



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

October 31, 2023

ALL AGREEMENT STATES
CONNECTICUT, INDIANA, WEST VIRGINIA

NOTICE OF EXTENSION OF COMMENT PERIOD ON THE REGULATORY BASIS FOR THE PLANNED 10 CFR PART 35 RULEMAKING TO ESTABLISH REQUIREMENTS FOR RUBIDIUM-82 GENERATORS, EMERGING TECHNOLOGIES, AND OTHER MEDICAL USE OF BYPRODUCT MATERIAL (STC-23-073)

Purpose: To provide notice that the comment period on the regulatory basis for the planned 10 CFR Part 35 rulemaking to establish requirements for rubidium-82 generators, emerging technologies, and other medical use of byproduct material, has been extended until December 15, 2023.

Background: On October 27, 2023, The National Regulatory Commission (NRC) published a *Federal Register* [notice](#) extending the public comment period on [Regulatory Basis for “Rubidium-82 Generators, Emerging Technologies, and Other Medical Use of Byproduct Material”](#). Comments will be accepted through December 15, 2023.

The original *Federal Register* [notice](#) was published on July 3, 2023. The original comment period deadline was October 31, 2023. Both *Federal Register* notices have been posted to <https://www.regulations.gov/> under Docket No. NRC-2018-0297.


Publication of this document is the first step in this rulemaking process, which the NRC staff began in 2022, following Commission approval of the staff’s recommendation in [SECY-21-0013, “Rulemaking Plan to Establish Requirements for Rubidium-82 Generators and Emerging Medical Technologies,”](#) to develop requirements for rubidium-82 generators and all current, well-established emerging medical technologies (EMTs), and to create added flexibility in Part 35 to accommodate future EMTs. In the rulemaking plan, the NRC staff estimated submitting the proposed rule to the Commission 14 months after the close of the regulatory basis comment period. However, the staff has delayed development of this proposed rule to accommodate the ongoing rulemaking on nuclear medicine injection extravasations. Under the new schedule, the staff will submit the proposed rule to the Commission in January 2026, and will submit the final rule in January 2027.

Discussion: More information about the rulemaking can be found on this web page under the heading “NRC Regulation of Emerging Medical Technologies”: <https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html>. More information about the NRC’s rulemaking process can be found at <https://www.nrc.gov/about-nrc/regulatory/rulemaking/rulemaking-process.html>. The NRC staff will use the Medical List Server e-mail to provide updates on this rulemaking as they become available.

If you have any questions regarding this correspondence, please contact the individuals listed below:

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Sincerely,



Signed by Giantelli, Adelaide
on 10/31/23

Adelaide Giantelli, Chief
State Agreement and Liaison Programs Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

NOTICE OF EXTENSION OF COMMENT PERIOD FOR INFORMATION REQUEST REGARDING THE REGULATORY BASIS FOR THE 10 CFR PART 35 RULEMAKING TO ESTABLISH REQUIREMENTS FOR RUBIDIUM-82 GENERATORS, EMERGING TECHNOLOGIES, AND OTHER MEDICAL USE OF BYPRODUCT MATERIAL DATE November 1, 2023

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