# **U.S. Nuclear Regulatory Commission Public Meeting Summary**

**Title:** Information Request Federal Register Notice Related to the Rulemaking on Reporting Nuclear Medicine Injection Extravasations as Medical Events

Meeting Identifier: 20230589

Date of Meeting: May 24, 2023

Location: Webinar

**Type of Meeting:** Information meeting with a question-and-answer session

**Purpose of Meeting:** To provide information to facilitate stakeholder feedback on the preliminary proposed rule language and questions included in the information request *Federal Register* notice (88 FR 24130) related to the rulemaking on reporting nuclear medicine injection extravasations as medical events.

General Details: The NRC staff published the official public meeting notice on May 3, 2023, providing the agenda and webinar log-in instructions for attendees (Agencywide Documents Access and Management System (ADAMS) Accession No. ML23128A025). The meeting was conducted remotely via webinar and began at 1:00 p.m. Eastern Time (ET). Dan Frumkin, the meeting facilitator, started the meeting by welcoming all attendees and discussing the meeting logistics. Kevin Williams from the Office of Nuclear Material Safety and Safeguards (NMSS) provided opening remarks, welcomed all attendees, and provided the purpose and agenda for the meeting. Irene Wu from NMSS presented background information on radiopharmaceutical extravasations, medical event reporting requirements, the NRC staff's evaluation of whether extravasations should be reported as medical events, the petition for rulemaking, and the rulemaking plan. Daniel DiMarco from NMSS presented the preliminary proposed rule language and the basis for the questions in the information request. After each group of questions (definitions, procedures, and healthcare inequities), the NRC staff provided an opportunity for members of the public to ask questions and provide feedback. Ms. Wu presented on how to prepare and submit comments and the next steps for the rulemaking. The NRC staff then provided another opportunity for members of the public to ask questions and provide feedback. Ms. Wu then presented on the contact information and resources for this rulemaking and how to provide meeting feedback. Mr. Williams provided closing remarks and then Mr. Frumkin adjourned the meeting. The staff's slide presentation is available in ADAMS at Accession No. ML23132A116. The meeting had over 200 participants from the NRC, medical community, patient advocates, Agreement States, and the public. A list of NRC and external meeting participants is enclosed. The meeting concluded at 3:21 p.m. ET. The staff has summarized the questions and feedback received and a transcript of the meeting is available in ADAMS at Accession No. ML23159A193.

# **Summary of Questions and Feedback:**

### **Definitions**

Regarding the proposed definition of "extravasation," one commenter stated that the term "leakage" is inconsistent with the use or characterization of an extravasation as a medical event and incompatible with this rulemaking. Another commenter asked if the NRC has considered substituting the word "leakage" for "infiltration" since infiltration is a more active process and

leakage is more passive. Another commenter asked about how extravasation and infiltration would apply to radioembolizations with microspheres.

Regarding the proposed definition of "medical attention," one commenter was looking for clarity in the definition and that it includes any techniques used to reduce the chance of suspected radiation injury.

Regarding the proposed definition of "suspected radiation injury," one commenter asked if it would be the patient or a medical professional that would be making the determination of suspected radiation injury. NRC staff responded that the determination would be made by a medical professional, such as an authorized user, who has the training and experience to identify a radiation injury.

One commenter asked what criteria the NRC will use to define suspected radiation injury and if a numerical value will be used. Another commenter indicated that using a dose threshold for suspected radiation injury is the most practical and that injection site dosimetry is the obvious way to determine that. Another commenter responded that calculating dose from extravasation is difficult and requires patient-specific biological data and they question the accuracy of the dosimetry with Versant and Lucerno Dynamic's technology.

One commenter asked what a deterministic health effect is from a suspected radiation injury and noted that erythema of skin is likely not a deterministic effect that could be attributed to radiation from injection. Another commenter responded that the vast majority of nuclear medicine injections that might lead to extravasations will not cause injury or deterministic effects.

