



LUCERNO DYNAMICS, LLC

140 Towerview Court
Cary, NC 27513
919-371-6800

March 22, 2022

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

Subject: Petition for Rulemaking (PRM)-35-22

Dear Chairman Hanson, Commissioner Wright, and Commission Baran,

In anticipation of your receipt of the Commission Paper: "Petition for Rulemaking and Rulemaking Plan on Reporting Nuclear Medicine Injection Extravasations as Medical Events" (RCPD-21-012), we reviewed all our written communications with NRC and found 28 communications submitting evidence on extravasations since 12/11/2018.

Commissioners were copied on just nine of these communications. To ensure you and your staff members are aware of the complete set of evidence shared with NRC, we are providing access to all our communications in this one document.

We have summarized the supporting evidence in each communication in a table at the end of this letter that includes the following information:

- Date of communication
- Recipients
- A brief summary of the evidence provided
- An access link to the original communication and attachments

Here are some key points from these communications.

1. Extravasations are avoidable

The 1980 NRC policy that exempts the reporting of all extravasations, no matter the absorbed dose to the patient tissue, was based on the belief that extravasations were "virtually impossible to avoid" and therefore nothing could be learned from these misadministrations. This belief is incorrect in 2022. Extravasations are almost completely avoidable, and their frequency can be reduced. As a result, there is no valid reason to exempt extravasations from medical event reporting. In 22 of the 28 communications, we provide evidence that extravasations are avoidable.

2. Performing extravasation dosimetry is simple, accurate, free, and fast

In 2022, characterizing the radiation dose to extravasated tissue is no longer a hurdle for any licensee. Using published patient-specific dosimetry methods is simple, accurate, free, and



adds just 3-4 minutes of work for licensees. Characterizing extravasations is also recommended by the IAEA and existing medical guidance. In 9 communications, we provide evidence that extravasation dosimetry is simple, accurate, free, and fast.

3. Dose threshold is the appropriate reporting criterion

In 1980, the Commission abandoned the concept of patient harm as a reporting threshold. In 2002, NRC implement a risk-informed reporting dose threshold using the logic that medical events that exceed this threshold suggest that a licensee may have trouble handling a radioisotope. A skin/tissue dose from an extravasation that exceeds the threshold should be treated no differently than the same dose from another cause of a medical event. Importantly, dose thresholds provide an objective reporting criterion. In 9 communications, we provide evidence to support dose threshold as a reporting criterion.

4. Extravasations can exceed current reporting dose thresholds

Based on published dosimetry methods that use patient-specific biological clearance and reasonable tissue volumes, extravasations of both diagnostic and therapeutic radiopharmaceuticals can and do exceed the dose threshold for medical event reporting. Furthermore, the most severe extravasations can also exceed the reporting threshold for Abnormal Occurrences. In addition to exceeding radiation dose thresholds, extravasations matter to patients clinically. In 23 communications, we provide evidence to support that extravasations can and do exceed reporting dose thresholds.

5. Correcting the exemption can improve patient protection with minimal burden

Removing the 1980 reporting exemption and ensuring an effective safety framework where significant extravasations are reported does not have to result in a burden on regulators. By providing a reporting grace period and ensuring smart rulemaking, regulators can minimize their burden while ensuring that the real frequency of extravasation decreases significantly. These steps will also minimize the burden on licensees who address their extravasations. Appropriately, reporting significant extravasations will be a burden on those licensees who routinely extravasate. In 10 communications, we provide evidence to support that steps can be taken to minimize the burden of removing the exemption.

6. Correcting the exemption is within the scope of NRC's role and responsibility

NRC is obligated and has the ability to provide for radiation safety of patients. The NRC Medical Use Policy Statement states that NRC will regulate to assure medical isotopes are used in accordance with physician's directions. Licensees are required to report unintentional exposures that exceed radiation dose limits. Extravasations meet reporting intent and criteria. In 14 communications, we provide evidence to support that removing the exemption is within the scope of NRC's role and responsibility.

Removing the extravasation reporting exemption will reduce inadvertent patient radiation exposures. The transparency of the petition process has resulted in public comments from hundreds of individuals and several medical societies. The incorrect information in these comments and past nuclear medicine community efforts to retain the exemption suggests that the



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community has not and will not adequately address this radiation protection issue on their own. Therefore, regulation is needed.

Ms. Laura Weil, the former patient advocate member of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and a member of the ACMUI Extravasation Subcommittee stated that significant extravasations:

“...should be reported just as any other misadministration of such magnitude would be reported as MEs. The fact that they may result in no patient harm should have no bearing on the requirement to report. This would be consistent with the fact that all other ME’s that cause no patient harm are currently required to be reported.”

