#### MEETING OF THE

#### ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

April 7, 2025

#### **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: <a href="https://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/">https://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/</a>. 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).

The ACMUI endorsed the following subcommittee report. This report and its recommendations can be viewed, in their entirety, on the NRC's ACMUI Subcommittee Reports webpage, located at the following link: <a href="https://www.nrc.gov/reading-rm/doc-collections/acmui/reports/index.html">https://www.nrc.gov/reading-rm/doc-collections/acmui/reports/index.html</a>.

The ACMUI unanimously endorsed the report from the Yttrium-90 (Y-90) Microsphere Gastrointestinal (GI) Deposition Medical Events, as presented.

The ACMUI unanimously endorsed the report from the Subcommittee on Training and Experience Requirements for All Modalities on Emerging Medical Technologies, as presented.

The ACMUI unanimously endorsed the report from the Subcommittee on Generic Process Checklist, as amended, with changes presented in the meeting.

The following actions resulted from discussion that took place during the meeting.

The ACMUI agreed that the current structure of reporting to the Office of Nuclear Material Safety and Safeguards continues to function effectively, and the meeting frequency is well-suited for the workload of the Committee.

Dr. Jadvar formed a subcommittee on Giving Advice on ADVANCE Act of July 2024 Mission Statement. The subcommittee's membership includes Harvey Wolkov as chair, Michael Folkert, Megan Shober, Hossein Jadvar, and Josh Mailman.

Dr. Jadvar formed a subcommittee ACMUI Generic Reporting Process. The subcommittee's membership includes Megan Shober as chair, Harvey Wolkov, Josh Mailman, Richard Green, and Zoubir Ouhib.

Dr. Jadvar formed a subcommittee on Potential Al Deep Learning Applications for NRC Medical Enterprise. The subcommittee's membership includes Andrew Einstein as chair, Hossein Jadvar, Michael Folkert, Joanna Fair, and Josh Mailman.

The ACMUI tentatively scheduled the fall 2024 meeting for October 27 - 28, 2025.

# Enclosures:

- 1. Meeting Attendees
- 2. Meeting Agenda

#### **MEETING ATTENDEES**

# **April 8, 2024**

# ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Hossein Jadvar, MD, PhD Chair

Richard Green Vice Chair

Richard Harvey, DrPh Member

Melissa Martin Member

Rebecca Allen Member

Zoubir Ouhib Member

Megan Shober Member

Harvey B. Wolkov, MD Member

Andrew Einstein, MD Member

Michael R. Folkert, MD, PhD Member

Joanna R. Fair, MD, PhD Member

John F. Angle, MD Consultant to the Committee

# **NRC STAFF**

Tammy Bloomer Director, Division of Materials Safety, Security, State, and

Tribal Programs (MSST)

Dafna Silberfeld Deputy Director, Division of Materials Safety, Security, State,

and Tribal Programs (MSST)

Christian Einberg Chief, Medical Safety and Events Assessment Branch (MSEB)

and Designated Federal Officer

Ally Marra NMSS/MSST/MSEB

Daniel Dimarco NMSS/MSST/MSEB

Vincent Holahan NMSS/MSST

Daniel Shaw NMSS/MSST/MSEB

Sarah Spence NMSS/MSST/MSEB

Katherine Tapp NMSS/MSST/MSEB

Andy Miller NMSS/MSST/MSEB

Magdalena Gryglak NMSS/MSST/MSEB

Logan Allen NMSS/MSST/MSEB

Maryann Ayoade NMSS/MSST/MSEB

Jennifer Fisher NMSS/MSST/MSEB

Lillian Armstead OCIO/SDOD/EAPSB

Celimar Valentin-Rodriguez COMM/OCMAC

Hector Rodriguez COMM/OCMJM

Christopher Rapson R-I/DRSS/MLAB

Netra Patel R-I/DRSS/MLAB

Jan Nguyen R-I/DRSS/MLAB

# **PUBLIC PARTICIPANTS**

Doug Burrichter

Carlie Jenney

Kendall Berry

Jonathan Otten

James Cordes

Mary Ann Spiker

Michelle Delgado

Sean Chapel

Ralph Lieto

**Daniel Doenges** 

Michael Welling

Joshua Westmoreland

Joseph Oberender

Brandi Woods

Tara Medich

William Hinchcliffe

Mike Drelich
Jeffrey Mason
Jeff Dovyak
Ariel Doucet
Boris Tsenov
Edward Case
Joseph Beckman
Cami Still
Riad Salem
Sophia Brodish
Carol Wen
Jennifer House
Deborah Barrickman
Phillip Peterson
Brian Kelley
Aaron Bartoo
David Crowley
Keith Brown
James Blacker
Scott Fuller
Amy Biggs
Kimberly Butler
Olwen Burton
Sandra Ramirez
Kevin Kunder
Mary Richardson
Leona Choi
Peter DiMarco

