RULEMAKING ISSUE
(Notation Vote)

August 13, 2024 SECY-24-0067

FOR: The Commissioners

FROM: Mirela Gavrilas, PhD
Executive Director for Operations

SUBJECT: PROPOSED RULE: REPORTING NUCLEAR MEDICINE INJECTION EXTRAVASATIONS AS MEDICAL EVENTS (RIN 3150-AK91; NRC--2022-0218)

PURPOSE:

The purpose of this paper is to request Commission approval to publish in the *Federal Register* the enclosed proposed rule (Enclosure 1), "Reporting Nuclear Medicine Injection Extravasations as Medical Events," that would amend regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material," to require reporting of certain nuclear medicine injection extravasations as medical events. The proposed rule would also require licensees to develop, implement, and maintain written procedures for evaluating and reporting extravasations. This rulemaking would affect medical licensees that administer intravascular radiopharmaceuticals for diagnostic or therapeutic purposes.

BACKGROUND:

In 1980, the U.S. Nuclear Regulatory Commission (NRC) amended its medical use regulations in 10 CFR Part 35 to require the reporting of medical misadministrations (later renamed medical events) (45 FR 31701; May 14, 1980). The reporting and analysis of medical events helps to identify deficiencies in the safe use of radioactive material and ensure that corrective actions are taken to prevent recurrence. In the 1980 rulemaking, the NRC stated in a comment response that it did not consider an extravasation to be a misadministration because "extravasations frequently occur in otherwise normal intravenous or intra-arterial injections[, and extravasations are] virtually impossible to avoid." While not specifically addressing extravasations, a 2002 final

CONTACT: Sarah L. Lopas, NMSS/REFS
301-415-6360

Daniel DiMarco, NMSS/MSST
301-415-3303

Enclosures 3 and 4 transmitted herewith contain Official Use Only - Sensitive Internal Information. When separated from Enclosures 3 and 4 this transmittal document is decontrolled.

~~**OFFICIAL USE ONLY**~~
~~SENSITIVE INTERNAL INFORMATION~~
~~LIMITED TO THE NRC UNLESS THE~~
~~COMMISSION DETERMINES OTHERWISE~~

rule removed the term "misadministration" and replaced it with the term "medical event." In 2008 and 2009, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) evaluated whether extravasations should continue to be excluded from medical event reporting. The ACMUI recommended the medical event reporting requirements should continue to exclude all extravasations, and the staff agreed with the recommendation.

On May 18, 2020, Lucerno Dynamics, LLC, submitted a petition for rulemaking (PRM), PRM-35-22 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20157A266), which requested the NRC to amend 10 CFR Part 35 to require medical event reporting of radiopharmaceutical extravasations that lead to an irradiation resulting in a localized dose equivalent exceeding 50 rem (0.5 sievert). In parallel with NRC review of the PRM, the staff was conducting an independent evaluation to determine whether extravasations should be reported as medical events. The staff provided its preliminary evaluation to the ACMUI and, in September 2021, the ACMUI held a public meeting and endorsed the staff's preliminary non-dose-based rulemaking option for reporting extravasations that result in a radiation injury.

On May 9, 2022, the staff submitted to the Commission SECY-22-0043, "Petition for Rulemaking and Rulemaking Plan on Reporting Nuclear Medicine Injection Extravasations as Medical Events (PRM-35-22; NRC-2020-0141)" (ML21268A005). In the paper, the staff sought Commission approval to consider the issues raised in PRM 35-22 in the rulemaking process and recommended initiating a rulemaking to require the reporting of extravasations that require medical attention for a suspected radiation injury. In the associated staff requirements memorandum, dated December 12, 2022 (ML22346A112), the Commission approved the staff's recommendation to amend 10 CFR Part 35 to include certain nuclear medicine injection extravasations as reportable medical events. Additionally, the Commission directed the staff to explore approaches to reduce reliance on patient reporting (discussed in section III.F of Enclosure 1), develop regulatory guidance for all medical events (discussed below under "Implementation Guidance"), and look for opportunities to accelerate the rulemaking schedule without shortening public comment periods (staff determined that the rulemaking did not require preparation of a regulatory basis document and instead issued a request for information and comment on preliminary proposed rule language).

Section II of Enclosure 1 provides additional details on the background of the rulemaking.

DISCUSSION:

Overview of Proposed Changes to NRC Regulations

The proposed rule would amend 10 CFR Part 35 to require reporting of certain nuclear medicine injection extravasations as medical events. Specifically, the staff is proposing that licensees report to the NRC "[t]he administration of byproduct material that results or has the potential to result in a radiation injury from an extravasation, as determined by a physician." The proposed changes would help the staff track extravasation medical events and collect information on their occurrence, detection, mitigation, and possible preventive strategies that would be available for licensee and public use. The proposed rule also would require licensees to develop, implement, and maintain written procedures for evaluating and reporting extravasation medical events. These procedures are necessary to provide high confidence that reportable extravasations will be detected in a timely manner and reported to the NRC. To help facilitate the implementation of these proposed changes, the staff is also proposing to add new definitions for "extravasation"

and "radiation injury." Other proposed revisions include minor changes to 10 CFR Part 35 for clarification, gender-inclusive language, and plain language. Section III of Enclosure 1 includes the basis for these proposed changes to 10 CFR Part 35.

