

MEETING OF THE
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

April 5, 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

Mr. Don Lowman discussed the ACMUI Open Recommendations and Actions Report in which staff proposed closure of 11 open items. The ACMUI endorsed the report and closure of the 11 items.

Other topics discussed and/or presented during the meeting included:

- Mr. Daniel DiMarco provided a detailed analysis of the fiscal year 2021 medical events.
- Mr. Kevin Williams gave a special presentation to Dr. Vasken Dilsizian, who will retire as a full member of the ACMUI, thanking him for his service to the ACMUI. Dr. Dilsizian will receive a United States flag that was flown over the U.S Capitol, a certificate of appreciation from Chairman Hanson, and a lapel pin from the NRC.
- Representatives of two manufacturers of Y-90 microspheres discussed their products and procedures for their use.
- Dr. John F. Angle delivered a presentation on reducing misadministration's and other medical events during Y-90 radioembolization procedures.
- Two presentations were given on the restart of the NIST Radioisotope Measurement Assurance Program.

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

- Isotopes used in medical applications are found in 10 CFR 30.71, Schedule B. The Medical Team will engage with an existing NRC working group that is tasked with drafting a rulemaking plan for the NRC's revision of Schedule B. The NRC working group is developing the rulemaking plan to request Commission approval to initiate a rulemaking to revise 10 CFR 30.71, "Schedule B," to include additional radionuclides that are currently not listed in the table. This table is used along with 10 CFR 30.18, "Exempt Quantities," in determining the need for a specific license. The staff also plans to revise certain sections in 10 CFR Part 30, "Rules of General applicability to Domestic Licensing of Byproduct Material," related to exemptions to clarify when a license is required. Anticipated completion date is May 2023.
- Due to the increased number of medical events in 2021, a suggestion was made that generic process checklists should be developed as a tool for authorized users. The ACMUI discussed whether the Committee or the professional licensing boards should take the lead on developing, communicating, and standardizing these checklists.
- The ACMUI tentatively scheduled its Fall 2022 meeting for September 19-20, 2022. The alternate meeting date is December 5-6, 2022. An in-person meeting is expected for these dates.

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

MEETING ATTENDEES

April 5, 2022

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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|--------------------------|---------------------|
| Darlene F. Metter, M.D. | Chairman |
| Vasken Dilsizian, M.D. | Vice Chairman |
| Rebecca Allen | Member |
| John F. Angle | Consultant to ACMUI |
| Ronald D. Ennis, M.D. | Member |
| Richard L. Green | Member |
| Hossein Jadvar, M.D. | Member |
| Josh Mailman | Member |
| Melissa Martin | Member |
| Michael D. O'Hara, Ph.D. | Member |
| Zoubir Ouhib | Member |
| Michael Sheetz | Consultant to ACMUI |
| Megan Shober | Member |
| Harvey B. Wolkov, M.D. | Member |

NRC STAFF

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| John Lubinski | Director, Office of Nuclear Material Safety and Safeguards |
| Kevin Williams | Director, Division of Materials Safety, Security, State and Tribal Programs |
| Chris Einberg | Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer |
| Maryann Ayoade | NMSS/MSST/MSEB |
| Hiba Ahmed | R-I/DRSS/MLAB |
| Kristen Bonds | R-I/DRSS/CIRDA |
| Andrew Carrera | NMSS/MSST/MSEB |
| Angela Coggins | OGC/LHE/MFW |
| Said Daibes Figueroa | NMSS/MSST/MSEB |
| Anne DeFrancisco | R-I/DRSS/MLAB |
| Lisa Dimmick | COMM/OCM |
| Daniel Dimarco | NMSS/MSST/MSEB |
| Robin Elliott | R-I/DRSS/MLAB |
| Christina England | OGC/LHE/MFW |
| Cindy Flannery | NMSS/MSST/MSEB |
| Monica Ford | R-I/DRSS |
| Cassandra Frazier | R-III/DNMS/MLB |
| Robert Gallagher | R-I/DRSS/MLAB |
| Farrah Gaskins | R-I/DRSS |
| Vincent Holahan | NMSS/MSST |
| Ian Irvin | OGC/LHE/MFW |
| Richard Jervey | NMSS/DFM/FFLB |
| Keith Lassman | R-III/DNMS/MLB |

