



July 31, 2023

Christopher Hanson, Chairman  
David Wright, Commissioner  
Annie Caputo, Commissioner  
Bradley Crowell, Commissioner  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Subject: SECY-22-0043 Information Correction Request and Appeal

Dear Chairman Hanson, Commissioner Wright, Commissioner Caputo, and Commissioner Crowell,

I am requesting that the NRC reconsider the nonacceptance decisions regarding my February 12, 2023, SECY-22-0043 Information Correction Request (ICR) and the related May 12, 2023, Appeal.

**Background**

On December 30, 2022, the NRC accepted a petition for rulemaking (PRM-35-22). The petition had asked NRC to eliminate their 43-year-old policy that exempted extravasations as reportable medical events. The petition asked that these accidental radiation exposures to medical patients be treated no differently than any other reportable medical event.

Rather than requiring medical providers to use the existing dose-based threshold criterion for reporting extravasations, the Commissioners asked the medical staff to create a new reporting criterion—just for extravasations. In their Notation Vote comments, the Commissioners referred to specific recommendations in SECY-22-0043 that informed their decision to initiate rulemaking, which would require patients to experience radiation injury in order for a large extravasation to be reportable.

This proposed rulemaking is inconsistent with the longstanding NRC approach to radiation protection; it does not provide adequate protection to patients. Rather than ensuring immediate mitigation efforts for patients experiencing large extravasations, NRC's proposed rulemaking would allow providers to ignore these misadministrations.



Patients would be sent home, unaware they have been extravasated. They would then be expected to associate vague radiation symptoms with an unknown medical error weeks, months, or years after the extravasation. Finally, the patient would be required to schedule and pay for an appointment with the doctor responsible for the misadministration in the hopes that the doctor would self-report the issue to the NRC.

PRM-35-22 was intended to reduce radiopharmaceutical extravasations and improve patient safety and care. But the proposed rulemaking will not lead to reduced extravasations and does not provide the intended improvement to patient safety and care. The proposed rulemaking has another important implication. Patients of color are more likely to experience a misadministered injection. These patients, as well as those with lower income, disability, and/or limited English proficiency, are disproportionately impacted as they are and less likely to report errors. The NRC's proposed ruling making will exacerbate healthcare inequities.

Once SECY-22-0043 was finally made public, it was readily apparent that a substantial amount of information included in this document was factually inaccurate, incomplete, unreliable, and biased.

The NRC is "committed to ensuring the quality of all information that it relies on or disseminates," but unfortunately, SECY-22-0043 does not fulfill this commitment. It is necessary for this to be corrected in order for the NRC to follow through on its commitment.

Provided that the SECY-22-0043 had contained the correct information, the Commissioners would have arrived at a very different conclusion, one in which patient safety was protected and safeguarded from preventable mistakes.

On February 15, 2023, I submitted an ICR to the NRC regarding SECY-22-0043, outlining thirty-five (35) specific examples of inaccurate, incomplete, unreliable, and biased information needing reviewing and updating. In accordance with NRC policies, I provided corrected information with appropriate supporting reference for the review and consideration of the Commission.

On April 13, 2023, Mr. Kevin Williams, Director Division of Materials Safety, Security, State, and Tribal Programs, informed me in a letter dated April 11<sup>th</sup> that NRC would not accept the ICR. Mr. Williams cited Management Directive 3.17 and informed me SECY documents were exempt from NRC's information quality guidelines and from public submission of correction requests. I was quite surprised and taken aback by this





response due to the lack of concern for incorrect data being leveraged on a decision impacting patient safety and the disregard for the NRC's own policies and procedures.

On May 12, 2023, I submitted an ICR Appeal, providing the NRC with information from NRC Management Directive 3.17 clarifying why SECY-22-0043 is not exempt by NRC's own rules from the ICR process.

On July 25, 2023, I received a letter dated June 28, 2023, from Mr. John Lubinski, Mr. Williams' direct supervisor and Director, Office of Nuclear Material Safety and Safeguards. Mr. Lubinski stated that "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." Mr. Lubinski's response causes me great concern and I believe should be a great concern to the Commissioners as well for the following reasons:

- While SECY documents are for intra-agency use and normally exempt from ICRs under Management Directive 3.17 as they are usually made available for the public, Management 3.17 states there are limited circumstances in which information would follow the ICR process and quality guidelines. SECY-22-0043 is an example in which the ICR process and quality guidelines should apply as it was never made available to the public at any time either as a draft, or after the normal 10-day period post-delivery to the Commission, nor at any time prior to the Commission ruling on the PRM-35-22 seven months later.
- Under the NRC's Management Directive 3.17 *ADMINISTRATIVE PROCESS FOR THE PUBLIC TO SUBMIT A REQUEST FOR CORRECTION OF INFORMATION*, there were multiple compliance failures.
  - *Non-Compliance Issue 1* - NRC is to communicate to the submitter of the ICR and Appeal within 5 days of receipt as to whether it will be accepted.
    - The ICR non-acceptance response was received 57 days after receipt (**52 days past the compliance timeframe**).
    - The Appeal non-acceptance response was received 74 days after receipt (**69 days past the compliance timeframe**).
  - *Non-Compliance Issue 2* - The non-acceptance determination is in conflict with the NRC's actions as per the NRC's process; NRC personnel are only assigned to the ICR and Appeal if the NRC has determined to accept them.
    - Both Mr. Williams and Mr. Lubinski were assigned to the ICR and appeal.



