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:

<u>Definitions</u>
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.

<u>Procedures</u>

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:
PUBLIC
RidsOpaMail
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CValentin-Rodriguez, NMSS
DBearde, NMSS
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RidsNmssRefs

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	IWu	DBearde	JShepherd	CEinberg
DATE	06/14/2023	06/14/2023	06/16/2023	06/22/2023

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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
Ian 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	

Public	
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	
Ashley A. Hanson	
Becki Harisis	
Anna Harrison	
Kathleen Harrison	

Public	
Name	**Affiliation (if provided)**
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	
Chris Mitchell	
Jonathan D Moore	
Mary E. Moore	
Helen Nadel	Lucile Packard Children’s Hospital Stanford
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Rachel Nichols	
Jordan Nofzinger	
Jaclyn O’Donnell	

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Jonathan J. Otten	
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 Environment
Rachael Picchi	
Carmine M Plott	Forsyth Medical Center
Kimyli Recca	
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.	Patients Rising
Dr. Smith	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	

Public	
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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.