



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

April 11, 2023

Ronald K. Lattanze  
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Cary, NC 27513  
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Dear Mr. Lattanze:

Thank you for taking the time on Friday, April 7, 2023, to discuss with me the letters submitted by you to the U.S. Nuclear Regulatory Commission (NRC) on February 16, 2023 (Agencywide Documents Access and Management System Accession No. ML23048A216) and April 4, 2023 (ML23096A013). In the letters, a request was made for the NRC staff to correct certain information in SECY-22-0043, "Petition for Rulemaking and Rulemaking Plan on Reporting Nuclear Medicine Injection Extravasations as Medical Events (PRM-35-22; NRC-2020-0141)" (ML21268A006). The request cited the NRC's Information Quality Guidelines as the basis for seeking this correction. Because SECY papers are produced for internal agency use, the NRC Information Quality Program does not provide an opportunity for a member of the public to submit an information correction request on this category of NRC documents.<sup>1</sup> Therefore, the NRC will not accept the request to correct SECY-22-0043 into the NRC's administrative information correction process.

However, based on Commission direction, the NRC has commenced rulemaking activities to amend Part 35 of Title 10 of the *Code of Federal Regulations* (10 CFR) to mandate reporting of extravasations that require medical attention for suspected radiation injury. As part of the rulemaking process, the NRC anticipates several interactions with members of the public, including at least one public meeting and the solicitation of comments. To begin the process, the NRC will publish a request for information in the *Federal Register* in April 2023. The *Federal Register* notice will also provide preliminary information about a public meeting planned for May 2023. During our interactions with the public, the NRC staff expects to hear a variety of views regarding the classification of certain extravasations as medical events. We welcome you to provide input during the May meeting and the rulemaking process regarding extravasations that should be reported as medical events.

The letter of February 16 also expresses concerns with the transparency of the Commission's process for voting on SECY-22-0043. The voting process was conducted in accordance with NRC's procedures for preparation and review of petitions for rulemaking, which reflect the agency's policy to make petition closure documents publicly available after the Commission has issued a decision and the petitioner has been informed of that decision. The final staff evaluation of whether to classify radiopharmaceutical extravasations as medical events

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<sup>1</sup> See NRC Management Directive 3.17 (<https://www.nrc.gov/docs/ML1610/ML16105A321.pdf>), Exhibit 2, Table 2, "Information Exempt from NRC Information Quality Guidelines and from the Public Seeking Correction."

reportable to the NRC, SECY-22-0043, was publicly released after the Commission issued a decision and, as the petitioner, we informed you of that decision. As reflected in SECY-22-0043, prior to preparing the recommendation, the staff sought and received significant public comments on the rulemaking petition.

In the letter, there is a statement that the NRC's annual Report to Congress on Abnormal Occurrences (AO) does not meet statutory requirements because it does not currently include extravasations. The NRC evaluates medical events, as defined in 10 CFR 35.3045 and reported by NRC and Agreement State licensees, against the existing AO criteria for inclusion in the annual report to Congress. SECY-22-0043 with its enclosures explains why the Commission has historically excluded extravasations from the definition of medical events. Therefore, the NRC's annual reports on AOs fully describe all currently reportable medical events, as legally required. Nonetheless, as the Commission recently approved initiating a rulemaking that would amend the NRC's regulations to mandate medical event reporting of extravasations that require medical attention for a suspected radiation injury, the NRC would evaluate any medical events involving this specific type of extravasation for inclusion in the annual report to Congress, should the rulemaking be finalized.

In accordance with 10 CFR 2.390 "Public inspections, exemptions, requests for withholding," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room and at ADAMS Accession Number ML23094A229. ADAMS is accessible at <https://www.nrc.gov/reading-rm/adams.html>.

If you have any questions or need additional information, please contact me at [Kevin.Williams@nrc.gov](mailto:Kevin.Williams@nrc.gov) or (301) 415-3340.

Sincerely,



Signed by Williams, Kevin  
on 04/11/23

Kevin Williams, Director  
Division of Materials Safety, Security, State  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

Response to Ronald Lattanze Letter to Commissioners dated February 16, 2023 re SECY-22-0043, "Petition for Rulemaking and Rulemaking Plan on Reporting Nuclear Medicine Injection Extravasations as Medical Events (PRM-35-22, NRC-2020-0141)" DATE April 11, 2023

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