



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 11, 2023

ALL AGREEMENT STATES
CONNECTICUT, INDIANA, WEST VIRGINIA

SUBJECT: NOTIFICATION OF ISSUANCE FOR PUBLIC COMMENT OF THE REGULATORY BASIS FOR THE RULEMAKING TO ESTABLISH REQUIREMENTS FOR RUBIDIUM-82 GENERATORS, EMERGING TECHNOLOGIES, AND OTHER MEDICAL USE OF BYPRODUCT MATERIAL (STC-23-049)

Purpose: To notify Agreement States that the U.S. Nuclear Regulatory Commission (NRC) has issued for public comment the regulatory basis document titled "Rubidium-82 Generators, Emerging Technologies, and other Medical Use of Byproduct Material."

Background: The regulatory basis document (Agencywide Documents Access and Management System Accession No. [ML23122A356](#)), along with public comments received, will inform the NRC staff's development of a proposed rule to revise certain requirements in Title 10 of the Code of Federal Regulations (10 CFR), Part 35, "Medical Uses of Byproduct Material." Specifically, the NRC is planning to add requirements to address calibration and dosage measurement for strontium-82/rubidium-82 generators (rubidium-82 (Rb-82) generators), establish performance-based requirements for existing and future emerging medical technologies (EMTs), and accommodate developments in the medical field related to EMTs and new radiopharmaceuticals. The Commission approved initiation of this rulemaking in staff requirements memorandum SRM-SECY-21-0013, "Staff Requirements – SECY-21-00013 – Rulemaking Plan to Establish Requirements for Rubidium-82 Generators and Emerging Medical Technologies," dated January 13, 2022 ([ML22013A266](#)).

Discussion: On July 3, 2023, the NRC published a notice in the *Federal Register* announcing the availability of this regulatory basis document for a 120-day public comment period (see [88 FR 42654](#)). The document summarizes the current regulatory framework, describes the regulatory issues and proposed changes to 10 CFR Part 35, and evaluates alternatives for establishing requirements in 10 CFR Part 35 for Rb-82 generators, EMTs, and other medical uses of byproduct material. The regulatory basis also includes preliminary cost estimates for the NRC, Agreement States, and licensees for each alternative.

In September 2022, the NRC provided a preliminary draft version of this document to the Agreement States for review and comment. The NRC received comments from the OAS Board. Section 7.1 of the document provides a summary of the comments and the NRC staff's responses. The OAS Board and the State of Arkansas also provided responses to the questions included in appendix A of the document. In addition, the Advisory Committee on the Medical Uses of Isotopes established a subcommittee to review the draft regulatory basis and provided its comments to the NRC in the "Report of Subcommittee on Emerging Medical Technologies/ Rubidium-82 Generator Rulemaking Draft Regulatory Basis," dated December 19, 2022 ([ML22353A053](#)). The NRC staff appreciates this input and will consider it while developing the proposed rule.

We welcome further comments on this document during the public comment period. Please provide any comments by October 31, 2023. You can access the *Federal Register* notice and the regulatory basis using the following link:

<https://www.federalregister.gov/documents/2023/07/03/2023-14018/rubidium-82-generators-emerging-technologies-and-other-medical-use-of-byproduct-material>.

We encourage electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2018–0297 in your comment submission.

Public Meeting: The NRC staff plans to hold a public meeting in August 2023 to provide an overview of the regulatory basis document and encourage the public to provide comments. The NRC staff will announce the details of this meeting in the coming months.

If you have any questions regarding this correspondence, please contact me at 301-415-3340 or the individual named below:

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Signed by Giantelli, Adelaide
on 07/11/23

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STC-23-049 NOTIFICATION OF ISSUANCE FOR PUBLIC COMMENT OF THE REGULATORY BASIS
FOR THE RULEMAKING TO ESTABLISH REQUIREMENTS FOR RUBIDIUM-82 GENERATORS DATE
July 11, 2023

DISTRIBUTION:

ADAMS Accession No.: ML23187A446

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