 103 or 104b of the AEA (i.e., commercial nuclear power reactors) to be within the scope of the Backfit Rule.¹ The NRC only recently issued a construction permit for a commercial NPUF under section 103 of the AEA for the first time, so no history or long-standing practice for whether commercial NPUFs are within the scope of the Backfit Rule exists.

In the original version of the Backfit Rule, which was published by the Atomic Energy Commission in 1970, neither the regulation nor the preamble could be read as excluding NPUFs from the scope of the rule. In both the proposed and final rules, as well as the associated preambles, the Atomic Energy Commission referred

¹ More than half of the currently licensed commercial nuclear power plants in the United States are licensed under section 104b of the AEA. Section 104b requires the NRC to impose the minimum amount of regulation to permit the NRC to fulfill its AEA obligations. The Commission has historically subjected commercial 10 CFR part 50 facilities licensed under section 103 or 104b of the AEA (i.e., nuclear power reactors) to the same public health and safety and common defense and security requirements. In the preamble to the 1991 final rule for 10 CFR part 54, “Requirements for Renewal of Operating Licenses for Nuclear Power Plants,” the Commission stated that for all practical purposes, there is little technical distinction between the class of nuclear power plants licensed under section 103 and the class licensed under section 104b. Only the 1970 change in the AEA separates these two classes of plants. See the final rule, “Nuclear Power Plant License Renewal” (56 FR 64943, 64962; December 13, 1991).

simply to “facility,” “facilities,” “production and utilization facility,” and “production and utilization facilities.” No reference was made to either “power” or “non-power” facilities.

The NRC amended the Backfit Rule in 1985 and 1988. The NRC did not make any revisions to the rule text in the 1985 or 1988 amendments to indicate that the Commission intended to modify the scope of the Backfit Rule. In the 1985 rulemaking, the Commission revised the definition of “backfitting” in 10 CFR 50.109 from the 1970 version to remove the reference to a “production and utilization facility” and replaced it with the general, undefined term “facility.” Neither “power” nor “non-power” is referenced in the rule text.

Although not indicated by the revised rule text, the Commission did clarify the scope of the Backfit Rule with the 1985 and 1988 rulemakings. The regulatory basis for the 1985 and 1988 rulemakings was expressed solely in terms of nuclear power reactors. The titles and pages of the NRC’s advance notice of proposed rulemaking and policy statement on backfitting in 1983, and the titles and preambles of the proposed and final rules for those amendments to § 50.109 involved only nuclear power reactors. The 1985 final rule stated that its purpose was to establish requirements for the future management of backfitting for power reactors.²

Moreover, the NRC practice has been to apply the Backfit Rule to only nuclear power reactors. In a 1980s rulemaking that would have required research reactors and testing facilities to switch from highly enriched uranium to low enriched uranium, the Commission declined to apply the Backfit Rule in that rulemaking, stating in its staff requirements memorandum, “[T]he backfit rule should not be applied to this amendment of the regulations which relates only to non-power reactors.” In a 2012 final rule concerning non-power reactors, the Commission stated that the NRC determined that the backfit provisions in § 50.109 do not apply to test, research, or training reactors because the rulemaking record for § 50.109

² “Revision of Backfitting Process for Power Reactors” (50 FR 38097; September 20, 1985).

indicates that the Commission intended to apply this provision to only power reactors, and NRC practice has been consistent with this rulemaking record.

In 2019, the Commission updated Management Directive (MD) 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests.” That MD provides the Commission’s policies and direction to the NRC staff on, among other things, the agency’s backfitting “of nuclear power reactor facilities and select nuclear materials facilities.” The MD does not mention NPUFs. This silence is consistent with the Commission position articulated in the 2012 final rule preamble that NPUFs are not within the scope of the Backfit Rule.

