



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 29, 2023

MEMORANDUM TO: Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety and Safeguards

A handwritten signature in black ink, appearing to read "Maryann Ayoade".

Signed by Ayoade, Maryann
on 09/29/23

FROM: Maryann Ayoade, Medical Radiation Safety Team Member
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety and Safeguards

SUBJECT: SUMMARY OF AUGUST 29, 2023, PUBLIC MEETING ON
REGULATORY BASIS FOR RULEMAKING ON RB-82 GENERATORS,
EMERGING TECHNOLOGIES, AND OTHER MEDICAL USE OF
BYPRODUCT MATERIAL

Meeting Identifier: 20230877

Date of Meeting: Tuesday, August 29, 2023; 2:00 p.m. EDT

Location: Webinar

Meeting Participation Level: Information meeting with Question-and-Answer Session

Meeting Notice: ML23212A385

Purpose of the Meeting: To provide an overview of and facilitate stakeholder feedback on the U.S. Nuclear Regulatory Commission (NRC) staff's regulatory basis document and questions included in the *Federal Register* notice ([88 FR 42654](#)) for the planned rulemaking on "Rubidium-82 Generators, Emerging Medical Technologies, and Other Uses of Byproduct Material," under Title 10 of the *Code of Federal Regulations* (10 CFR), Part 35, "Medical Uses of Byproduct Material."

Background: On July 3, 2023, the NRC published the *Federal Register* notice (FRN) announcing the availability of the regulatory basis document (Agencywide Documents Access and Management System (ADAMS) Accession No. [ML23122A356](#)), for a 120-day public comment period. The document summarizes the current regulatory framework, describes the regulatory issues and proposed changes to the regulations in 10 CFR Part 35, includes specific questions for feedback to better inform the proposed changes, and evaluates alternatives for

establishing requirements for rubidium-82 generators, EMTs, and other medical uses of byproduct material. The regulatory basis also includes preliminary cost estimates for the NRC, Agreement States, and licensees for each alternative. The regulatory basis document, along with public comments received, will inform the NRC staff's development of a proposed rule to revise certain requirements in Part 35.

General Details: The NRC published the official public meeting notice on July 31, 2023, providing the agenda and webinar registration instructions for attendees ([ML23212A385](#)). The staff gave detailed presentations on the contents of the regulatory basis document and the questions included in the document and in the FRN. The staff also explained that the purpose of the meeting was not to receive comments on the regulatory basis document. The staff described how to provide comments on the document and outlined the next steps in the rulemaking process. The staff's presentations are available at [ML23240A718](#). At designated points during the presentations, the staff provided opportunities for meeting attendees to ask questions. The meeting was attended by about 122 people, including NRC staff, medical community representatives, Agreement State representatives, and members of the public. The meeting concluded at 3:32 p.m. EDT. A list of NRC and external meeting participants is enclosed. Below is a summary of the questions and comments received, and a transcript of the meeting is available at [ML23257A263](#).

Summary of Questions and Comments Received:

During the meeting, the NRC received the following questions or comments:

- Questions about the availability and current use of GliaSite radiation therapy system, which is currently identified in the regulatory basis as an emerging medical technology;
- A question about whether the NRC would maintain or change the current guidelines for germanium-68/gallium-68 breakthrough testing;
- A question about the source of the statement in the regulatory basis that interventional radiologists receive only 80 hours of training to use microspheres; and
- A question about whether the rulemaking will allow for decay-in-storage of radionuclides with half-lives greater than 120 days.

Next Steps: The regulatory basis comment period closes on October 31, 2023. The NRC staff will consider the comments received as we develop the proposed rule package, recognizing the delay in this rulemaking to accommodate another ongoing rulemaking to address nuclear medicine injection extravasations. The staff expects to have more dialogue with the medical community in the second half of 2024 as we prepare the proposed rule. The staff expects to submit the proposed rule package to the Commission in January 2026.