Several commenters stated that diagnostic procedures are not likely to cause radiation injury and that reporting diagnostic infiltrations would be onerous, and therefore, they are mostly concerned with theranostic therapeutic procedures. Several commenters supported the idea for theranostics extravasations to be reported because of the written directive requirement. One commenter countered that diagnostic injections including positron emitters can actually result in a dose of multiple Gray.

One commenter said that there can be late effects considerably down the line, which is why they would advocate for all extravasations to be reported regardless of suspected radiation injury. Another commenter countered in saying that reporting every extravasation would be extremely cumbersome and that the NRC's rulemaking makes more sense as a middle-of-the-road approach.

#### Procedures

One commenter described an endoline catheter with positive blood return and multiple successful flushes as an example of a technique used. Another commenter asked if there is data about injection techniques in relation to extravasations. Another commenter provided information on sensing technologies for extravasation detection. Another commenter indicated that the cost and practical availability of these technologies need to be considered.

Multiple commenters indicated that suspected infiltrations should be imaged to determine the extent of an extravasation. One commenter asked about pure beta emitters and how to image them if there is an extravasation since that cannot be done with conventional imaging devices. One commenter indicated that it is becoming more common that these radiopharmaceuticals will be administered in urology clinics and radiation oncology therapy centers where there is no

imaging and they are concerned that licensees will be required to somehow investigate every administration for extravasations.

One commenter stated that allowing facilities to develop their own action plan as far has how they are going to address and protect their patients is a good position to take and that adding extra steps and requiring reporting would slow down the workflow and adversely impact patient care. Another commenter agreed with that position and indicated that extravasations are an important quality assurance issue that need to be handled at each licensee site and that adding extravasations as a medical event is not going to improve the process. Another commenter raised their concern about adding burden to the patient to identify suspected radiation injury.

#### **Healthcare Inequities**

One commenter recommended having cautionary screening after a potential extravasation event so patients do not leave the facility and are put back in an environment in which they may not feel comfortable speaking with their doctor or have difficulty accessing transportation back to the facility. Several commenters stated that patient self-reporting is unacceptable as patients may not realize that they have experienced an extravasation and the symptoms may not be immediately apparent, which is particularly worrisome for patients with limited literacy. Another commenter asked the NRC to immediately issue interim guidance while the rulemaking progresses.

One commenter stated that whatever the presumed benefits are of screening for extravasations, there is a potential downside in terms of cost, patient throughput, and availability of tests and there may be the unintended consequence of lesser availability of high-tech imaging modalities in underserved communities. Several commenters followed up by asking if a financial impact statement or analysis will be done as part of this rulemaking.

Two commenters indicated that there are other classes of patients where extravasations tend to be more common, such as with obese patients, patients who have previously had chemotherapy, patients with extensive tattoos, small children, and infants.

One commenter indicated that improvement of monitoring and training and the use of technology will reduce extravasations and improve equity.

### Additional Feedback

Several commenters expressed that the rulemaking plan, which the Commission's decision was based on, was somewhat flawed, incomplete, and biased. One commenter applauded NRC staff for the questions raised in and the structure of the information request.

Several commenters stated that several of the questions in the information request were beyond the scope of NRC's regulatory oversight and intruded into medical practice. One commenter disagreed and stated that it is NRC's job to get involved.

Several commenters asked for the source of the questions included in the information request and the preliminary proposed rule language, specifically if they were generated by NRC staff or if they were from the Commissioners' staff requirements memorandum. NRC staff responded that they were developed from both sources. Several commenters asked if the NRC had any plans to review and use existing national standards for this rulemaking and if staff had any plans to consult with drug manufacturers, the U.S. Food and Drug Administration, standards organizations, creditors, payers, and public health agencies. NRC staff responded that they will

be getting information from as many sources as possible, which includes Federal partners and other stakeholders.

One commenter stated that over-regulation is detrimental to patient safety and that technologists may not do procedures because they do not want to ruin their record of having no medical events and facilities may decide not to do procedures to avoid receiving violations from the NRC.