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| Sarah Lopas | NMSS/MSST/MSEB |
| Don Lowman | NMSS/MSST/MSEB |
| Ed Miller | NRR/DORL/LPL2-1 |
| Kathy Modes | NMSS/MSST/SLPB |
| Janice Nguyen | R-I/DRSS/MLAB |
| Netra Patel | R-I/DRSS/MLAB |
| Gretchen Rivera-Capella | NMSS/MSST/MSEB |
| Kevin Roach | OGC/LHE/MFW |
| Shawn Seeley | R-I/DRSS/MLAB |
| Valerie Stowell | OCHCO/ADHRTD/NRANB |
| Katherine Tapp | NMSS/MSST/MSEB |
| Celimar Valentin-Rodriguez | NMSS/MSST/MSEB |

PUBLIC PARTICIPANTS

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|------------------------------|-------------------------------|------------------------|
| James M. Adams | Scott Bruce Dubick | Donna-Beth Howe |
| Dave Adler | Kelsey Everett | Thomas E. Huston |
| Joaquin Altamirano | Lynne Fairobent | Jeremy Iman |
| Jose Antony | Ching Mei Feng | Alan Jackson |
| Xander Arena | Roger Fenner | Janelle E. Jesikiewicz |
| Jinsy Babu | Scott M. Finch | Paula Jeter |
| Jaime Barnes | Sandy Gabriel | Brian M. Kelley |
| Matt Barrett | Wendy K. Galbraith | Jessica Kendrick |
| Deborah M. Barrickman | Charlotte Gallagher | Josh Knowland |
| Kendall Berry | William Gibbons | Paul J. Kovach |
| Erin R. Bertelsen | Robert Golduber | Kevin Kunder |
| David Bierman | Marjorie Gonzalez | Georgia Lawrence |
| Bette Blankenship | John Gough | Olusegun Akano Larinde |
| Mary Burkhart | Carl Granlund | Christopher Lease |
| Paul Burns | Colt L. Greer | Bryan P. Lemieux |
| Olwen F. Burton | Uli Graf | Collin Ma |
| David L. Bushnell | Stephen A. Graves | Vente Maarten |
| Katherine R. Boyd | Matthew Greenwood | Archie Manoharan |
| Peter F. Caracappa | Serena Groff | A. Marks |
| Carrie R. Carson | Sebastien Gros | Jeffrey S. Mason |
| Jeffrey T. Cessna | Yu Guangfeng | Richard Martin |
| Sean Chapel | Michael Guastella (Presenter) | Trenton L. Mays |
| Jessica B. Clements | Steven Griffith | Franklin G. McCammon |
| Ashley Cockerham (Presenter) | Joseph Grudzinski | Tara Medich |
| Tom Conley | Kathi Haldeman | Michael J. Merrick |
| James Cook | Matthew Hall | John P. Metyko |
| Whitney Cox | Amin M. Hamideh | Andy Miller |
| Bruce Curran | Glenn Hathaway | Vivek Mishra |
| Anthony R. Davila | Pete J. Hernandez | Jorge D. Munoz |
| Michelle A. Delgado | Bill Hinchcliffe | Ashli L. Nieves |
| Miguel de la Guardia | George Hinkle | Peter Oehlberg |
| Dan J. Devries | Kathleen Hintenlang | Nick Dorrell |
| Ariel Doucet | Michaela Hollis | Alyssa Oskin |
| Bill Dowling | Timothy Houston | Lara Renz Paciello |

