MEETING OF THE

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

November 4, 2024

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: <u>https://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/</u>. 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: <u>https://www.nrc.gov/reading-rm/doc-collections/acmui/reports/index.html</u>.

The ACMUI unanimously endorsed the report from the Subcommittee on ACMUI bylaws regarding disclosures related to conflicts of interest.

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

The ACMUI tentatively scheduled the spring 2025 meeting for April 7 - 8, 2025.

Enclosures:

- 1. Meeting Attendees
- 2. Meeting Agenda

MEETING ATTENDEES

November 4, 2024

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

| Hossein Jadvar, MD, PhD | Chair |
|-----------------------------|-----------------------------|
| Richard Green | Vice Chair |
| Richard Harvey, DrPh | Member |
| Josh Mailman | Member |
| Melissa Martin | Member |
| Michael D. O'Hara, PhD | 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

| Dafna Silberfeld | Director, Division of Materials Safety, Security, State, and Tribal Programs (MSST), Acting | |
|-------------------|---|--|
| Christian Einberg | Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer | |
| Katherine Tapp | NMSS/MSST/MSEB | |
| Lillian Armstead | NMSS/MSST/MSEB and Designated Federal Officer | |
| Maryann Ayoade | NMSS/MSST/MSEB | |
| Daniel Dimarco | NMSS/MSST/MSEB | |
| Cindy Flannery | NMSS/MSST/MSEB | |

| NMSS/MSST | | |
|-------------------|--|--|
| NMSS/MSST/MSEB | | |
| NMSS/MSST/MSEB | | |
| NMSS/MSST/MSEB | | |
| RES/DSA/RPB | | |
| NMSS/MSST/MSEB | | |
| NMSS/MSST/MSEB | | |
| OCHCO/ADHRLD/EDPB | | |
| NMSS/MSST/SLPB | | |
| COMM/OCM | | |
| COMM/OCMAC | | |
| RGN I/DRSS/MLAB | | |
| OEDO/EO | | |
| R-I/DRSS/CIRDA | | |
| NMSS/DFM/IOB | | |
| OCHCO/ADHRLD/EDPB | | |
| RGN I/DRSS/MLAB | | |
| COMM/OCBRC | | |
| COMM/OCMDW | | |
| OCHCO/ADHRLD/EDPB | | |
| RGN I/DRSS/MLAB | | |
| | | |

PUBLIC PARTICIPANTS

| Jessica Rodgers |
|-----------------|
| Ahmad Hatami |
| Roger Sit |
| Thomas Cornwell |
| Virginia Pappas |
| Bushra Intakhab |

Saad Bin Saeed Ahmed

Peter Crane

Frank Dawry

Diana Thompson

Jeffrey Rasmituth

Jeffrey S. Mason

Ralph Lieto

Andrew Brown

Lara Renz Paciello

Wendy Terrenoire

Eric Andersen

Josh McIlvain

Korressa Lee

Stanley D Hampton

Bryan P. Lemieux

Deirdre H. Elder

Carmine M. Plott

Hamsini Sundararaman

Todd Senglaub

Vineetha Ram

Kevin Kunder

Subashri Kurgatt

Kathleen Hintenlang

John Sahlbom

Carol Wen

John Follette

Lisa Marie Guarino

Sean Chapel

Sally M. Pasell

Ashley L. Gray

Cami Still Christopher M. Helstern Cindy Tomlinson Matthew Williamson Caitlin Root Eugenio Silvestrini Hernandez Shannon Lacasse Alyssa Sullivan Joyce L Petersen Chu Wang Michael Peters Paul Wallner Olwen F. Burton Jonathan D. Moore Sripriya Rayadurgam Olusegun Akano Larinde David Crowley Lee Korressa Joseph S. Oberender William White William R. Ruck II Nicole G. William Hinchcliffe Stephen Holmes Jaime A. Barnes Robert Naylor Andrew Hoy Evan J. Boote Teresa Fisher Brian Erasmus

Richard Peros Steven O'Brien Ariel Doucet Janell D. Anderson Nicholas Borges Christopher Comfort Gabriel J. Munoz Kara Duncan Weatherman Laurenti Ngutter Kelly Mannella Matt Hall Mary Ann Spilker Micheal Smith Jennifer Gersman Ann Marie Derby Mike N. Stephens Robert Golduber Michael A. Welling Carl Granlund Jonathan J. Otten Donna Newman Ashley Cockerham Vivek Dharne Kimyli Lemieux James, Lauren Amanda Jesz Michael Martin Agnes Barlow Leon Brown Becki Harisis

