

MEETING OF THE  
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

October 4, 2021

**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 ACMUI endorsed the following subcommittee reports. The reports and their recommendations can be viewed, in their entirety, on the NRC's ACMUI Subcommittee Reports webpage, located at: <https://www.nrc.gov/reading-rm/doc-collections/acmui/reports/>.

- Dr. Ronald Ennis provided an analysis of the fiscal year 2020 medical events. The ACMUI endorsed the Medical Events Subcommittee report and its recommendations, as presented. The recommendation passed unanimously.
- Mr. Richard Green provided the Radionuclide Generator Knowledge and Practice Requirements Subcommittee report. The ACMUI endorsed the subcommittee report and its recommendations, as presented. The recommendation passed unanimously.
- Dr. Hossein Jadvar presented the Emerging Radiopharmaceutical Therapy Knowledge Requirements in Theranostics Subcommittee report. The ACMUI endorsed the subcommittee report with the following change:

**FROM:**

Authorized User responsibilities:

The authorized user (AU) must be present at the time of dose administration; AU is responsible for patient concerns related to RPT, including radiation induced injuries; AU is encouraged to avail themselves of all the latest training information for each new theranostics as they emerge.

**TO:**

Authorized User responsibilities:

The AU should be present, either virtually or in person, at the time of dose administration; AU is responsible for patient concerns related to RPT, including radiation induced injuries; AU is encouraged to avail themselves of all the latest training information for each new theranostics as they emerge.

The proposed change passed unanimously.

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

- Dr. Rob Hobbs presented on the future of personalized dosimetry and the work of a new American Association of Physicists in Medicine (AAPM) task group on this subject. This presentation was informational and requires no action of the ACMUI.
- Ms. Megan Shober presented on the production challenges for therapeutic radiopharmaceuticals. She discussed the challenges facing production of emerging radiotherapeutics and unique radiation safety concerns for end users. This presentation was informational and requires no action of the ACMUI.
- Mr. Robert Lewis gave a special presentation to Mr. Michael Sheetz, thanking him for his service to the ACMUI. Mr. Sheetz 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. Mr. Sheetz has retired as a full member of the ACMUI but will continue in a consultant role.

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

- The ACMUI formed a new subcommittee to evaluate the issue of Y-90 microspheres medical events in more depth and, in consultation with vendors, propose methods to decrease the number of Y-90 microsphere-related medical events. The subcommittee is expected to report at the spring 2022 meeting. Subcommittee membership includes Dr. Dilsizian, Dr. Angle, Dr. O'Hara (chair), Ms. Shober, Mr. Mailman, and Ms. Martin. The NRC staff resource is Dr. Katie Tapp.
- The NRC staff requested the formation of a subcommittee to review the Liberty Vision technology and comment on the NRC staff's draft Liberty Vision Y-90 Eye Brachytherapy Source Licensing Guidance. The subcommittee is expected to report at the spring 2022 meeting. Subcommittee membership includes Mr. Ouhib (chair), Dr. Wolkov, Ms. Shober, Dr. O'Hara, and Ms. Allen. Mr. Sheetz will serve on the subcommittee as a non-voting consulting member. The NRC staff resource is Ms. Maryann Ayoade.
- The ACMUI tentatively scheduled its spring 2022 meeting for April 4-5, 2022. The alternate meeting date is March 21-22, 2022. An in-person meeting is expected for these dates.

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

## MEETING ATTENDEES

October 4, 2021

### ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

|                          |               |
|--------------------------|---------------|
| Darlene F. Metter, M.D.  | Chairman      |
| Vasken Dilsizian, M.D.   | Vice Chairman |
| Rebecca Allen            | Member        |
| Ronald D. Ennis, M.D.    | Member        |
| Richard L. Green         | Member        |
| Hossein Jadvar           | 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        |

### NRC STAFF

|                                   |   |
|-----------------------------------|---|
| Chris Einberg                     | Chief, Medical Safety and Events Assessment Branch (MSEB)<br>and Designated Federal Officer |
| Maryann Ayoade                    | NMSS/MSST/MSEB  |
| Theresa Clark                     | NMSS/MSST   |
| Kellee Jamerson                   | NMSS/MSST/MSEB  |
| Robert Lewis                      | NMSS  |
| Daniel DiMarco                    | NMSS/MSST/MSEB  |
| Sarah Lopas                       | NMSS/MSST/MSEB  |
| Donna-Beth Howe, Ph.D.            | NMSS/MSST/MSEB  |
| Celimar Valentin-Rodriguez, Ph.D. | NMSS/MSST/MSEB  |

### PUBLIC PARTICIPANTS

|                |                    |
|----------------|--------------------|
| Thomas Eiden   | Public Participant |
| Calvin Han     | Public Participant |
| Robert Hobbs   | AAPM               |
| Michael Sheetz | Public Participant |

**MEETING AGENDA**  
**ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES**  
**October 4, 2021**  
**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.

**Monday, October 4, 2021**

**OPEN SESSION**

- |               |   |  |
|---------------|---|--|
| 10:00 – 10:15 | <b>1. Opening Remarks</b><br>Mr. Einberg will formally open the meeting and Ms. Clark will provide opening remarks.   | <b>C. Einberg, NRC</b><br><b>T. Clark, NRC</b> |
| 10:15 – 10:30 | <b>2. Old Business</b><br>Mr. DiMarco will review past ACMUI recommendations and provide NRC responses.   | <b>D. DiMarco, NRC</b>                         |
| 10:30 – 11:00 | <b>3. Medical Events Subcommittee Report</b><br>Dr. Ennis will provide an analysis of FY20 medical events.  | <b>R. Ennis, ACMUI</b>                         |
| 11:00 – 11:45 | <b>4. Radionuclide Generator Knowledge and Practice Requirements Subcommittee Report</b><br>Mr. Green will discuss the subcommittee’s recommendations on the knowledge and specialized practice requirements for eluting, measuring, and testing, and processing the eluate from radionuclide generator systems | <b>R. Green, ACMUI</b>                         |
| 11:45 - 12:00 | <b>5. Open Forum</b><br>The ACMUI will identify medical topics of interest for further discussion.  | <b>ACMUI, NRC</b>                              |

**12:00 - 12:45 LUNCH**

- |              |  |                         |
|--------------|--|-------------------------|
| 12:45 – 1:30 | <b>6. Emerging Radiopharmaceutical Therapy Knowledge Requirements in Theranostics Subcommittee</b><br>Dr. Jadvar will discuss the subcommittee’s recommendations on the knowledge and specialized practice requirements needed for the safe use and handling of emerging radionuclides in theranostics | <b>H. Jadvar, ACMUI</b> |
| 1:30 - 2:15  | <b>7. Future of Personalized Dosimetry</b><br>Discuss the work of new AAPM task groups on this subject   | <b>R. Hobbs, AAPM</b>   |

2:15 - 3:00

**8. Production Challenges for Therapeutic Radiopharmaceuticals**

**M. Shober, ACMUI**

Discuss production methods of emerging therapeutic radiopharmaceuticals and effects on radiation safety for end users, and the challenges of various production methods

3:00 – 3:15

**BREAK**

3:15 - 3:30

**9. Special Presentation to Mr. Michael Sheetz**

**R. Lewis,  
NRC**

3:30 - 3:45

**10. Open Forum**

The ACMUI will continue discussion on medical topics of interest.

**ACMUI, NRC**

3:45 – 4:00

**11. Administrative Closing**

Mr. DiMarco will provide a meeting summary and propose dates for the spring 2022 meeting.

**D. DiMarco, NRC**

**ADJOURN**