U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Public Meeting on Information Request

Rulemaking on Reporting Nuclear Medicine Injection Extravasations as Medical Events

May 24, 2023

Logistics

- Meeting is being transcribed
- Keep the line muted until you intend to speak
- Raise hand button in Teams (*5 on phone)
- Unmute button in Teams (*6 on phone)
- Chat feature available
- Presentation slides shown on the Microsoft Teams screen and in ADAMS at ML23132A116
- Phone attendees should email Irene.Wu@nrc.gov for attendance

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Opening Remarks

Kevin Williams
Division Director
Division of Materials Safety, Security, State, and Tribal Programs

Purpose

- Provide information to help stakeholders prepare comments on the information request related to the rulemaking on reporting nuclear medicine injection extravasations as medical events
  - The NRC is not seeking comments at this meeting. Comments should be submitted according to the instructions in the FRN (88 FR 24130) by July 18, 2023.
  - While the NRC intends to use the comments to develop the proposed rule, the NRC does not plan to provide specific responses to all comments.

Agenda

- Welcome and Logistics
- Opening Remarks
- Background
- Information Request and Preliminary Proposed Rule Language
- How to Prepare and Submit Comments
- Next Steps
- Public Feedback and Questions

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Background

Irene Wu
Project Manager
Division of Rulemaking, Environmental, and Financial Support

Medical Event Reporting Requirements

- In a 1980 final rule (45 FR 31701), the Commission did not require licensees to report extravasations to the NRC.
- Radiopharmaceutical extravasations are currently not required to be reported by the Commission.

NRC Staff Evaluation

- Beginning in January 2020, staff conducted an independent evaluation of whether extravasations should be reported as medical events.
- Stakeholder engagement included:
  - Public meeting in December 2020 (ML21005A436)
  - ACMUI meeting in September 2021 (ML21267A021)

Petition for Rulemaking and Rulemaking Plan

- In May 2020, PRM-35-22 requested the NRC revise its regulations to require medical event reporting of extravasations.
- In May 2022, NRC staff provided a rulemaking plan to the Commission (SECY-22-0043).
- In December 2022, the Commission approved staff's recommendation with changes (SRM-SECY-22-0043).

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Information Request and Preliminary Proposed Rule Language

Daniel DiMarco
Health Physicist
Division of Materials Safety, Security, State, and Tribal Programs

Information Request

- The information request was published in the *Federal Register* on April 19, 2023 (88 FR 24130).
- The deadline for comments is July 18, 2023.
- The notice made the preliminary proposed rule language for the rulemaking available and posed questions to obtain input from stakeholders.

Preliminary Proposed Rule Language

The preliminary proposed rule language does not represent a final NRC staff position, nor has it been reviewed by the Commission. Therefore, the preliminary proposed rule language may undergo revision during the rulemaking process.

Preliminary Proposed Rule Language

§ 35.2 Definitions.

- ***Extravasation*** means the leakage of a radiopharmaceutical from the blood vessel into the surrounding tissue.

- ***Medical attention*** means any techniques used to reduce the chance, severity, or symptoms of a suspected radiation injury.

- ***Suspected radiation injury*** means a potential or observable deterministic health effect to the area around an injection site that can be attributed to radiation.

Information Request Questions

Definitions

1. What term should the NRC use (e.g., extravasation, infiltration) when describing the leakage of radiopharmaceuticals from a blood vessel or artery into the surrounding tissue?
2. What criteria should the NRC use to define “suspected radiation injury”?
3. What techniques or methods should be included in the definition of “medical attention”?

Preliminary Proposed Rule Language

§ 35.42 Procedures for evaluating and reporting extravasations.

(a) For any administration in which an extravasation can occur, the licensee must develop, implement, and maintain written procedures to provide high confidence that an extravasation that requires medical attention for a suspected radiation injury will be detected and reported in a timely manner and in accordance with § 35.3045.

(b) The written procedures required by paragraph (a) of this section must address how the licensee determines that an extravasation meets the criteria in § 35.3045(a)(3) for a medical event.

(c) A licensee must retain a copy of the procedures required under paragraph (a) in accordance with § 35.2042.

Preliminary Proposed Rule Language

§ 35.2042 Records for procedures for evaluating and reporting extravasations.

A licensee must retain a copy of the procedures required by § 35.42(a) for the duration of the license.

Preliminary Proposed Rule Language

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which –

(1) * * *

(2) * * *

(3) The administration of byproduct material results in an extravasation that requires medical attention for a suspected radiation injury.