Radiation safety needs to catch up with the introduction of new medical uses of isotopes since 1980. In 2022, there is no reason why licensees should not identify, mitigate, characterize, and report extravasations that exceed reporting criteria so that learnings can be shared. Approving the petition now will achieve Ms. Weil’s suggestion and will drive authorized users to improve their radiation safety competence to ensure adequate protection of patients. Approval will also immediately start to improve care for the hundreds of patients who are significantly extravasated every day in the United States.

Sincerely,

DocuSigned by:
A handwritten signature in black ink that reads "Ronald K. Lattanze".
7A15DCB142CA41B...

Ronald K. Lattanze

Cc: Marian Zabler
Bernice Ammon
Kevin Williams

Index of Lucerno Communications to NRC

Number	Date Sent & Weblink Sent To		Topics Covered in the Communication						
			Avoidable	Dosimetry Fast & Simple	Dose is Appropriate Criterion	Exceed Threshold	Minimal Burden	Within NRC Scope	
1	12/11/2018	Medical Staff	✓			✓			
	<i>Summary: Presentation to medical staff regarding frequency & severity of infiltrations, and that they can be reduced quickly.</i>								
2	4/2/2019	Medical Staff, Commissioners	✓			✓	✓	✓	
	<i>Summary: Request NRC and ACMUI re-evaluate 1980 decision to exempt extravasations from reporting, with justification.</i>								
3	4/3/2019	ACMUI, Medical Staff	✓			✓	✓	✓	
	<i>Summary: Presentation to ACMUI requesting re-evaluation of 1980 decision to exempt extravasations from reporting.</i>								
4	10/9/2019	Medical Staff	✓			✓	✓	✓	
	<i>Summary: Request NRC reject ACMUI 9/10/19 recommendation to retain 1980 exemption as ACMUI did not reconcile its recommendation with new evidence and ACMUI provided NRC with inaccurate and incomplete information. Includes 8 extravasation case reports.</i>								
5	11/12/2019	Medical Staff		✓		✓	✓		
	<i>Summary: Provide explanation of dosimetry methods for extravasations, per NRC request. Includes 1 extravasation case report.</i>								
6	11/18/2019	Medical Staff				✓			
	<i>Summary: Provide additional information to add to the 10/9/19 request. Includes 1 extravasation case report.</i>								
7	12/20/2019	Medical Staff				✓			
	<i>Summary: Additional information on dosimetry method for extravasation. Includes 3 extravasation case reports.</i>								
8	1/10/2020	Medical Staff		✓					
	<i>Summary: Provide copy of ACNM presentation of dosimetry method for extravasations, per NRC request.</i>								
9	1/22/2020	Medical Staff	✓		✓	✓			
	<i>Summary: Provide 2 relevant papers and offer to meet. Includes 3 extravasation case reports.</i>								
10	2/12/2020	Medical Staff	✓			✓	✓		
	<i>Summary: Provide relevant paper, discuss SNMMI guidelines and RSNA/QIBA protocol regarding extravasations. Includes 3 extravasation case reports.</i>								
11	3/4/2020	Medical Staff	✓		✓				✓
	<i>Summary: Provide relevant paper that extravasations can be avoided and OAS letter to NRC.</i>								
12	3/16/2020	Medical Staff	✓			✓			✓
	<i>Summary: Provide relevant paper summarizing IAEA 2018 Technical Meeting. Includes 3 extravasation case reports.</i>								