David Bierman
Caitlin Root
Rebecca Hunt
Kevin Tello
Taylor Brown
Ashley Gray
Olusegun Akano Larinde
Mike Stephens
Matthew Williamson
Brad Kelly
Emily Rostel
Tianliang Gu
Jason Hout
Georgia Lawrence
Erin Niven
Lina Planutyte
Joyce Petersen
Adam Ekstedt
Emma Anderson
Nicholas Borges
Diana Thompson
Heather Merchantz
Rebecca Grabarkewitz
Brent Colby
Christopher Pagan
Zerak Sarki
Nick Dorrell
Evan Boote

Eugenio Silvestrini Hernandez Daniel Lapkoff Jenna Engelking Hanna Heibel William White Pat Zanzonico Christopher Helstern **Emily Chou** Jennifer Gersman Julia Bellinger Assen Kirov Daniel Miodownik **Toby Irving** Alyssa Sullivan Billie Harvey Laurenti Ngutter Sally Pasell Matthew Hall Robert Golduber Thomas Cornwell Ashley Cockerham Andrew Polemi Cheri Douglas Tracy Jue Jam Mailman Ann Marie Derby Vivek Dharne

Neil Worlikar

Candi Mcdowell Louie Cueva Steven O'Brien Jose Macatangay Doug Burrichter Hillary Haskins David Adams Mike Melton Ching Mei Feng Laurence Donahue Justin Brown Ulysses Rodriguez David Bushnell Ian Irvin Sandy Gabriel Matt Hough Michael Martin Lisa Egle Barbara Hamrick Samantha Tobin Michael Stanfield Mike Welling Cindy Tomlinson Michael Peters Abbey Van Haren Catherine Hess

Rachel Nichols

# MEETING AGENDA ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES April 7 - 8 2025

One White Flint North Building, 11555 Rockville Pike, Commissioner's Hearing Room North Bethesda, Maryland 20852

NOTE: Sessions of the meeting may be closed pursuant to 5 U.S.C. 552(b) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACMUI; information the release of which would constitute a clearly unwarranted invasion of personal privacy; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and disclosure of information which would risk circumvention of an agency regulation or statute.

	Monday, April 7, 2025 OPEN SESSION	
9:00 – 9:10	<ol> <li>Opening Remarks         Mr. Einberg will formally open the meeting, and Ms. Silberfeld will provide opening remarks.     </li> </ol>	C. Einberg, NRC D. Silberfeld, NRC
9:10 - 9:20	2. Old Business Dr. Tapp will review past ACMUI recommendations and provide NRC responses.	K. Tapp, NRC
9:20 – 9:40	3. Open Forum The ACMUI will identify medical topics of interest for further discussion.	ACMUI
9:30 – 10:15	4. Medical Related Events  Mr. Dimarco will provide an update on recent medical events.	D. Dimarco, NRC
10:15 – 10:30	BREAK	
10:30 – 11:00	5. Yttrium-90 (Y-90) Microsphere Gastrointestinal (GI) Deposition Medical Events Subcommittee Report  Dr. Harvey will discuss the subcommittee's evaluation of recent Y-90 microsphere medical events to identify potential cause of sudden increase in reported events involving unexpected GI deposition.	R. Harvey, ACMUI
11:00 – 11:45	6. Training and Experience Requirements for All Modalities Subcommittee Report on Emerging Medical Technologies Dr. Folkert will discuss the subcommittee's recommendations to the NRC on knowledge topics encompassing the safety related characteristics of emerging medical technologies.	M. Folkert, ACMUI
11:45 – 1:00	LUNCH	
1:00 - 1:30	7. Generic Process Checklist Subcommittee Report Mr. Green will discuss the subcommittee's recommendations regarding development of process checklists to minimize medical events.	R. Green, ACMUI
1:30 – 2:15	8. NRC Medical Radiation Safety Team Updates Dr. Tapp will provide an update on the Medical Radiation Safety Team's activities, including efforts to increase efficiency in licensing and oversight in response to the Advanced Act.	K. Tapp, NRC

2:15 – 2:30	9. Special Recognition for Ms. Allen Ms. Bloomer will make a special presentation to Ms. Allen	T. Bloomer, NRC
2:30 – 2:45	10. Thoughts on Leaving the ACMUI  Ms. Allen will share her thoughts on leaving the ACMUI.	R. Allen, ACMUI
2:45 – 3:00	BREAK	
3:00 – 3:15	11. ACMUI Reporting Structure  Ms. Marra will provide an overview of the current reporting structure.  Members will discuss the reporting structure of the Committee and provide feedback to the NRC.	A. Marra, NRC
3:15 – 3:30	<b>12. Open Forum</b> The ACMUI will discuss medical topics of interest previously identified.	ACMUI
3:30- 3:45	13. Administrative Closing  Ms. Marra will provide a meeting summary and propose dates for the fall 2025 meeting.	A. Marra, NRC
3:45 – 4:00	BREAK	
	Closed Session	
4:00 – 4:30	14. ACMUI Working Session: Biennial Evaluations	ACMUI

Tuesday, April 8, 2025 Open Session				
10:00 - 12:00	<b>15. Commission Meeting with the ACMUI</b> The ACMUI will brief the Commission on various topics in a public meeting.	ACMUI		
	16. Group Photo  The ACMUI will take a group photo with and without the Commission.	ACMUI		
12:00	ADJOURN			