

MEETING OF THE  
ADVISORY COMMITTEE ON THE  
MEDICAL USES OF ISOTOPES

April 3-4, 2019

**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 ACMUI Meetings Web page, located on NRC's public Web site:

<http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/>

**RECOMMENDATIONS AND ACTIONS**

The following recommendations and actions resulted from the discussions that took place on the topics listed on the ACMUI meeting agenda (Enclosure 2):

The Committee recommended that the NRC add an additional column to the Recommendations and Action Items Chart to include the anticipated date of completion for NRC staff actions.

The Committee recommended that the NRC staff request a presentation from the National Nuclear Security Administration to provide a review of their plans for isotope utilization in the United States. The presentation will be given at the fall 2019 ACMUI Meeting.

Dr. Palestro formed a subcommittee to review the NRC's 1980 determination related to infiltrations and medical event reporting [45 FR 31703]. The subcommittee is expected to report to the Committee at the fall 2019 meeting with any recommendations. Subcommittee membership includes Dr. Dilsizian, Mr. Green, Ms. Martin (chair), Mr. Sheetz, Ms. Shober, and Ms. Weil. The NRC staff resource is Ms. Maryann Ayoade.

Dr. Palestro formed a subcommittee to improve the ACMUI's institutional memory and provide possible recommendations for methods of tracking and/or retrieving ACMUI documents. Subcommittee membership includes Dr. Ennis, Dr. O'Hara, Dr. Schleipman (chair), Ms. Shober, and Ms. Weil. The NRC staff resource is Ms. Kellee Jamerson.

The Committee endorsed the Yttrium-90 Microspheres Brachytherapy Licensing Guidance, Rev. 10 Subcommittee report, and the recommendations therein, with the caveat to replace the term “drug” with the term “device.”

The Committee endorsed the Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance, Rev. 1 Subcommittee report and the recommendations therein.

The Committee endorsed the ACMUI Bylaws Subcommittee report, with the following amendments: 1) amend the subcommittee’s recommendation regarding the ACMUI Chairman’s role on subcommittees in Section 1.3.6 to remove the phrase “in these instances”; 2) add language in Section 1.3.6 regarding the ACMUI Chairman serving on a subcommittee at the subcommittee’s discretion; and 3) amend the subcommittee’s recommendation regarding the explicit language defining Conflict of Interest in Section 4.1 to instead reference the appropriate Office of Government Ethics citation.

The NRC staff will amend its Opening Remarks such that a statement regarding conflict of interest will be included at every ACMUI meeting.

The Committee tentatively scheduled the fall 2019 meeting for September 11-12, 2019. The alternate meeting date is September 10-11, 2019.

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

## MEETING ATTENDEES

### ACMUI

Christopher J. Palestro, M.D.	Chairman
Darlene F. Metter, M.D.	Vice Chairman
Vasken Dilsizian, M.D.	Member
Ronald D. Ennis, M.D.	Member
Richard Green	Member
Melissa Martin	Member
Michael D. O'Hara, Ph.D.	Member
Zoubir Ouhib	Member
A. Robert Schleipman, Ph.D.	Member
Michael A. Sheetz	Member
Megan Shober	Member
Laura M. Weil	Member
<i>Harvey B. Wolkov, M.D.</i>	<i>Non-Voting Member</i>

### NRC

Scott Moore	Deputy Director, Office of Nuclear Material Safety and Safeguards (NMSS)
Kevin Williams	Deputy Director, Division of Materials Safety, State, and Tribal Programs (MSST)
Chris Einberg	Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Lisa Dimmick	Team Lead, Medical Radiation Safety Team, MSEB
Kellee Jamerson	Designated Federal Officer and ACMUI Coordinator
Maryann Ayode	NMSS
Laura Cender	RIII
Jennifer Dalzell	RIII
Said Daibes, Ph.D.	NMSS
Sara Forster	RIII
Cassandra Frazier	RIII
Robert Gallagher	RI
Sophie Holiday	NMSS
Vincent Holahan, Ph.D.	NMSS
Esther Houseman	OGC
Donna-Beth Howe, Ph.D.	NMSS
Ian Irvin	OGC
Donna Janda	RI
Janelle Jessie	COMM/OCMJB
Erin Kennedy	RIII
Penny Lanzisera	RI
Sarah Lopas	NMSS
Henry Lynn	OCHCO
Robert MacDougall	NMSS
Janice Nguyen	RI
Dennis O'Dowd	RIII