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| Willie Regits | Mary Ann Spilker | Kendall A. Williams |
| Ron Parsons | Michael Lee Stanfield | Matthew H. Williams |
| Sally M. Pasell | Mike N. Stephens | Matthew Williamson |
| Michael Peters | Kim Steves | Sean O. Wilson |
| John Pfabe | Diana Thompson (Presenter) | Charles Wilson |
| Josie Piccone | Wendy W. Terrenoire | Melonie Wissing |
| Sandra M. Ramirez | Matthew Torrico | Brandi Woods |
| Kimyli Recca | Brian Vamvakias | Michael J. Wutkowski |
| Manar K. Sakalla | David Vassy | Christin E. Young |
| Mark Seddon | Jason Vognetz | Miyuki Yoshida-Hay |
| Mr. Shaw | Lora Weidner | Brian E. Zimmerman (Presenter) |
| Dominic Siewko | Wang Wei-Hsung | |
| Hernandez Eugenio Silvestrini | Michael Welling | |
| Chad Smith | Carol Wen | |
| Danielle Hjelm | Akin Ogretici | |
| Jill Southerland | Kim C. Wiebeck | |
| Justin Spence | William White | |

**MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
April 5, 2022
Virtual Meeting**

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.

**TUESDAY, APRIL 5, 2022
OPEN SESSION**

10:00 a.m. to
12:15 p.m.
EST

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| 1. Opening Remarks | Mr. Einberg will formally open the meeting and Mr. Williams will provide opening remarks. | C. Einberg, NRC K. Williams, NRC |
| 2. Old Business | Mr. Lowman will review past ACMUI recommendations and provide NRC responses. | D. Lowman, NRC |
| 3. Open Forum | The ACMUI will identify medical topics of interest for further discussion. | ACMUI |
| 4. Medical Related Events | Mr. Dimarco will provide an overview of the NRC staff's assessment of FY21 medical events. | D. Dimarco, NRC |

12:15 p.m. to
12:45 p.m.
EST

LUNCH

12:45 p.m. to
3:15 p.m. EST

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| 5. ACMUI Reporting Structure | Mr. Lowman will provide an overview of the current reporting structure. Members will discuss the reporting structure of the Committee and provide feedback to the NRC. | D. Lowman, NRC |
| 6. Special Presentation to Dr. Vasken Dilsizian | | J. Lubinski, NRC |
| 7. TheraSphere™ Y-90 Glass Microspheres | A representative from Boston Scientific will provide an overview of the TheraSphere™ Y-90 glass microspheres. | Ashley Cockerham, Boston Scientific |
| 8. SIR-Spheres® Y-90 Resin Microspheres | A representative from Sirtex Medical will provide an overview of the SIR-Spheres® Y-90 resin microspheres. | Diana Thompson, Sirtex Medical |

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| <p>9. Minimizing Risk of Medical Events Dr. Angle will provide an overview institutional processes and team approaches to reducing errors.</p> | <p>J. Angle, NRC</p> |
| <p>10. CORAR Comments on the NIST Radioisotope Measurement Assurance Program Mr. Guastella will discuss CORAR’s request that NIST facilitate the restart of NRMAP and provide sufficient resources to NRMAP and Radioactivity Measurement Group.</p> | <p>M. Guastella, CORAR</p> |
| <p>11. Update on NIST Radioisotope Measurement Assurance Program Dr. Zimmerman will provide an update on the NRMAP program and an overview of NIST’s plan to reorganize the program.</p> | <p>B. Zimmerman, PhD, NIST</p> |

3:15pm to
3:30pm EST

BREAK

3:30pm to
5:00pm EST

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| <p>12. Non-Medical Events Mr. Sheetz will provide an analysis of FY20-FY21 non-medical events reported by medical use facility and commercial pharmacies.</p> | <p>M. Sheetz, NRC</p> |
| <p>13. Medical Team Updates Dr. Valentin-Rodriguez will provide an update on Medical Radiation Safety Team activities.</p> | <p>C. Valentin- Rodriguez, PhD, NRC</p> |
| <p>14. Open Forum The ACMUI will continue discussion on medical topics of interest.</p> | <p>ACMUI</p> |
| <p>15. Administrative Closing Mr. Lowman will provide a meeting summary and propose dates for the fall 2022 meeting.</p> | <p>D. Lowman, NRC</p> |

5:00pm EST

ADJOURN