ENCLOSURE:
NRC Meeting Participants

SUMMARY OF AUGUST 29, 2023, PUBLIC MEETING ON REGULATORY BASIS FOR PART
35 RULEMAKING ON RB-82 GENERATORS, EMERGING TECHNOLOGIES, AND OTHER
MEDICAL USE OF BYPRODUCT MATERIAL

DATE: XXXXXX

ENCLOSURE:
NRC Meeting Participants

DISTRIBUTION:
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NMSS/MSST/MSEB
ACarrera, NMSS/REFS

ADAMS Accession Nos.: Package ML23257A262; Meeting Summary ML23257A264;
Slides ML23240A718; Transcript ML23257A263; Meeting Notice ML23212A385

ENCLOSURE

MEETING ATTENDEES

**Public Meeting on the Regulatory Basis for Part 35 Rulemaking on Rb-82 Generators,
Emerging Technologies, and Other Medical Use of Byproduct Material
August 29, 2023**

U.S. Nuclear Regulatory Commission	
Maryann Ayoade	Antonio Gomez
Ken Brenneman	Anita Gray
Laura Cender	Vincent Holahan
Andrew Carrera	Sarah Lopas
Theresa Clark	Jan Nguyen
Daniel Dimarco	Christine Pineda
Lisa Dimmick	Daniel Shaw
Christian Einberg	Jill Shepherd
Robin Elliott	Sarah Spence
Linda Eusebio	Katie Tapp
Monica Ford	Elizabeth Tindle-Engelmann
Farrah Gaskins	Celimar Valentin Rodriguez

Public	
Name	Affiliation (if provided)
Logan Allen	
Mouaz Al-mallah	
Janell D. Anderson	
Kristin Anson	
Julia Bellinger	
James Blacker	
Michael Boutwell	
Jared Brokke	
Emily A Brower	
Judi Buckalew	
Molly E Buffington	
Janet Bryant	
Ashley Cockerham	
Willie M. Crawford	
Corey Creveling	
David Crowley	
Cathy S. Cutler	
Karen M. Deibert	
Christine Dobert	
Nick Dorrell	
Cheri Douglas	
Stephen C. Dragotakes	

Michele Egberts	
Adam Ekstedt	
Bassem A. Elshahat	
Brian S. Fairchild	
Teresa Fisher	National Institutes of Health
Mary C Furan	
S. Gabriel	
Tianliang Gu	
Andrew Halloran	
Kaylie Hammersborg	Defense Health Agency
Stanley D Hampton	
Barbara Hamrick	
Megan Harkins	
Ahmad Hatami	
Matt Hendrickson	Oregon Department of Energy
Kathleen Hintenlang	
Andrew Holcomb	
Lauren James	
Friederike Keating	
Brian M Kelley	
Nathaniel A Kishbasugh	
Sue Kurgatt	
Florentina Kurti	
Ian P. Lake	
Olusegun Akano Larinde	
Jerry Lee	
Ramon Li	
Ralph Lieto	
David Luechtefeld	
Melissa Martin	
Undria McCallum	
Candi McDowell	
Kasey McGinty	
Lawrence McKenzie	
Josh McIlvain	
Tara Medich	
Douglas L. Miller	
Emine Ocak	
Akin Ogretici	
Jonathan J. Otten	
Reiko Oyama	
Ron Parsons	
John Pavlica	Texas Department of State Health Services
Lawrence Phillips	
Ronald Raunikar	
Gloria Romanelli	

Emily C Rostel	
Daniel J Samson	
Tim Sanchez	
Amber L. Schmidt	Kansas Department of Health and Environment
Todd Senglaub	
Roger C Sit	
Dr. Smith	Defense Health Agency
Jill Southerland	Kansas Department of Health and Environment
David W. Stradinger	
Kaci Studer	
Cindy Tomlinson	
Paul Wallner	
Kara Duncan Weatherman	
Karen Wheeler	
Steven Whitesides	
Melonie Wissing	
Aaron Short	Kansas Department of Health and Environment
Jimmy Uhlemeyer	
Michael Welling	
Carol Wen	
Brandi Woods	

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

Summary of August 29, 2023, Public Meeting on Regulatory Basis for Part 35 Rulemaking on Rb-82 Generators, Emerging Technologies, and Other Medical Use of Byproduct Material DATE September 29, 2023

DISTRIBUTION:

ACarrera, NMSS/REFS/MRPB

CValentin-Rodriguez, NMSS/MSST

AGomez, NMSS/REFS/RASB

CEinberg, NMSS/MSST/MSEB

MAyoade, NMSS/MSST/MSEB/MRST

MFord, R1/DRSS

LCender, R-III/DNMS/MLB

ADAMS Accession No.: ML23257A262; ML23257A264

OFFICE	NMSS/MSST/MSEB /MRST	NMSS/REFS/MRPB	NMSS/MSST/MSEB	NMSS/MSST/MSEB /MRST
NAME	MAyoade MA	JShepherd JS	CEinberg CE	MAyoade MA
DATE	Sep 22, 2023	Sep 25, 2023	Sep 28, 2023	Sep 29, 2023

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