## Enclosure 1

Patricia Pelke  
David Pelton  
Shawn Seeley  
Vered Shaffer  
Alexa Sieracki  
Katie Tapp, Ph.D.  
Irene Wu

RIII  
RIII  
RI  
RES  
NMSS  
NMSS  
NMSS

## MEMBERS OF THE PUBLIC

Jenna Abbot  
Danny Allen  
Eric Andersen  
Michael Baxter  
Bette Blankenship  
Kendall Berry  
Jeff Brunette  
Janet Bukovcan  
Mary Burkhart  
Steven Chilinski  
Ashley Cockerham  
Jason Collier  
Whitney Cox  
Willie Crawford  
Cory Daignault  
Nick Dorrell  
Ariel Doucet  
Mark Driscoll  
Brian Erasmus  
Lynne Fairbent  
Sherrie Flaherty  
Mark Flickinger  
Michael Fuller  
Sandy Gabriel  
Reid Gadziala  
Wendy Galbraith  
Noel Geier  
Vinson Gibb  
Rebecca Grabarkewitz  
Matthew Hadden  
Gary Hall  
Matthew Hall  
Stanley Hampton  
Curtis Hicks  
William Hinchcliffe  
William House  
Sarah Hughes  
Paul Kanabrocki  
Heather Karmansky  
Caitlin Kubler  
Ralph Lieto

Illinois Emergency Management Agency  
NuTech, Inc.  
Dana-Farber Cancer Institute  
American Pharmacists Association  
American Association of Physicists in Medicine (AAPM)  
Fox Chase Cancer Center  
Mayo Clinic  
British Technology Group  
Illinois Emergency Management Agency  
Radiopharmacy  
SirTex Medical  
Lehigh Valley Health Network  
Illinois Emergency Management Agency  
Virginia Office of Radiological Health  
Virginia Office of Radiological Health  
University of Virginia  
Virtua Health  
University of Michigan  
British Technology Group  
*Unaffiliated*  
Minnesota Radioactive Materials Unit  
Virginia Office of Radiological Health  
Virginia Office of Radiological Health  
*Unaffiliated*  
PharmaLogic  
University of Oklahoma Health Sciences Center  
Froedtert & the Medical College of Wisconsin  
Illinois Emergency Management Agency  
Virginia Office of Radiological Health  
Virginia Office of Radiological Health  
Virginia Office of Radiological Health  
NorthShore University Health System  
Eli Lilly  
Brigham and Women's Hospital, Harvard Medical School  
Yale New Haven Hospital  
Virginia Office of Radiological Health  
University of Louisville  
Virginia Office of Radiological Health  
SirTex Medical  
Society of Nuclear Medicine and Molecular Imaging  
St. Joseph Mercy Health System

Enclosure 1

William Lorenzen	Boston Children's Hospital, Harvard Medical School
Richard Martin	American Association of Physicists in Medicine (AAPM)
Jeff Mason	Virginia Office of Radiological Health
Steve Mattmuller	Kettering Health
Andy McKinley	American Society of Nuclear Cardiology (ASNC)
Andrew McKusick	<i>Unknown</i>
Ashley Mishoe	University of California San Francisco
Christopher Mitchell	Kettering Health
Joshua Myers	Pennsylvania Department of Environmental Protection
Christopher Nation	Virginia Office of Radiological Health
Scott Nemmers	U.S. Air Force
Joseph Oberender	Virginia Office of Radiological Health
Michael Peters	American College of Radiology (ACR)
Brad Price	GE Healthcare
Priya Rayadurgam	Cleveland Clinic
Joe Rubin	United Pharmacy Partners, Inc. (UPPI)
Manar Sakalla	Georgetown University
Eugenio Silvestrini	Northwell Health
Ed Sims	Cleveland Clinic
Andres Sinisterra	UConn Health
Lakshmi Sivasubramanian	University of Massachusetts Medical School
Diana Thompson	University of Illinois at Chicago
Cindy Tomlinson	American Society of Radiation Oncology (ASTRO)
David Townsend	<i>Unaffiliated</i>
Michael Ujhelyi	British Technology Group
Matthew White	SSM Health
Neil Whiteside	Yale New Haven Hospital
Matthew Williams	Georgetown University
Matthew Williamson	Memorial Sloan Kettering Cancer Center
Robert Wilson	University of Tennessee Health Science Center
Melonie Wissing	Virginia Office of Radiological Health
Miyuki Yoshida-Hay	Northwell Health

**MEETING AGENDA**  
**ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES**  
**April 3-4, 2019**  
**Three White Flint North Building, 11601 Landsdown Street, Room 1-C03/1-C05,**  
**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.