Several commenters asked about the availability of the dosimetry model. NRC staff responded that the dosimetry model is being developed and will be made available as part of the draft guidance along with the proposed rule.

One commenter asked if there was the potential for something other than a medical event reporting methodology for extravasations as there are better avenues to go about addressing this issue and improving patient care and safety without medical event reporting. NRC staff responded that there is the potential for staff's recommendation to change as the comments from this information request are considered. NRC staff also indicated that when the proposed rule is provided to the Commission, the Commission will decide which direction they would like NRC staff to proceed with.

**Next Steps:** The NRC staff will consider the comments received on the information request as it develops the proposed rule. The proposed rule is currently scheduled to be delivered to the Commission in August 2024. If approved by the Commission, the NRC staff will publish the proposed rule in the *Federal Register* for public comment.

SUBJECT: SUMMARY OF MAY 24, 2023, PUBLIC MEETING ON THE INFORMATION

REQUEST FEDERAL REGISTER NOTICE RELATED TO THE RULEMAKING ON REPORTING NUCLEAR MEDICINE INJECTION EXTRAVASATIONS AS

MEDICAL EVENTS

### **DISTRIBUTION:**

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# ADAMS Accession Nos.: Package ML23165A253; Meeting Summary ML23165A284; Slide Presentation ML23132A116; Meeting Notice ML23128A025; Meeting Transcript ML23159A193

#### \*via email

OFFICE	NMSS/REFS/MRPB/ PM	NMSS/REFS/MRPB/ RS	NMSS/REFS/MRPB/ BC	NMSS/MSST/MSEB/ BC
NAME	lWu	DBearde	JShepherd	CEinberg
DATE	06/14/2023	06/14/2023	06/16/2023	06/22/2023

OFFICIAL RECORD COPY

### **ENCLOSURE**

### **MEETING ATTENDEES**

Public Meeting on the Information Request Federal Register Notice Related to the Rulemaking on Reporting Nuclear Medicine Injection Extravasations as Medical Events

# May 24, 2023 Webinar 1:00 – 4:00 PM (Eastern Time)

U.S. Nuclear Regulatory Commission		
Hiba Ahmed	Tricia Lizama	
Brian Allen	Fajr Majeed	
Maryann Ayoade	Marianne Narick	
Jessica Bielecki	Janice Nguyen	
Cindy Bladey	Christine Pineda	
Andrew Carrera	Ronald Raunikar	
Sara Cody	Katie Rouse	
David Cullison	Dan Ruby	
Anne DeFrancisco	Kevin Salcedo	
Diana Diaz-Toro	Jen Scro	
Daniel DiMarco	Daniel Shaw	
Lisa Dimmick	Sahej Sharma	
Christian Einberg	Jill Shepherd	
Robin Elliott	Maxwell Smith	
Cindy Flannery	Sarah Spence	
Mark Franke	Candace Spore	
Dan Frumkin	John Tomon	
Nick Hefferle	Celimar Valentin-Rodriguez	
lan Irvin	Kevin Williams	
Janelle Jessie	Susanne Woods	
William Johnson	Irene Wu	

Public		
Name	Affiliation (if provided)	
Mary Ajango	Young Survivors Coalition	
James Albright		
Lauren Allaire		
Holi Allen		
Rich Anderson		
Xander Arena		
Lillian Armstead		
Amy Barocsi		
Joseph M. Beckman		
Julia Bellinger		
Kendall E Berry		
David Bierman		
Willam Bilotta		