Gilbert Suphatra Scott Fuller Gunjan Kayal Lukas Carter Aaron Bartoo Alexandra Terres Adam Kesner Mary K. Richardson Akin Ogretici Emma Anderson Amy E. Biggs Muhammad Hamza Abbasi Ike Hall Leona Choi Valerie Stowell **David Salerius** Georgette M. Lauersdorf Matt Hough Chris Eastlee lan Irvin Valerie Stowell Ashley A. Hanson **Michael Famiano** Heather Merchantz Jeremy Mangum Jenna E. Nicolae Achim Clements, Jessica Jeffrey J. Brunette Shelli Kritzman

Ann Derby Stacie Aman Jeff Moirano Brian M. Kelley William Lorenzen Sandy Gabriel Georgia Lawrence Chris Alston Daniel Januseski Stephen A. Graves Bonnie Clarke Pat Zanzonico Erin Grady Matt Barrett **Cathey Rivers** Julia Bellinger **Doug Burrichter** Ira Goldman Reed G Selwyn Rachel Qian Jaime Barnes Timothy Jay Sanchez Daniel Chiappetta Juan Ocampo Jason D. Hout Kyle K. Underwood Kim C. Wiebeck Kendall E. Berry Wendy W. Terrenoire Stanley D. Hampton

Lina Planutyte Joyce L. Petersen Noelle G. Grace Pennington Kara Duncan Weatherman Lisa Dimmick Michael Welling Robin Elliott Vivek Dharne Lauren James Suphatra Gilbert Christopher Rapson Noelle G. Jessica Clements Luis Betancourt Cathy Cutler Reed G. Selwyn Keith Brown Jennifer Beaton David Brown James Cordes - Court Reporter

MEETING AGENDA ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES November 4 – 5, 2024 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. 552b 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, November 4, 2024 OPEN SESSION | | |
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| | OPEN SESSION | |
| 10:00 - 10:15 | Opening Remarks Mr. Einberg will formally open the meeting and Mr. Williams will provide opening comments. | C. Einberg, NRC K. Williams, NRC |
| 10:15 - 10:30 | Old Business Ms. Armstead/Ms. Roszkowski will review past ACMUI recommendations and provide NRC responses. | L. Armstead, NRC T. Roszkowski, NRC |
| 10:30 - 10:45 | Open Forum The ACMUI will identify medical topics of interest for further discussion. | ACMUI, NRC |
| 10:45 - 11:00 | BREAK | |
| 11:00 - 11:45 | ACMUI Bylaws Subcommittee Ms. Allen will provide an update to the ACMUI Bylaws. | R. Allen, ACMUI |
| 11:45 – 12:15 | Y-90 Microspheres Medical Events Ms. Spence will provide an overview of the NRC follow-up to the ACMUI recommendations on medical events related to the use of Y-90 microspheres. | S. Spence, NRC |
| 12:15 - 1:30 | LUNCH | |
| 1:30 – 1:50 | Advance Act The NRC staff will provide an overview of the Advance Act. | M. King, NRC |
| 1:50 – 2:30 | Medical Team Updates Dr. Tapp will provide an update on the Medical Radiation Safety Team's activities | K. Tapp, NRC |
| 2:30 - 3:15 | NRC Evaluation of Current Patient Waste Guidance and Regulations Mr. DiMarco will provide an overview of the current patient waste guidance and regulations. | D. DiMarco, NRC |
| 3:15 – 3:30 | BREAK | |
| 3:30 - 4:00 | 9. Status of Patient Release Guidance Revision Dr. Tapp will provide a status update to the revision of RG 8.39, "Release of Patients Administered Radioactive Material." | K. Tapp, NRC |
| 4:00 - 4:20 | 10. Open Forum The ACMUI will identify medical topics of interest for further discussion. | ACMUI, NRC |
| 4:20 – 4:35 | 11. Administrative Closing Ms. Armstead/Ms. Roszkowski will provide a meeting summary and propose dates for the spring 2025 meeting. | L. Armstead, NRC T. Roszkowski, NRC |
| | BREAK | |

| | Tuesday, November 5, 2024 CLOSED SESSION | |
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| 9:30 - 10:30 | 12. Ethics Training | B. Klukan, NRC |
| 10:30 - 11:00 | 13. Allegations Training | S. Hawkins, NRC |
| 11:00 - 11:30 | 14. INFOSEC Training | M. MacDonald, NRC |
| | ADJOURN | |