



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

April 28, 2023

ALL AGREEMENT STATES  
CONNECTICUT, INDIANA, WEST VIRGINIA

NOTIFICATION OF ISSUANCE OF FEDERAL REGISTER NOTICE REQUESTING  
INFORMATION REGARDING A RULEMAKING ON THE REPORTING OF NUCLEAR  
MEDICINE INJECTION EXTRAVASATIONS AS MEDICAL EVENTS (STC-23-033)

**Purpose:** To provide notification that the U.S. Nuclear Regulatory Commission (NRC) has published a *Federal Register* notice (FRN) that requests feedback to be considered in the development of a proposed rulemaking on the reporting of nuclear medicine injection extravasations as medical events.

**Background:** On May 18, 2020, the NRC received a petition for rulemaking requesting that the NRC amend 10 CFR Part 35, "Medical Use of Byproduct Material," to require medical event reporting of radiopharmaceutical extravasations that lead to an irradiation resulting in a localized dose equivalent exceeding 50 rem (0.5 Sieverts). The NRC reviewed the petitioner's request and conducted an independent evaluation, considering input from the Advisory Committee on the Medical Uses of Isotopes, Agreement States, external stakeholders, and available published literature on extravasations. On May 9, 2022, the NRC staff issued a rulemaking plan in [SECY-22-0043](#), "Petition for Rulemaking and Rulemaking Plan on Reporting Nuclear Medicine Injection Extravasations as Medical Events," that presented options for amending Part 35 and recommended including certain nuclear medicine injection extravasations as reportable medical events. On December 12, 2022, the Commission approved the staff's recommendation in the [staff requirements memorandum](#) (SRM) for SECY-22-0043.

**Discussion:** The NRC issued an FRN (88 FR 24130) on April 19, 2023, which is available at: <https://www.regulations.gov/document/NRC-2022-0218-0004>. This FRN can also be accessed on <https://www.regulations.gov> by searching for Docket ID No. NRC-2022-0218. The notice announces a 90-day public comment period on information related to the NRC's rulemaking to require the reporting of certain nuclear medicine injection extravasations as medical events. The FRN contains questions that the NRC is seeking feedback on in the following areas: definitions, procedures, and healthcare inequities. The FRN also announces the availability of preliminary proposed rule language. The preliminary rule language is available at [www.nrc.gov/docs/ML2308/ML23083B332.pdf](http://www.nrc.gov/docs/ML2308/ML23083B332.pdf).

More information on this rulemaking can be found on the NRC's public website at <https://www.nrc.gov/materials/miau/med-use-toolkit/reporting-nuclear-medicine-injection-extravasations.html> and at <https://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/active/ruledetails.html?id=2180>.

A public meeting will be held virtually on Wednesday, May 24, 2023, from 1:00 p.m. to 4:00 p.m. Eastern Daylight Time. The NRC will publish a notice with the meeting link and agenda on

NRC's public meeting website at least 10 calendar days before the meeting. Stakeholders should monitor the NRC's public meeting website (<https://www.nrc.gov/public-involve/public-meetings/>) for information about the public meeting.

If you have any questions regarding this correspondence, please contact me at [Sherrie.Flaherty@nrc.gov](mailto:Sherrie.Flaherty@nrc.gov), or the individual listed below:

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Signed by Flaherty, Sherrie  
on 04/28/23

Sherrie Flaherty, Acting Branch Chief  
State Agreement and Liaison Programs Branch  
Division of Materials Safety, Security, State,  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

STC-23-033 Notification of Issuance of Federal Register Notice Requesting Information Regarding a Rulemaking on the Reporting of Nuclear Medicine Injection Extravasations as Medical Events DATE April 28, 2023

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