Information Request Questions

Procedures

4. What steps could the licensee take to minimize the chance of a radiopharmaceutical extravasation occurring?
5. What steps should the licensee take when an extravasation is suspected or discovered?
6. What techniques, technologies, or procedures (e.g., post-treatment imaging, visual observation, patient feedback) should be used to help identify an extravasation during or immediately after a radiopharmaceutical injection?

Information Request Questions

7. What techniques, technologies, or procedures (e.g., post-treatment imaging, survey measurement) should be used to better characterize an extravasation after radiopharmaceutical treatment?
8. What information should licensees provide to nuclear medicine patients on how to identify an extravasation and how to follow up with their physician if they suspect a radiation injury?
9. When should a reportable extravasation be counted as “discovered” for the purposes of notification (e.g., when medical attention is administered, when the physician identifies that the injury is from radiation)?

Information Request Questions

10. The NRC requires that licensees notify the referring physician and the individual who is the subject of a medical event no later than 24 hours after discovery of the medical event. When should licensees be required to provide notification of an extravasation medical event to the referring physician and the individual?
11. Who (e.g., patient's primary physician, authorized user, nuclear medicine technician) should be able to identify an extravasation that could result in a "suspected radiation injury"?
12. What topics should the NRC include in guidance to assist licensees to accurately identify, characterize, and report extravasation events in a timely manner?

Information Request Questions

Healthcare Inequities

13. What regulatory actions could help ensure that extravasations in patients affected by healthcare inequities are accurately assessed and reported?
14. Are vascular access tools and other technologies (e.g., ultrasound guided vein finders) likely to reduce the potential for an extravasation in all patients, particularly in patients of color?

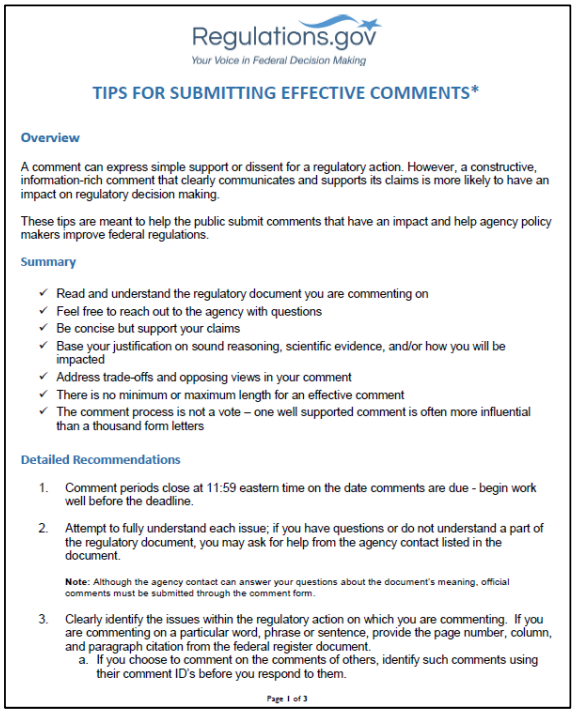
U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

How to Prepare and Submit Comments

Irene Wu
Project Manager
Division of Rulemaking, Environmental, and Financial Support

Tips for Preparing Comments

- Review the Commenter's Checklist on Regulations.gov



Regulations.gov
Your Voice in Federal Decision Making

TIPS FOR SUBMITTING EFFECTIVE COMMENTS*

Overview

A comment can express simple support or dissent for a regulatory action. However, a constructive, information-rich comment that clearly communicates and supports its claims is more likely to have an impact on regulatory decision making.

These tips are meant to help the public submit comments that have an impact and help agency policy makers improve federal regulations.

Summary

- ✓ Read and understand the regulatory document you are commenting on
- ✓ Feel free to reach out to the agency with questions
- ✓ Be concise but support your claims
- ✓ Base your justification on sound reasoning, scientific evidence, and/or how you will be impacted
- ✓ Address trade-offs and opposing views in your comment
- ✓ There is no minimum or maximum length for an effective comment
- ✓ The comment process is not a vote – one well supported comment is often more influential than a thousand form letters

Detailed Recommendations

1. Comment periods close at 11:59 eastern time on the date comments are due - begin work well before the deadline.
2. Attempt to fully understand each issue; if you have questions or do not understand a part of the regulatory document, you may ask for help from the agency contact listed in the document.

   Note: Although the agency contact can answer your questions about the document's meaning, official comments must be submitted through the comment form.
3. Clearly identify the issues within the regulatory action on which you are commenting. If you are commenting on a particular word, phrase or sentence, provide the page number, column, and paragraph citation from the federal register document.
   a. If you choose to comment on the comments of others, identify such comments using their comment ID's before you respond to them.

