[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM-35-22; NRC-2020-0141]

Reporting Nuclear Medicine Injection Extravasations as Medical Events

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; notice of docketing and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has received a petition for rulemaking from Ronald K. Lattanze on behalf of Lucerno Dynamics, LLC, dated May 18, 2020. The petitioner requests that the NRC revise its regulations to require reporting of certain nuclear medicine injection extravasations as medical events. The NRC docketed the petition on June 5, 2020, and assigned it Docket No. PRM-35-22. The NRC is examining the issues raised in PRM-35-22 to determine whether they should be considered in rulemaking. The NRC is requesting public comment on this petition at this time.

DATES: Submit comments by November 30, 2020. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web site:** Go to https://www.regulations.gov and search for Docket ID NRC-2020-0141. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail 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: Pamela Noto, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6795; e-mail: Pamela.Noto@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2020-0141 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 Web site:** Go to https://www.regulations.gov and search for Docket ID NRC-2020-0141.

- **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, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the SUPPLEMENTARY INFORMATION section.

- **Attention**: The Public Document Room (PDR), where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via e-mail at pdr.resource@nrc.gov or call 1-800-397-4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC-2020-0141 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. The Petitioner

The petition for rulemaking (PRM) was filed by Ronald K. Lattanze, on behalf of Lucerno Dynamics, LLC. Ronald K. Lattanze is the Chief Executive Officer of Lucerno Dynamics, LLC. Lucerno Dynamics, LLC, is a North Carolina-based company that specializes in the design and development of systems that detect the presence of radiolabeled biomarkers in patients.

III. The Petition

The petitioner requests that the NRC amend part 35 of title 10 of the *Code of Federal Regulations* to require the reporting of certain nuclear medicine injection extravasations as medical events. Extravasation is the infiltration of injected fluid into the tissue surrounding a vein or artery. The petition may be found in ADAMS at Accession No. ML20157A266.

IV. Discussion of the Petition

The petition states that, in 1980, the NRC exempted extravasations from medical event reporting with the understanding that extravasations are virtually impossible to avoid. The petition further states that, since that time, ample evidence has been published demonstrating that nuclear medicine extravasations are avoidable and are capable of causing considerable harm to patients. Referencing literature research and case studies, the petition asserts that extravasations can result in patient tissue doses that exceed existing NRC medical reporting limits and can harm patients in many ways. In light of this evidence, the petition requests that the NRC revisit the policy established in 1980 and require the reporting of medical events of extravasations that result in a localized dose equivalent exceeding 50 rem (0.5 Sv). The petition asserts that the reporting of certain extravasations as medical events will not only alert the NRC to instances of serious misuse of byproduct material, but also will incentivize practitioners to improve injection and infusion quality. The petition states that this is intended to ensure that diagnostic and therapeutic nuclear medicine patients are protected from avoidable irradiation and given access to vital information to understand when and how medical events impact their care.

V. Request for Public Comment

The NRC's Medical Use Policy Statement (65 FR 47654) states, in part, that the NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public. It also states that the NRC will, when justified by the risk to patients, regulate the radiation safety of patients

primarily to assure the use of radionuclides is in accordance with the physician's directions. Considering these policy objectives and how they may relate to radiopharmaceutical extravasations, the NRC is requesting public comment on the following specific questions.

Injection Quality Monitoring

The NRC encourages licensees to use quality assurance tools and available technology to ensure that the licensee delivers the administration that the physician intended. The NRC requires certain quality assurance procedures—such as calibrating instruments used to measure patient dosages and recording dosages administered—but there are other procedures that the NRC does not require that could be relevant to extravasation. The NRC is seeking information on use of quality assurance tools and technologies for radiopharmaceutical injection quality monitoring and extravasation.

1. How frequently does radiopharmaceutical extravasation occur?
2. Do you know of any extravasations that have resulted in harm to patients? If so and without including information that could lead to the identification of the individual, describe the circumstances, type of effect harm, and the impacts.
3. For medical use licensees, does your facility currently monitor for radiopharmaceutical extravasation? If so, why and how do you monitor? If not, why not?
4. Do you expect that monitoring for extravasation and reviewing the results would improve radiopharmaceutical administration techniques at medical use licensee facilities? If so, how? If not, why not?
5. Do you believe an NRC regulatory action requiring monitoring and review of extravasation would improve patient radiological health and safety? If so, how?

If not, why not?

Medical Event Classification and Reporting Criteria

Currently, the NRC excludes extravasation of radiopharmaceuticals from its medical event reporting regulations. Medical events may not necessarily result in harm to the patient, but they can indicate a potential problem in a medical facility's use of radioactive materials or in administration as directed by the physician. Because licensees are not required to report extravasations to the NRC, extravasation events are not documented in the NRC's Nuclear Material Events Database (NMED), which contains records of events involving nuclear material reported to the NRC.

1. Are there any benefits, not related to medical techniques, to monitoring and reporting certain extravasations as medical events? What would be the burden associated with monitoring for and reporting certain extravasations as medical events?
2. If the NRC were to require that licensees report certain extravasations as medical events (recorded in NMED), what reporting criteria should be used to provide the NRC data that can be used to identify problems, monitor trends, and ensure that the licensee takes corrective action(s)?
3. If the NRC requires reporting of extravasations that meet medical event reporting criteria, should a distinction be made between reporting extravasations of diagnostic and therapeutic radiopharmaceuticals? If so, why? If not, why not?

VI. Conclusion

The NRC has determined that the petition meets the sufficiency requirements for docketing at § 2.803. The NRC will examine the issues raised in PRM-35-22 and any comments received on this document to determine whether these issues should be considered in rulemaking.

Dated: September 3, 2020.

For the Nuclear Regulatory Commission.

/RA/

Annette L. Vietti-Cook,
Secretary of the Commission.