

U.S. Nuclear Regulatory Commission Public Meeting Summary

Title: Information Meeting with Q&A Session on the Proposed Revision to Regulatory Guide (RG) 8.39, "Release of Patients Administered Radioactive Material"

Meeting Identifier: 20230784

Date of Meeting: July 20, 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 draft regulatory guide (DG), DG-8061, "Release of Patients Administered Radioactive Material," included in the *Federal Register* notice (88 FR 24495).

General Details: The NRC staff published the official public meeting notice on July 6, 2023, providing the agenda and webinar log-in instructions for attendees (Agencywide Documents Access and Management System (ADAMS) Accession No. [ML23201A106](#)). The meeting was conducted remotely via webinar and began at 12:00 p.m. Eastern Time (ET). Sophie Holiday, the meeting facilitator, started the meeting by welcoming all attendees and discussing the meeting logistics and goals for the meeting. Dr. Celimar Valentin-Rodriguez 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. Dr. Katherine Tapp from NMSS presented an overview of DG-8061 from a patient perspective, including the purpose of the guidance, and proposed changes made since the last revision such as the new baseline equations and modifying factors. Dr. Tapp also discussed how the proposed DG-8061 provides ways physicians could use information provided by patients to demonstrate patients could be released under current regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material." Dr. David Hamby, contractor for the Office of Nuclear Regulatory Research (RES) provided a technical overview of the modifying factors and example calculations using the new proposed methodology. After each presentation, the NRC staff provided an opportunity for members of the public to ask questions and provide feedback. Dr. Tapp presented on how to prepare and submit comments and the next steps for the rulemaking. Ms. Holiday then presented on the contact information and resources for this rulemaking and how to provide meeting feedback. Dr. Valentin-Rodriguez provided closing remarks and then Ms. Holiday adjourned the meeting. The staff's slide presentation is available in ADAMS at Accession No. [ML23198A203](#). The meeting had over 250 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 3:15 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. [ML23226A087](#).

Summary of Questions and Feedback:

Overview of Proposed Changes in Revision 2 of Regulatory Guide 8.39

One commenter inquired about why DG-8061 did not include references to two regulatory

information summaries issued in 2008 and 2011.

One commenter asked why the National Council on Radiation Protection and Measurements (NCRP) Report No. 155 biokinetic models were not used to formulate baseline values in this RG.

One commenter asked whether the NRC anticipated a trend towards less outpatient releases if the conservative values published in DG-8061 are used.

One commenter asked about DG-8061 potential implementation timeline for agreement states.

Overview of the Modifying Factors and Examples of Calculations

One commenter asked whether biokinetic modifying factor accounts for attenuation of larger patients. Another commenter asked if DG-8061 addressed service worker that may be exposed to a patient or multiply patients. Another commenter inquired about other acceptable biokinetic models that could be used to meeting the regulations.

Three commenters asked whether the NRC is confident that revision 2 of RG 8.39 would reflect the real-world situation at a hospital or clinical. Another commenter stated their concerns about the voluntary nature of regulatory guide.

Two commenters asked if the theoretical model used in DG-8061 was compared to published literatures. Another commenter inquired whether the draft regulatory guide went through any sort of peer review process.

One commenter asked about the logic the NRC used to add Yttrium-90 threshold values to DG-8061 since the radionuclide was removed from earlier version of the RG.

One commenter asked whether the NRC considered providing release guidance for patients that are undergoing dialysis. Another commenter asked how the ACMUI recommendations on revision 1 of the RG 8.39 were used to modify revision 2 of DG-8061.

One commenter asked why the NCRP Report No. 155 approach was not adopted into the revision 2 of DG-8061.

One commenter asked why Fludeoxyglucose (FDG) was listed as the only Flourine-18 diagnostic imaging agent in the breastfeeding interruption tables. Another commenter asked if DG-8061 could be used for animals, such as cat and dogs.