Number	Date Sent & Weblink Sent To		Topics Covered in the Communication					
			Avoidable	Dosimetry Fast & Simple	Dose is Appropriate Criterion	Exceed Threshold	Minimal Burden	Within NRC Scope
13	4/1/2020	Medical Staff, OAS	✓		✓			✓
	<i>Summary: Request NRC reject ACMUI 3/30/20 recommendation that patient intervention causes extravasations and therefore should not be reported, review of previous ACMUI meeting minutes where extravasations were deemed to be caused by technologist training/experience, tools and technique.</i>							
14	5/18/2020	NRC Secretary	✓		✓	✓	✓	✓
	<i>Summary: Petition for rulemaking to require reporting as medical events of certain extravasations. Includes 22 extravasation case reports.</i>							
15	7/20/2020	Medical Staff, OAS	✓			✓		✓
	<i>Summary: Provide relevant paper describing the need for extravasation guidelines with respect to prevention and to early and late treatment, request NRC to initiate modifications to VARSKIN6 software to accommodate extravasations, link to a white paper from radiation protection experts supporting the petition. Includes 13 extravasation case reports.</i>							
16	11/20/2020	Medical Staff	✓		✓	✓		✓
	<i>Summary: Provide answers to the 3 questions Kevin Williams identified in his meeting with Commissioner Baran on 11/5/20.</i>							
17	12/11/2020	Medical Staff	✓					
	<i>Summary: Object to misleading statements made by ACMUI members at their 12/8/20 meeting.</i>							
18	2/12/2021	Medical Staff	✓	✓		✓		
	<i>Summary: Provide independent research that confirms diagnostic extravasations can lead to high dose, published extravasation dosimetry paper, published papers on therapy extravasation, published paper on the importance of extravasation in SPECT MPI, and SNMMI leaflet with incorrect guidance for extravasated cases. Includes 4 extravasation case reports.</i>							
19	5/13/2021	Medical Staff, OAS	✓			✓		
	<i>Summary: Provide analysis of 3/16/21 ACMUI meeting transcript, identifying contradictory, circular and untenable positions from ACMUI members regarding extravasations.</i>							
20	5/31/2021	Medical Staff	✓			✓		✓
	<i>Summary: Provide comments on AltusLearn Webinar on extravasations, information on 2 examples of patient harm from extravasation discussed in the webinar.</i>							
21	6/28/2021	Medical Staff, Commissioners, OAS	✓			✓		✓
	<i>Summary: Provide published paper challenging extravasation assumptions, identify illogic of spills onto a patient being reportable while extravasations are not, analysis of non-reportable therapy extravasation.</i>							

Number	Date Sent & Weblink Sent To		Topics Covered in the Communication					
			Avoidable	Dosimetry Fast & Simple	Dose is Appropriate Criterion	Exceed Threshold	Minimal Burden	Within NRC Scope
22	8/31/2021	Medical Staff, Commissioners, OAS, FDA	✓	✓	✓	✓	✓	✓
	<i>Summary: As input to the 9/2/21 ACMUI public meeting on extravasations, provide comprehensive review of the evidence related to extravasations, analysis of the 4/1/21 NRC staff preliminary evaluation and 7/30/21 ACMUI draft response, analysis of ACMUI "pocket" extravasation hypothesis.</i>							
23	9/20/2021	Medical Staff, Commissioners, OAS	✓	✓		✓	✓	
	<i>Summary: Express concern over the continued delays in the petition decision, provide a list of 57 publications (with synopses) discussing harm from diagnostic extravasations and 27 publications that support monitoring of radiopharmaceutical administrations, published paper on the need to identify extravasations quickly to reduce patient exposure. Includes 1 extravasation case report.</i>							
24	10/8/2021	Commissioner Hanson Staff		✓		✓		
	<i>Summary: Email providing information to clarify misrepresentations from ACMUI during 10/5/21 meeting with the Commissioners, specifically that extravasation dosimetry is simple, free and accurate, significant extravasations can result in serious harm, and requiring patient harm would be a paradigm shift for medical event reporting.</i>							
25	1/11/2022	Commissioner Wright	✓		✓	✓		
	<i>Summary: Email follow up to 1/10/22 meeting, provide copy of slides, ACMUI transcript from 2008 illustrating that the medical staff knew the exemption was incorrect since that meeting, discuss patient harm vs. dose threshold for reporting criterion.</i>							
26	2/7/2022	Commissioners, OGC, Medical Staff, OAS	✓	✓	✓		✓	✓
	<i>Summary: Provide analysis of staff's extravasation Draft Commission Paper, describe inconsistencies with existing NRC safety concepts/policies/positions, proposed recommendation was abandoned by NRC in 1980 and relies on inaccurate comments from members/societies regulated by NRC.</i>							
27	2/28/2022	Commissioners, OGC, Medical Staff, OAS	✓	✓	✓	✓	✓	✓
	<i>Summary: Follow up to 2/14/22 meeting, provide copy of slides, published paper discussing the limited radiation knowledge of patients, extravasation case that would qualify as Abnormal Occurrence (AO) if not for the exemption, comments on proposed revisions to AO reporting criteria. Includes 5 extravasation case reports.</i>							
28	3/21/2022	Commissioners, OGC, Medical Staff, OAS		✓		✓		
	<i>Summary: Provide accepted paper on extravasation dosimetry tools and published paper on method, discussion of simple, fast and free dosimetry method for extravasations. Includes all 47 extravasation case reports previously provided.</i>							