Underlying the practice of excluding NPUFs from the scope of the Backfit Rule are statutory restrictions on the amount of regulation that the NRC can impose on facilities licensed under section 104 of the AEA. NPUFs have typically been licensed under section 104a or 104c of the AEA for non-commercial medical therapy or non-commercial research and development facilities, respectively. Sections 104a and 104c require the NRC to impose, in general, the minimum amount of regulation to permit the NRC to fulfill its AEA obligations. The NRC’s record demonstrates the agency’s adherence to the “minimum regulation” standard for NPUFs. Since 1990, the NRC has imposed requirements on NPUFs through only four rulemakings and six orders (that were not issued in response to a request or application).

In 2016, the NRC issued a construction permit under 10 CFR part 50 to SHINE Medical Technologies, Inc. (SHINE). SHINE applied for an operating license under 10 CFR part 50 in 2019. SHINE proposes to operate a medical isotope production facility to produce molybdenum-99. The facility would meet the definition of an NPUF if the NRC issues SHINE an operating license because the facility would not be a nuclear power reactor, and the facility would not be a production facility as defined under paragraphs (1) and (2) of the definition of “production facility” in § 50.2. SHINE would be issued an operating license pursuant to section 103 of the AEA and 10 CFR 50.22, because SHINE proposes to engage in activities that satisfy the statutory

and regulatory provisions for commercial licenses. Therefore, SHINE would be a commercial NPUF. The NRC is clarifying whether commercial NPUFs like SHINE are within the scope of the Backfit Rule.

III. Interpretation

The NRC interprets its regulations to include within the scope of 10 CFR 50.109 commercial NPUFs licensed under section 103 of the AEA and exclude from the scope of 10 CFR 50.109 non-commercial NPUFs licensed under section 104 of the AEA.

Commercial facilities licensed under section 103 or 104b of the AEA have always been considered within the scope of the Backfit Rule. In contrast, the Commission has excluded from the scope of the Backfit Rule non-commercial facilities licensed under section 104a or 104c of the AEA. Consistent with this approach, the Commission concludes that commercial NPUFs licensed under section 103 of the AEA and 10 CFR 50.22 are within the scope of the Backfit Rule and non-commercial facilities licensed under section 104a or 104c of the AEA and 10 CFR 50.21 are outside the scope of the Backfit Rule.

IV. Request for Comment

The NRC is requesting comments on this interpretation. The NRC will publish a document in the *Federal Register* containing an evaluation of the significant comments and any revisions to this interpretation made as a result of the comments and their evaluation.

V. Availability of Documents

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

DOCUMENT	ADAMS ACCESSION NO. / WEB LINK / FEDERAL REGISTER CITATION
SRM-M240904: Affirmation Session – SECY-19-0062, “Final Rule: Non-power Production or Utilization Facility License Renewal (RIN 3150-AI96, NRC-2011-0087),” September 4, 2024	ML24248A208 (package)
Management Directive (MD) 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,” September 20, 2019	ML18093B087
<i>Federal Register</i> Notice—Final Rule; Non-Power Production or Utilization Facility License Renewal, December 30, 2024	89 FR 106234
<i>Federal Register</i> Notice—Final Rule; Nuclear Power Plant License Renewal; Final Rule, December 13, 1991	56 FR 64943, 64962
<i>Federal Register</i> Notice—Final Rule; Revision of Backfitting Process for Power Reactors; Final Rule, June 6, 1988	53 FR 20603
<i>Federal Register</i> Notice—Final Rule; Revision of Backfitting Process for Power Reactors, September 20, 1985	50 FR 38097

VI. Paperwork Reduction Act

This proposed interpretation does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing collections of information were approved by the Office of Management and Budget (OMB), approval number 3150-0011.

Public Protection Notification

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

VII. Regulatory Planning and Review

Executive Order (E.O.) 12866, as amended by E.O. 14215, provides that the Office of Information and Regulatory Affairs (OIRA) will determine whether a regulatory action is significant as defined by E.O. 12866 and will review all significant regulatory actions. OIRA determined that this notice of interpretation is not a significant regulatory action under E.O. 12866.

VIII. Congressional Review Act

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

Dated: January 14, 2026.

For the Nuclear Regulatory Commission.

Jeremy Groom,
Acting Director,
Office of Nuclear Reactor Regulation.

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