Next Steps: The NRC staff will consider the comments received as it finalizes DG-8061. Once the NRC staff has incorporated the feedback received, they will transmit the draft final regulatory guide to the Advisory Committee for the Uses of Medical Isotopes (ACMUI) for review and comment.

SUBJECT: SUMMARY OF JULY 20, 2023, PUBLIC MEETING ON THE Revision to REGULATORY GUIDE 8.39, "RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIAL"

DISTRIBUTION:
PUBLIC
KTapp, NMSS
CValentin-Rodriguez, NMSS
BAllen, RES
JTomon, RES
CEinberg, NMSS

ADAMS Accession Nos.: Meeting Summary ML23226A087; Slide Presentation ML23198A203; Meeting Notice ML23201A106; Meeting Transcript ML23226A087

***via email**

OFFICE	RES/DSA/RPB/ PM	NMSS/MSST/MSEB/ PM	RES/DSA/RPB/ BC	NMSS/MSST/MSEB/ BC
NAME	BAllen	KTapp	JTomon	CEinberg
DATE	08/18/2023	08/21/2023	8/22/2023	8/22/2023

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ENCLOSURE

MEETING ATTENDEES

Public Meeting on the Proposed Revision to Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material"

July 20, 2023

Webinar

12:00 – 3:00 PM (Eastern Time)

U.S. Nuclear Regulatory Commission	
Tapp, Katherine	
Valentin-Rodriguez, Celimar	
Allen, Brian	
Harvey, Edward	
Holiday, Sophie	
Shaw, Daniel	
Ayoade, Maryann	
Flora, Rigel	
Brenneman, Ken	
Williams, Kevin	
Spence, Sarah	
Evans, Carly	
Tomon, John	
Armstead, Lillian	
Dimarco, Daniel	
Dimmick, Lisa	
Einberg, Christian	
Cook, Jackie	
Karagiannis, Harriet	

Public	
Name	Affiliation (If provided)
Lieto, Ralph	
Michalski, Jeff	
Miller, John J.	
Barrickman, Deborah M.	
Buckalew, Judi	
Mason, Jeffrey S	
Spilker, Mary Ann	
Siegel, Barry	
Yonemitsu, Ron	
Bravenec III, Joseph S	

Enclosure

Public	
Name	Affiliation (If provided)
Rodgers, Jessica	
Cohn, Gregg	
Andersen, Eric	
Freeland, Jon L.	
Rook, Alan	
Ogretici, Akin	
Thomas, Jerry	
Kovats, Catalina E..	
Senglaub, Todd	
Drelich, Mike	
Dickson, Allan W	
Tawatao, James	
Von Ahn,Karl	
Stephens, Mike N	
Isaac Gonzalez	
Speers,Robert	
Amurao, Max	
Hall, Ike	
Bailey , Derek	
Dufford, Chris	
Johnson, Jennifer E.	
Blum,Stefanie	
Bruner, Angela P	
Chek, Roman	
Anger, Bob	
Dundulis, Bill	
Franklin, Elizabeth	
Thorvaldson, Tim	
Sit, Roger	
Studer, Kaci	
Williamson, Matthew	
Gu, Tianliang	
Sheetz, Michael A	
Hewadikaram, Kamani	
Hampton, Stanley D	
Day, Alexis	
Hamrick, Barbara	
Tomlinson,Cindy	
Ramirez,Sandra M	
Phillip Peterson	
Peros, Richard	

