



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

June 28, 2023

Ronald K. Lattanze
Lucerno Dynamics, LLC
140 Towerview Court
Cary, NC 27513

Dear Mr. Lattanze:

Thank you for expressing your concern through your May 12, 2023 and June 15, 2023, letters (Agencywide Documents Access and Management System (ADAMS) Accession No. ML23137A235 and ML23177A044) requesting to appeal the U.S. Nuclear Regulatory Commission (NRC) Information Quality Program Information Correction Request (ICR) nonacceptance decision communicated to you by letter dated April 11, 2023, from Mr. Kevin Williams, Director, Division of Materials Safety, Security, State and Tribal Programs, Office of Nuclear Material Safety and Safeguards (ML23094A229). Your initial ICR was not accepted because SECY papers are exempt from the NRC's ICR process. However, I have reviewed your letter, in which you request that the NRC make an exception and accept your ICR as a matter of discretion, and correct certain information in SECY-22-0043. I also discussed your ICR appeal request with members of my organization. In looking at the information provided, there is no new information or additional information that warrant a change and I agree with the April 11, 2023, decision. Since the substance of your concerns relates to an ongoing NRC rulemaking activity, as previously stated, the appropriate vehicle for raising these concerns before the agency is your continued participation in this rulemaking (discussed below), not the ICR process.

Your letter also expresses concerns with the transparency of the decision making (i.e., voting) process on SECY-22-0043. We would like to emphasize that the NRC follows its established procedures. We understand the importance of transparency and want to clarify that the voting process was conducted in accordance with the NRC's procedures for the preparation and review of petitions for rulemaking. These procedures reflect the agency's commitment to ensuring fairness and accountability. These procedures implement the agency's policy to make petition closure documents publicly available only after the Commission has issued a decision and the petitioner has been informed of that decision. The final NRC staff evaluation of whether to classify radiopharmaceutical extravasations as medical events reportable to the NRC, as presented in SECY-22-0043, was released publicly after the Commission issued a decision and you, as the petitioner, were informed of that decision. Furthermore, as indicated in SECY-22-0043, the NRC staff actively sought and received significant public comments on your rulemaking petition.

In response to Commission direction, the NRC has initiated rulemaking activities to amend Part 35 of Title 10 of the *Code of Federal Regulations* (10 CFR) to mandate the reporting of extravasations that require medical attention for suspected radiation injury. As part of this

rulemaking process, the NRC is engaging in various interactions with the public, including public meetings and solicitation of comments. In April 2023, the NRC published a request for information in the *Federal Register* (FR) (88 FR 24130), which made available preliminary proposed rule language and included a number of questions, for stakeholders to provide input on to help the NRC staff's development of the proposed rule. The NRC staff held a public meeting held on May 24, 2023, to provide information and answer questions to help stakeholders prepare their comments on this information request. During this public meeting, which had over 200 attendees, the NRC staff listened to a variety of views regarding the classification of certain extravasations as medical events. We encourage you to provide your perspectives and concerns through the methods in the *Federal Register* notice by July 18, 2023, when the comment period closes. The NRC staff will evaluate the comments and will use the feedback received on the information request to inform the development of the proposed rule; however, there will not be a formal comment resolution process as the proposed rule language is developed. In addition, as we proceed with the rulemaking process, there will be further opportunities, such as when the proposed rule is published for public comment, for you and others to provide input on how extravasations should be reported as medical events. The NRC staff plans to provide the draft proposed rule to the Commission in August 2024. The Commission typically makes the draft proposed rule available to the public for information 10 business days after receipt.

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 No. ML23158A281. ADAMS is accessible at <https://www.nrc.gov/reading-rm/adams.html>.

Thank you for bringing your concerns to our attention, and we appreciate your engagement with the NRC's rulemaking process. We continue to work to ensure transparency in our processes and strive to maintain transparency throughout our decision-making process. If you have any questions or need additional information, please contact me at john.lubinski@nrc.gov or 301-415-0595.

Sincerely,



Signed by Lubinski, John
on 06/28/23

John W. Lubinski, Director
Office of Nuclear Material Safety
and Safeguards

SUBJECT: RESPONSE TO RONALD LATTANZE APPEAL LETTER TO THE NRC INFORMATION QUALITY COORDINATOR DATED MAY 12, 2023, REGARDING SECY-22-0043, "PETITION FOR RULEMAKING AND RULEMAKING PLAN ON REPORTING NUCLEAR MEDICINE INJECTION EXTRAVASATIONS AS MEDICAL EVENTS (PRM-35-22, NRC-2020-0141)" DATED: June 28, 2023

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ADAMS Accession No.: ML23137A236; Ltr ML23158A281

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NAME	CValentin-Rodriguez	KWilliams	MNarick	JFeibus
DATE	6/8/2023	6/8/2023	6/8/2023	6/9/2023
OFFICE	OGC/GCRPS/LCLSP/NLO	OGC/GCRPS/RMR	Tech Ed	NMSS
NAME	EMichel	MSmith	MPringle	JLubinski
DATE	6/14/2023	6/14/2023	6/16/2023	6/28/2023

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