



April 4, 2023

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

Chairman Hanson and Commissioners,

On February 15, 2023, I submitted an Information Correction Request (ICR) to info.quality@nrc.gov regarding the contents of SECY-22-0043. This request was submitted in accordance with NRC's Information Quality Guidelines, published in OMB Federal Register Notice Vol. 67, Num. 190. I notified you of the ICR on February 16, 2023 and followed up withininfo.quality@nrc.gov twice on February 28 and March 21 to ensure receipt of my correction request.

The NRC's Information Quality Guidelines state that the requestor will be notified as soon as possible within 45 days or if the NRC will require more than 45 calendar days to resolve the correction request, the NRC will inform the requestor that more time is required, state the reason why, and include an estimated decision date.

The 45 calendar days period for my correction request ended on April 1, 2023. I am writing you to make you aware that as of today, I have not received any response from the NRC to my request or follow-up emails.

The correction request comprehensively outlined how the SECY-22-0043 document failed to meet the NRC quality guidelines. This document influenced your decision to direct the medical staff to abandon the existing dose-based threshold used for all other medical events and to establish a unique patient injury reporting criterion. Since patients continue to experience large extravasations every day, I am asking for your direct involvement to ensure the corrections to the SECY-22-0043 are addressed promptly.

PRM-35-22, which you accepted on December 30, 2022, definitively showed that the NRC's internal exemption policy was no longer appropriate. This policy was not a regulation. But the exemption had been repeatedly endorsed by members of the regulated community and the Advisory Committee on the Medical Uses of Isotopes to ensure that no extravasation was ever reported to the NRC. PRM-35-22 requested rulemaking to ensure that the regulation clearly states that extravasations that meet existing medical event criteria be reported.

I continue to believe that rulemaking is required to ensure that extravasations are specifically addressed and handled similarly to all other medical events. Since the reporting exemption was an internal NRC policy, the Commission could issue Interim Staff Guidance now to help improve radiation protection for patients immediately. This guidance should include:

- Initiating rulemaking to ensure extravasations are reported using the existing dose-based threshold,



- standardizing an extravasation dosimetry model for tissue using the latest published method, and
- requiring licensees begin immediate efforts to monitor for and reduce extravasations.

Thank you for your prompt attention to this matter.

Sincerely,

Ronald K.
Lattanze

Digitally signed by Ronald K. Lattanze
DN: cn=Ronald K. Lattanze, o, ou,
email=rlattanze@lucerno.com, c=US
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Ronald Lattanze
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Cc:

- Chair Cathy McMorris Rodgers (R-WA), House Energy & Commerce Committee
- Ranking Member Frank Pallone (D-NJ), House Committee on Energy & Commerce
- Chairman Tom Carper (D-DE), Senate Committee on Environment & Public Works
- Ranking Member Shelley Moore Capito (R-WV), Senate Committee on Environment & Public Works
- Chairman Jeff Duncan (R-SC), House Energy & Commerce Subcommittee on Energy, Climate & Grid Security
- Ranking Member Diana DeGette (D-CO), House Energy & Commerce Subcommittee on Energy, Climate & Grid Security
- Chairman Ed Markey (D-MA), Senate Environment & Public Works Subcommittee on Clean Air, Climate, and Nuclear Safety
- Ranking Member Pete Ricketts (R-NE), Senate Environment & Public Works Subcommittee on Clean Air, Climate, and Nuclear Safety
- Chairman Morgan Griffith, House Energy & Commerce Subcommittee on Oversight & Investigations
- Ranking Member Kathy Castor (D-FL), House Energy & Commerce Subcommittee on Oversight & Investigations
- Chairman Chuck Fleischmann (R-TN), House Appropriations Subcommittee on Energy & Water Development
- Ranking Member Marcy Kaptur (D-OH), House Appropriations Subcommittee on Energy & Water Development
- Chair Dianne Feinstein (D-CA), Senate Appropriations Subcommittee on Energy & Water Development
- Ranking Member John Kennedy (R-LA), Senate Appropriations Subcommittee on Energy & Water Development
- White House Office of Management & Budget
- White House Office of Science & Technology Policy
- Patients for Safer Nuclear Medicine
- Organization of Agreement States Executive Board
- NRC General Counsel

Chair Resource

From: Ron Lattanze <rlattanze@lucernodynamics.com>
Sent: Tuesday, April 4, 2023 2:15 PM
To: Christopher Hanson; David Wright; Jeff Baran; Annie Caputo; Bradley Crowell
Cc: Marian Zabler (She/Her/Hers); Bernice Ammon; steve.seeger@tn.gov; augustinus.ong@dhhs.nh.gov; CMRCrowell Resource
Subject: [External_Sender] Information Correction Request Follow-up
Attachments: 2023-04-04 ICR Follow-up letter signed.pdf

Chairman Hanson and Commissioners Baran, Caputo, Crowell, and Wright,

Please see the attached update on my February 15, 2023, Information Correction Request.

Thank you.

Ron Lattanze

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



From: Ron Lattanze
Sent: Thursday, February 16, 2023 2:43 PM
To: christopher.hanson@nrc.gov; 'david. wright' <david.wright@nrc.gov>; jeff.baran@nrc.gov; annie.caputo@nrc.gov; bradley.crowell@nrc.gov
Cc: 'marian zabler' <marian.zabler@nrc.gov>; 'bernice ammon' <bernice.ammon@nrc.gov>; steve.seeger@tn.gov; augustinus.ong@dhhs.nh.gov; cmrcrowell@nrc.gov
Subject: Extravasation, Abnormal Occurrence reporting, and Information Correction Request

Chairman Hanson and Commissioners Baran, Caputo, Crowell, and Wright,

I am following up with you regarding your decision on the extravasation petition. I appreciated the Commission's acceptance of the petition based on the scientific evidence we presented. However, the Commission's adoption of the medical staff's recommendation to create a unique reporting criterion for extravasations adds an unnecessary burden to patients and will not address the underlying issues that cause extravasations. The unique reporting criterion also creates other issues.

I have attached a letter to you highlighting how the unique criterion has implications on Abnormal Occurrence reporting to Congress as well as compliance with existing NRC policies. This letter also references the attached Information Correction Request (ICR), which I submitted to NRC's Information Quality Coordinator yesterday afternoon via an email to info.quality@nrc.gov.

As stated in your Notation Vote comments, Commission Paper SECY-22-0043 played a role in your decision making process. Unfortunately, this document was not shared with me or the public before you considered the petition. As a result, we were unable to correct many deficiencies in the quality of information that you relied on during the decision making process. We have submitted the ICR to address all of these SECY-22-0043 issues so the Commission can quickly reevaluate the extravasation reporting criterion using accurate, complete, reliable, and unbiased information as required by NRC.

Please let me know if you have any questions.

Sincerely,

Ron

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