Regulatory Analysis

Enclosure 2, "Regulatory Analysis for the Proposed Rule: Reporting Nuclear Medicine Injection Extravasations as Medical Events," demonstrates that the proposed rule recommended by staff would result in quantitative costs to the NRC, industry, and Agreement States over the analysis horizon (10 years) of the rule of $29.4 million using a 7% discount rate or $35.9 million using a 3% discount rate. However, the analysis discusses that the rulemaking will provide qualitative benefits that outweigh the quantitative costs in the areas of public health, improvements in knowledge, and public confidence in the NRC. By way of comparison, implementation of the reporting criteria as proposed in the petition for rulemaking would result in quantitative costs to the NRC, industry, and Agreement States over the analysis horizon of the rule of $3.9 billion using a 7% discount rate or $5.1 billion using a 3% discount rate.

Stakeholder Engagement

The NRC conducted several public outreach activities during the development of the proposed rule. These activities included publishing an information request in the *Federal Register*, making available preliminary proposed rule language (88 FR 24130; April 19, 2023), and holding a public meeting to facilitate stakeholder feedback. Section II.B.5. of Enclosure 1 provides additional details on public interactions during the development of the proposed rule.

An Organization of Agreement States representative participated on the rulemaking working group, and the staff coordinated with the Agreement States and the Standing Committee on Compatibility and considered their feedback during the development of the proposed rule. Enclosure 3, "Summary of Comments from the Agreement States and the Standing Committee on Compatibility" (non-public), summarizes the feedback received from Agreement States and the Standing Committee on Compatibility, and the staff's responses.

Implementation Guidance

Concurrent with publication of the proposed rule, the NRC staff will issue for public comment draft guidance in DG-8062, "Medical Event Evaluation and Reporting" (ML24016A109). The draft regulatory guide describes an approach acceptable to the NRC to meet the requirements for evaluating and reporting all medical events, including extravasations as described in the proposed rule.

Backfitting and Issue Finality Considerations

The staff has determined that the backfitting provisions in 10 CFR 50.109, 70.76, 72.62, and 76.76, all entitled "Backfitting," and the issue finality provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," do not apply to the proposed rule. The regulations in 10 CFR Part 35 do not contain a backfitting provision. The new extravasation reporting requirement would apply to reportable extravasations occurring after implementation of the final rule. Section VIII of Enclosure 1 includes additional details on backfitting and issue finality.

RECOMMENDATION:

The staff recommends that the Commission approve the enclosed proposed rule for publication in the *Federal Register*. If the Commission approves publication of the proposed rule, the staff will complete the following activities:

- The staff will publish the proposed rule in the *Federal Register* for a 90-day public comment period.
- The staff will submit information collection requirements to the Office of Management and Budget for its review and approval on or immediately after the date of publication of the proposed rule in the *Federal Register*.
- The Office of Congressional Affairs will inform the appropriate congressional committees.
- The staff will work with the Office of Public Affairs on an appropriate public communication when the NRC publishes the proposed rule in the *Federal Register*.
- The staff will hold a public meeting during the comment period for the proposed rule.

COORDINATION:

The Office of the General Counsel reviewed this package and has no legal objection to the publication of the proposed rule. The Office of the Chief Financial Officer reviewed this package and has no concerns with the estimated resources in Enclosure 4, "Estimated Resources for the Rulemaking on Reporting Nuclear Medicine Injection Extravasations as Medical Events" (non-public). The ACMUI met on June 17, 2024, to discuss their recommendations on the proposed rule and draft guidance. In a final report dated June 18, 2024 (ML24170A316), the ACMUI recommended that the staff should proceed with this rulemaking package. The staff's responses to the recommendations in the ACMUI final report are available in a memorandum to the ACMUI Subcommittee on Extravasations (ML24190A072).

Mirela Gavrilas, PhD
Executive Director
for Operations

Enclosures:
1. Federal Register Notice
2. Draft Regulatory Analysis
3. Agreement States and ACMUI Comment Summaries and Responses (non-public)
4. Estimated Rulemaking Resources (non-public)

SUBJECT: PROPOSED RULE: REPORTING NUCLEAR MEDICINE INJECTION EXTRAVASATIONS AS MEDICAL EVENTS (RIN 3150-AK91; NRC-2022-0218)
DATED: August 13, 2024

ADAMS Accession Number: ML24016A294 WITS: SRM-S22-0043-3 *via email

OFFICE	NMSS/REFS/ MRPB	NMSS/MSST/ MSEB	NMSS/REFS/ MRPB	QTE	NMSS/MSST /MSEB
NAME	IWu	DDiMarco	DBearde	JDougherty	CValentin-Rodriguez
DATE	01/17/24	01/18/24	01/18/24	01/31/24	2/7/24
OFFICE	NMSS/REFS/ MRPB	NMSS/MSST/ MSEB	RES/DE/ RGPMB	RI/DRSS/ MLA	OE/EB
NAME	JShepherd	CEinberg	MRahimi	ADeFrancisco	JPeralta
DATE	2/2/24	2/9/24	2/5/24	2/20/24	2/26/24
OFFICE	NMSS/REFS	NMSS/MSST	OCIO/GEMSD/ FLICB/ICT	OCFO	RI/DRSS
NAME	MRalph	KWilliams	DCullison	LYee	PKrohn
DATE	2/26/24	2/29/24	6/26/24	3/22/24	3/22/24
OFFICE	RES/DE	NMSS/REFS/ RASB	OGC	NMSS	OEDO
NAME	MSampson	CBladey	Msmith	RLewis	MGavrilas
DATE	3/22/24	6/26/24	7/23/24	7/23/24	08/13/24

OFFICIAL RECORD COPY