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Name	Affiliation (if provided)		
Jerry Bingaman			
Nicholas Borges			
Louis Brayboy			
Jeffrey J. Brunette			
Janet Bryant			
Sue Bunning			
Ebony M. Bush			
David Carlson			
Carrie R Carson			
Rosinda Castanon			
George Chacko			
Allegra Chilstrom	Neal R. Gross & Co., Inc.		
Jessica Clements			
Chris Comfort			
Caitlynn Couch			
Logan A. Cowart			
David P Crowley			
Ron Crihfield			
Cathy Cutler	Brookhaven National Laboratory		
Simon Davies	Teen Cancer America		
Leland Davis	National Institutes of Health		
Sussie DeMello			
Matt Dennis			
Ann Marie Derby			
Newbegin Devaraj			
Michele Edwards			
Chinwe Ekwuribe			
Diane M Elmer			
Laura M. Evans	U.S. Department of Veterans Affairs		
Brain S. Fairchild	Harry Truman Memorial Veterans' Hospital		
Janet Franco			
Elizabeth Franklin			
Jennifer Freeman			
Scott Fuller			
James A Futch			
Andrew Garner			
Stravroula Giannouli			
William Gibbons			
Daniel Gomez-Cardona	Gundersen Health System		
Matthew Greenwood			
Kendall Greer			
Allen Grewe			
Stanley D Hampton			
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Becki Harisis			
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Kathleen Harrison			

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Billie Harvey	·	
Richard Harvey		
Lyndsi Hay		
Meredith Henderson		
Abdulla Hidayat		
William Hinchcliffe	Yale New Haven Hospital	
Kathleen Hintenlang	American College of Radiology	
Buffy M. Hofschild		
Jennifer R. House		
William Janes		
Paul E Kanabrocki		
Olivia Karoly		
Ramsey Kilani	Global Security Innovative Strategies	
Tracy King	Medical Physics Consultants	
Paul Knapp		
Josh Knowland	Lucerno Dynamics	
Laura M. Knox		
Arda Konik		
Karl G. Korneffel		
Catalina E. Kovats		
Angela Kwon		
Sathish Kumar Lageshetty		
Olusegun Akano Larinde		
Ronald Lattanze	Lucerno Dynamics	
Bryan P. Lemieux	,	
Ralph Lieto		
Roger Macklin		
Josh Mailman		
Anna Manfredo		
Matthew J. Marzano		
Lynes Matos		
Josh McIlvain		
Mahta Mirzaei McKee		
Amy McKenna		
Tara Medich		
Douglas L. Miller		
Angela Minden		
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Thai Q. Nguyen		
Rachel Nichols		
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Jaclyn O'Donnell		
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Zoubir Ouhib		
Michele Panichi-Egberts		
Tina Papagiannopoulos		
Virginia Pappas		
Jade M. Parisey		
Luke Park		
Ron Parsons		
Michael Peters		
Christopher A. Peterson		
Phillip Peterson	Colorado Department of Public Health and	
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Rachael Picchi		
Carmine M Plott	Forsyth Medical Center	
Kimyli Recca	1 Stoyar Modical Corner	
Robert Reiman Jr.		
Grace Roemer		
Gloria Romanelli		
Casey Schmitz		
Brian Serencsits		
Michael A Sheetz		
Beth Shelton		
Tina Shoemaker		
Justin D. Silkwood Albert Sinusas		
Roger C Sit Jim Sliney Jr.	Detients Dising	
Dr. Smith	Patients Rising	
	Defense Health Agency	
Gina Kell Spehn	New Day Foundation for Families	
Gabriela Spilberg		
Mary Ann Spilker		
Gregory Stackenwalt		
Mike N Stephens		
Kristen E Stryker		
Jason Timm		
Mike Timmerman		
Cindy Tomlinson		
Matthew Torrico		
Brittany Varney		
Arianna Vinales		
Karl Von Ahn	Texas Department of State Health Services	
Paul Wallner		
Chu Wang		
Hayley Weaver		
Mike Welling		
John C. White		

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William White		
Christopher Whitener		
Kim C. Wiebeck		
Matthew Williamson		
Sean Odell Wilson		
Melonie Wissing		
Harvey Wolkov		
Pat Zanzonico	Memorial Sloan Kettering Cancer Center	
Michael Zgaljardic		

Note: The attendance list is based on the Microsoft Teams attendance report and transcript. This list does not include individuals who called in and individuals who did not provide their last name when signing into the meeting.