

MEETING OF THE
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

December 5th, 2022

MEETING SUMMARY

PURPOSE

To discuss issues related to the implementation of the medical regulations in Title 10 of the Code of Federal Regulations (10 CFR) Part 35, "Medical Use of Byproduct Material."

OUTCOME

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) made recommendations, and the U.S Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the ACMUI, as well as other stakeholders' views and opinions. The NRC staff will consider these views in its continuing effort to make 10 CFR Part 35 more useful, practical, and not overly burdensome on licensees, while maintaining public health and safety.

Full transcripts and handouts from the ACMUI meeting can be found on the NRC's ACMUI Meetings webpage, located at: <https://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/>. The meeting attendees are listed in Enclosure 1.

RECOMMENDATIONS AND ACTIONS

The following provides a summary of the discussions that took place on the topics on the ACMUI meeting agenda (Enclosure 2).

Dr. O'Hara provided an overview of the Y-90 Medical Events Subcommittee report. This evaluated the issue of Y-90 microsphere medical events and propose how to decrease the number of medical events through consultation with the vendors.

Dr. Jadvar discussed the Training and Experience for All Modalities subcommittee's ongoing evaluation of the potential impact of the American Board of Radiology's request to terminate NRC recognition of their board certification process.

Dr. Brenneman from the NRC provided an overview of the NRC's staff review of a new lutetium (Lu)-177-PSMA radiopharmaceutical approved by the FDA. This radiopharmaceutical is specifically for the treatment of patients with prostate-specific membrane antigen positive metastatic castration resistant prostate cancer.

Mr. Carrera from the NRC provided an overview of the NRC's rulemaking to amend its regulations to require safety and security equipment and facilities to be in place for certain applicants before granting a license for possession and use of radioactive materials regulations.

Ms. Shober provided an overview the Emerging Medical Technologies/Rubidium (Rb)-82 Generator Subcommittee's report, including comments and recommendations, regarding the NRC staff's draft regulatory basis for the rulemaking to establish requirements for Rb-82 generators and emerging medical technologies.

Mr. Trussell from the NRC provided a status update on the NRC's rulemaking that would amend its regulation for decommissioning financial assurance for sealed and unsealed radioactive materials.

The full committee unanimously accepted the Y-90 Medical Events Subcommittee report, which included recommendations that the NRC issue an information notice to licensees regarding Y-90 microsphere medical events and that the NRC review vendor-prepared, spreadsheets, and other tools. The full committee also unanimously approved the Emerging Medical Technologies/Rb-82 Generator Rulemaking Subcommittee report.

Two new subcommittees were established, including a subcommittee to create generic process checklists to be used during medical administrations and a subcommittee to review the proposed rule for decommissioning financial assurance for sealed and unsealed radioactive materials. The Subcommittee for Nursing Mother Guidelines was reestablished to update the guidelines last updated in 2019. Finally, the membership of the Medical Events Subcommittee was updated.

The ACMUI tentatively decided to meet for the Spring 2023 meeting for May 1st or May 15th.

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

MEETING ATTENDEES

December 5th, 2022

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Darlene F. Metter, M.D.	Chair
Hossein Jadvar, M.D., Ph.D.	Vice Chair
Rebecca Allen	Member
Ronald D. Ennis, M.D.	Member
Richard Green	Member
Richard Harvey, Ph.D.	Member
Josh Mailman	Member
Melissa Martin	Member
Michael D. O'Hara, Ph.D.	Member
Zoubir Ouhib	Member
Megan Shober	Member
Harvey B. Wolkov, M.D.	Member
John F. Angle, M.D.	Consultant to the Committee
Andrew Einstein, M.D.	Future Member

NRC STAFF

Theresa Clark	Deputy Director, Division of Materials Safety, Security, State, and Tribal Programs (MSST)
Chris Einberg	Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Celimar Valentin- Rodriguez	Medical Team Leader, NMSS/MSST/MSEB
Trisha Gupta Sarma	ACMUI Coordinator, NMSS/MSST/MSEB
Maryann Ayoade	NMSS/MSST/MSEB
Kenneth Brenneman	NMSS/MSST/MSEB
Andrew Carrera	NMSS/MSST/MSEB
Daniel Dimarco	NMSS/MSST/MSEB

Cindy Flannery	NMSS/MSST/MSEB
Anita Gray	NMSS/MSST/SMPB
Vincent Holahan	NMSS/MSST
Sarah Lopas	NMSS/REFS
Christine Pineda	NMSS/MSST/MSEB
Jill Shepherd	NMSS/REFS/MRPB
Adam Schwartzan	NMSS/DUWP
Katherine Tapp	NMSS/MSST/MSEB
Gregory Trussell	NMSS/REFS/MRPB
Kelly Sullivan	OCHCO/HRTD/NRAN
Suzanne Dennis	COM/Wright
Lisa Dimmick	COM/Hanson
Kathy Modes	NMSS/MSST/SLPB
Shirley Xu	NMSS/MSST/MSTB
Luis Cruz Rosado	OCHCO/HRTB/NRAN
Marilyn Diaz Maldonado	COM/Caputo
Nathan Denny	OCHCO/HRTD/NRAN
Stephanie Garza	OCHO/HRTD/NRAN
Daniel Fiedorek	OCHCO/HRTD/NRAN
Jade Adams	OCHCO/HRTD/NRAN
Torre Taylor	REFS/MRPB
Anthony Valiaveedu	OCHCO/HRTD/NRAN
Miranda Ross	OCHCO/HRTD/NRAN
Kayla Gamin	OGC/LHE/SE
Blake Vaisey	OGC/LRAA/RASFB
Candance Spore	NMSS/MSST
Andrew Pessin	OGC/LRAA/RASFB
Ryan Whited	NMSS/DUWP
George Tartal	REFS/MRPB

PUBLIC PARTICIPANTS

Alan David Jacobson
Alex Carter
Alyssa Afram
Andreai Mouzorou
Andy Miller
Ashley Cockerham
Bill Erwin
Bill Hinchcliffe
Bradley Kelly
Brent Colby
Brent Wagner
Brian Kelley
Brian Serencsits
Bryan Lemieux
Candi Mcdowell
Carl Granlund
Cindy Tomlinson
Charles Kreuzberger
Chris Alston
Chris Mitchell
Christopher Helstern
Christopher Lease
Clay Nuquist
Dan C
Daniel McDonald
Daniel Miodownik
Daniel Yokell
Danielle Goetz
Danielle Hjelm
David Bierman
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Jeffrey Mason
Jennifer Gersman
Jeremy Iman
Jerry Thomas
Jessica Clements
Jessica Rodgers
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Jose Antony
Joseph Giardina
Judi Buckalew
Karen Langley
Katherine Boyd
Kavya Prasad
Kay Moyer
Kelsey Everett
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Marc Gregoire
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Mark Seddon
Mark Sitek
Mary Ann Spilker

Mary Burkhart
Mateo Kajic
Matt Barrett
Matt Dennis
Matt Hall
Matthew Williamson
Matty Mozzor
Meghan Cromie
Melonie Wissing
Michael Bellamy
Michael Benson
Michael Sheetz
Michael Stanfield
Miguel de la Guardia
Mike Blair
Mike Peters
Miyuki Yoshida-Hay
Nathan Denny
Nicholas Paul Borges
Paul Wallner
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Phillip Peterson
Ralph Lieto
Richard Martin
Robert Golduber
Robert Wilson
Ron Lattanze
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