- *Non-Compliance Issue 3 – Under NRC’s Management Directive 3.17, “The IOC will assign the appeal for evaluation to a management official, typically at the division director level, who is a member of the Senior Executive Service and who, in most cases, does not supervise the management official who was responsible for the initial response to the ICR.”*
  - The NRC official assigned to the Appeal was Mr. Lubinski, who is Mr. Williams’ supervisor. For clarity, Mr. Williams was the NRC official responsible for the initial response to the ICR.
  - Based on this assignment decision, the review of the ICR and Appeal has been entirely conducted by the staff responsible for SECY-22-0043. This is inappropriate.
  - Management Directive 3.17 does specify “in most cases;” however, given the nature and the extent of the issues identified in the ICR and Appeal, it is extremely surprising that no one outside that department became involved in adjudication of the ICR or Appeal.
- *Non-Compliance Issue 4 - Mr. Lubinski stated that the Appeal presented no new or additional information that warrants a change in the original ICR decision by his direct report, Mr. Williams. This is untrue.*
  - Mr. Williams stated SECY-22-0043 was exempt from the ICR process. In my appeal, I provided additional information regarding NRC Management Directive 3.17. This is new and additional information supporting how SECY-22-0043 is in fact the exact type of document that is covered by a public ICR.

The American public trusts the NRC to regulate fairly the many positive uses of radiation and above all, ensure the safety of the American public and nation. As a result, it is critical for the NRC’s conduct to reflect this trust. Unfortunately, the NRC’s conduct in regard to SECY-22-0043 has thus failed to uphold this trust, but it can easily be remedied by the Commission now. The lives of the American people are dependent upon you to safeguard them.

### **Request**

I respectfully ask the NRC to immediately correct SECY-22-0043. This will demonstrate that the Commissioners are acting to ensure the protection of patients’ health and safety by requiring that extravasations that exceed existing, objective, dose-based thresholds to reasonable volumes of healthy tissue be reported like any other medical event.





NRC should act now to stop the current rulemaking. No patient is capable of or willing to report a large extravasation. This has been and should be the responsibility of the medical providers. It is important for the NRC to publish a standard dosimetry model, which captures the vast majority of tissue affected and reports on the dose to a reasonable volume of 5-10 cc around the highest voxel. With NRC's support and requirement of extravasation reporting, the implementation timeline could provide a grace period to help ease the transition for both the NRC and medical providers. For instance, a grace period of twelve to eighteen months would provide time for medical providers to fix the issues leading to extravasations.

With the NRC's support, the American public can be adequately protected from radiation and receive safer and improved medical care. In addition, the American public would be able to more fully recognize the role the NRC takes in helping to protect them in their day to day lives and build tremendous goodwill and trust in the NRC's leadership.

Thank you for your time and consideration.

Sincerely,

**Ronald K. Lattanze**

Digitally signed by Ronald K.  
Lattanze  
Date: 2023.07.31 09:08:47 -04'00'

Ronald Lattanze  
Chief Executive Officer  
Lucerno Dynamics, LLC  
rlattanze@lucerno.com  
919.371.6800 x101

CC: Jonathan Feibus via [Jonathan.Feibus@nrc.gov](mailto:Jonathan.Feibus@nrc.gov)

**From:** Ron Lattanze <rlattanze@lucernodynamics.com>

**Sent:** Monday, July 31, 2023 9:17 AM

**To:** Christopher Hanson <Christopher.Hanson@nrc.gov>; Annie Caputo <Annie.Caputo@nrc.gov>; David Wright <David.Wright@nrc.gov>; Bradley Crowell <Bradley.Crowell@nrc.gov>

**Cc:** Jonathan Feibus <Jonathan.Feibus@nrc.gov>

**Subject:** [External\_Sender] Reconsideration

Chairman Hanson and Commissioners Caputo, Wright, and Crowell,

Please see the attached request for reconsideration of my ICR regarding SECY-22-0043.

Thank you,

Ron Lattanze

**Ron Lattanze | 919.371.6800 ext. 101 | 919.608.0341 (c)**