Enclosure

Public	
Name	Affiliation (If provided)
Harvey Wolkov	
Fairchild, Greg	
Kircher, Philip	
Norton, Gregory	
Ma, Collin	
Le, Dao	
Eiden, Thomas	
White, William	
Kimes, Roxanna	
Golan, Amir	
Iman, Jeremy	
Dawry, Frank P.	
Wayson, Michael B	
Otten, Jonathan J.	
Whitelock, Lisa	
Deibert, Karen M.	
Lee, Korressa	
Neil Petry	
Bailey Burks	
Chu Wang	
Andreani Mouzourou	
Kudchadker, Rajat J	
Kelley, Brian M	
Benke, Roland	
Colby, Brent	
Guastella, Michael	
Wiggins, John	
Byrnes, Heather	
Cromie, Meghan	
Sitek, Mark A.	
Derby, Ann Marie	
Williams, Kendall A	
Hall, Matt	
Denman, Morgan	
Garellick, Ira	
Crawford, Willie M.	
Naylor, Robert	
Greger, Robert	
Krebs, Jordan	
Turner, Adam	
Yokell, Daniel L.	

Enclosure

Public	
Name	Affiliation (If provided)
Larinde, Olusegun Akano	
Peters, Michael	
Harkness, Kathleen	
Plathe, Michael D.	
Nation, Christopher D.	
Aman, Stacie	
Munisamy, Sivakumar	
Still, Cami	
Nair, Satish	
Jones, Rosaliz	
Galbraith, Wendy K.	
Aumen, Laura	
Frye, Ross J.	
Patel, Neena	
Fuller, Scott	
Yoder, Bryan C	
Wride, Rick	
Garcia, Jose	
Bosley, William LTC	
Rostel, Emily C	
Mamoun, Eslam Kamal	
Gift, Matt	
Mannella, Kelly	
Schmidt, Lorie	
Crane, Peter	
Gabriel, Sandy	
Tubbs, Brenda	
Coffman, Daisy	
Lorenzen, William	
Recca, Kimyli	
Bierman, David	
Giardina, Joseph	
Fischer, Karl	
Martin-Macintosh, Erica	
Newman, Donna	
Serfass, Jacob Z.	
Helstern, Christopher M	
Collier, Jason	
Terrenoire, Wendy W	
Hammersborg, Kaylie	
Peralta, Byron Eduardo	

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Public	
Name	Affiliation (If provided)
Sanchez, Tim	
Johnson, Bella Elizabeth	
Farukhi, Irfan M.	
Blacker, James	
Harisis, Becki	
Plott, Carmine M	
Lewis-Kraitsik, Jay	
Flanigan, Karen	
Mekuria, Ephrime	
Boyd, Katherine	
McIlvain, Josh	
Knox, Laura M.	
Galbraith, Wendy	
Lyons, Erik	
Ouhib, Zoubir	
House, Jennifer R.	
Lake, Ian P.	
Gersman, Jennifer	
Ruck II, William R.	
Goetz, Danielle M	
Bergvall, Ethan S LTC	
Lakey, Beth	
Swanson, Jasen L MAJ	
Dehdashti, Farrokh	USARMY MEDCOM NRMCM (USA)
Vognetz, Jason	
Luechtefeld, David	USARMY DHA MADIGAN AMC (USA)
Grigsby, Perry	
Woods, Brandi	
Kelley, Brian M	
Ma, Collin	
Zoberi, Jacqueline	
Beckham, Thomas H	
Bhakta, Viharkumar S	
Kunder, Kevin	
Burton, Olwen F.	
Berry, Kendall E	
Gutierrez-Garcia, Nina	
Boote, Evan J.	
Redman, Harrison	
Neti, Prasad	
Merchantz, Heather	

Enclosure

Public	
Name	Affiliation (If provided)
Higgins, Kevin	
Boyd, Katherine R	
Thompson, Diana	
Wilson, Jamie	Stanford University
Amurao, Max	
Lysik, Andrew E.	
Pasell, Sally M.	
Samii, Jason M.	
Ford, Monica	
Hjelm, Danielle	
Matos, Lynes	
Sarfaraz, Esfandiar	
Welling, Michael	
Green, Joseph	
Nichols, Rachel	
Hintenlang, Kathleen	
Huston, Thomas E.	

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.

Enclosure