**Wednesday, April 3, 2019**  
**OPEN SESSION**

8:30 – 10:30	<b>1. Opening Remarks</b> Mr. Einberg will formally open the meeting and Ms. Kock will provide opening remarks.	<b>C. Einberg, NRC</b> <b>A. Kock, NRC</b>
	<b>2. Old Business</b> Ms. Holiday will review past ACMUI recommendations and provide NRC responses.	<b>S. Holiday, NRC</b>
	<b>3. Open Forum</b> The ACMUI will identify medical topics of interest for further discussion.	<b>ACMUI</b>
	<b>4. Yttrium-90 Microspheres Brachytherapy Licensing Guidance Subcommittee Report</b> Dr. O'Hara will discuss the subcommittee's recommendations on the NRC's draft Revision 10 to the Yttrium-90 Microspheres Brachytherapy Licensing Guidance.	<b>M. O'Hara, ACMUI</b>
	<b>5. Lucerno Dynamic's LARA Infiltration Detection</b> Mr. Lattanze will provide an overview about a product that can assist with detecting nuclear medicine injection infiltrations.	<b>R. Lattanze,</b> <b>Lucerno Dynamics</b>

**10:30 – 10:45** **BREAK**

10:45 – 12:00	<b>6. Summary of Changes to 10 CFR Part 35</b> Ms. Dimmick will discuss the changes to the final rule 10 CFR Part 35 that went into effect January 2019.	<b>L. Dimmick, NRC</b>
	<b>7. Germanium-68/Gallium-68 Subcommittee Report</b> Ms. Shober will discuss the subcommittee's recommendations on the NRC's draft revision to the Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance.	<b>M. Shober, ACMUI</b>

**12:00 – 1:00** **LUNCH**

1:00 – 2:45	<b>8. Medical Related Events</b> Dr. Howe will provide an update on recent medical events.	<b>DB. Howe, NRC</b>
	<b>9. Appropriateness of Medical Event Reporting Subcommittee Report</b> Dr. Ennis will discuss the subcommittee's recommendations on the appropriateness of the required medical event reporting in accordance with 10 CFR 35.3045.	<b>R. Ennis, ACMUI</b>

2:45 – 3:15

**BREAK** (public portion ends)

**WEDNESDAY, APRIL 3, 2019**  
**CLOSED SESSION**

3:15 – 5:00

**10. ACMUI Working Session: Biennial Evaluations and Commission Meeting Presentation Development**

**ACMUI**

**THURSDAY, APRIL 4, 2019**  
**OPEN SESSION**

**11. ACMUI Reporting Structure**

Members will discuss the reporting structure of the Committee and provide feedback to the NRC staff.

**K. Jamerson, NRC**

8:30 – 9:30

**12. Special Presentation to Ms. Weil**

Mr. Moore will make a special presentation to Ms. Laura Weil

**S. Moore, NRC**

**13. Thoughts on Leaving the ACMUI**

Ms. Weil will share her thoughts on leaving the ACMUI, after serving two full terms (8 years).

**L. Weil, ACMUI**

9:30 – 10:00

**BREAK**

**14. Commission Meeting with the ACMUI**

The ACMUI will brief the Commission on various topics in a public meeting.

**ACMUI**

10:00 – 12:15

**15. Group Photo**

The ACMUI will take a group photo with and without the Commission.

**ACMUI**

12:15 – 1:15

**LUNCH**

**16. ACMUI Bylaws Subcommittee Report**

Ms. Weil will discuss the subcommittee's recommendations for changes to the ACMUI's Bylaws – with particular focus on the ACMUI Chair's role with respect to subcommittees.

**L. Weil, ACMUI**

1:15 – 2:45

**17. Open Forum**

The ACMUI will discuss medical topics of interest previously identified.

**ACMUI**

**18. Administrative Closing**

Ms. Jamerson will provide a meeting summary and propose dates for the fall 2019 meeting.

**K. Jamerson, NRC**

2:45

**ADJOURN**