Page 1 of 3

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Methods for Submitting Comments

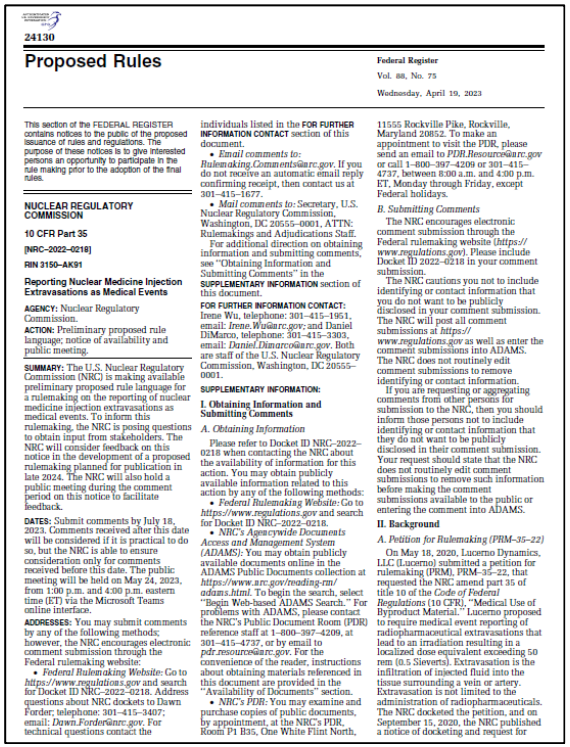
- **Regulations.gov**: comment form
  Docket ID NRC-2022-0218

  or

- **Email**: Rulemaking.Comments@nrc.gov

  or

- **Mail**: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001
  ATTN: Rulemakings and Adjudications Staff



24130

Proposed Rules

Federal Register
Vol. 88, No. 75
Wednesday, April 19, 2023

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[NRC–2022–0218]

RIN 3150–AK91

Reporting Nuclear Medicine Injection Extravasations as Medical Events

AGENCY: Nuclear Regulatory Commission.

ACTION: Preliminary proposed rule language; notice of availability and public meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is making available preliminary proposed rule language for a rulemaking on the reporting of nuclear medicine injection extravasations as medical events. To inform this rulemaking, the NRC is posing questions to obtain input from stakeholders. The NRC will consider feedback on this notice in the development of a proposed rulemaking planned for publication in late 2024. The NRC will also hold a public meeting during the comment period on this notice to facilitate feedback.

DATES: Submit comments by July 18, 2023. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received before this date. The public meeting will be held on May 24, 2023, from 1:00 p.m. and 4:00 p.m. eastern time (ET) via the Microsoft Teams online interface.

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–2022–0218. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals 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.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

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: Irene Wu, telephone: 301–415–1951, email: *Irene.Wu@nrc.gov;* and Daniel DiMarco, telephone: 301–415–3303, email: *Daniel.Dimarco@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2022–0218 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–2022–0218.
- *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 Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 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:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. 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 8:00 a.m. and 4:00 p.m. ET, 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 2022–0218 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

A. Petition for Rulemaking (PRM–35–22)

On May 18, 2020, Lucerno Dynamics, LLC (Lucerno) submitted a petition for rulemaking (PRM), PRM–35–22, that requested the NRC amend part 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material." Lucerno proposed 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). Extravasation is the infiltration of injected fluid into the tissue surrounding a vein or artery. Extravasation is not limited to the administration of radiopharmaceuticals. The NRC docketed the petition, and on September 15, 2020, the NRC published a notice of docketing and request for

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Next Steps

- Public comment period ends: July 18, 2023
- Proposed rule to the Commission: August 2024 (estimated)
- Proposed rule publication: December 2024 (estimated)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Public Feedback and Questions

Contact Information and Resources

Irene Wu, Rulemaking Project Manager
Irene.Wu@nrc.gov; (301) 415-1951

Daniel DiMarco, Technical Lead
Daniel.Dimarco@nrc.gov; (301) 415-3303

Extravasations Rulemaking Website

NRC Rulemaking Process Website

Acronyms

ACMUI	Advisory Committee on the Medical Uses of Isotopes
ADAMS	Agencywide Documents Access and Management System
FR	*Federal Register*
FRN	*Federal Register* notice
NRC	U.S. Nuclear Regulatory Commission
PRM	petition for rulemaking
SRM	staff requirements memorandum