

MEETING OF THE
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

March 30, 2020

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 and Related Documents webpage, located at: <https://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/2020.html>.

RECOMMENDATIONS AND ACTIONS

The ACMUI endorsed the following subcommittee reports. These 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/>.

The ACMUI endorsed the Patient Intervention Subcommittee report and its recommendations, as presented.

The ACMUI endorsed the Bylaws Subcommittee report and its recommendations, as presented.

The ACMUI endorsed the Interventional Radiology Subcommittee report and its recommendations, as presented.

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

Dr. Metter formed a subcommittee to evaluate the impacts of COVID-19 on the medical community and provide recommendations for potential regulatory relief measures during the COVID-19 pandemic. Due to the urgency of the topic, the subcommittee is expected to provide its recommendations to the Committee at an upcoming public teleconference. Subcommittee membership includes Dr. Dilsizian, Mr. Green, Dr. Jadvar (chair), Ms. Martin, Ms. Shober, and Dr. Wolkov. Mr. Bloom and Mr. Ouhib will serve on the subcommittee as non-voting consulting members. The NRC staff resource is Ms. Lisa Dimmick.

Dr. Metter amended the membership of the Training and Experience Requirements for All Modalities Subcommittee to add Dr. Jadvar and remove Mr. Bloom. Subcommittee membership now consists of Dr. Ennis, Dr. Jadvar, Dr. Metter, Dr. Schleipman (chair), Mr. Sheetz, and Ms. Shober. Mr. Bloom will serve on the subcommittee as a non-voting consulting member. Ms. Maryann Ayode remains the NRC staff resource.

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.

The NRC staff requested that the ACMUI provide some clarity on the working definition of the practice of medicine and how it should inform NRC's decision making as it relates to the regulation of the medical use of radioactive material. The ACMUI stated that the practice of medicine is a very broad topic to define but will assess issues on the topic on a case-by-case basis.

Dr. Metter formed an Abnormal Occurrence (AO) Subcommittee to (1) define patient harm in AO; (2) reassess the current AO criteria; (3) define goals of AO criteria and reporting; and (4) determine if current AO criteria is adequate regarding public health and safety. Subcommittee membership includes Mr. Bloom, Dr. Ennis, Dr. Jadvar, Mr. Ouhib, Mr. Sheetz (chair) and Ms. Shober. The NRC staff resource is Dr. Katie Tapp. This subcommittee is currently placed on hold until further notice from NRC staff.

The ACMUI tentatively scheduled its fall 2020 meeting for September 21-22, 2020. The alternate meeting date is September 14-15, 2020.

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

MEETING PARTICIPANTS

ACMUI

Darlene F. Metter, M.D.	Chairman
A. Robert Schleipman, Ph.D.	Vice Chairman
Gary Bloom	Member
Vasken Dilsizian, M.D.	Member
Ronald D. Ennis, M.D.	Member
Richard Green	Member
Hossein Jadvar, M.D.	Member
Melissa Martin	Member
Michael D. O'Hara, Ph.D.	Member
Zoubir Ouhib	Member
Michael A. Sheetz	Member
Megan Shoher	Member
Harvey B. Wolkov, M.D.	Member

NRC STAFF

Kevin Williams	Deputy Director, Division of Materials Safety, Security, State, and Tribal Programs (MSST)
Chris Einberg	Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Kellee Jamerson	Designated Federal Officer and ACMUI Coordinator, MSEB
Maryann Ayoade	NMSS/MSST/MSEB
Said Daibes, Ph.D.	NMSS/MSST/MSEB
Daniel Dimarco	NMSS/MSST/MSEB
Lisa Dimmick	Medical Radiation Safety Team Leader, MSS/MSST/MSEB
Jason Draper	R-III/DNMS/MIB
Robin Elliott	R-I/DNMS/MLAB
Jennifer Fisher	NMSS/MSST/MSEB
Sara Forster	R-III/DNMS/MLB
Robert Gallagher	R-I/DNMS/MLAB
Anita Gray, Ph.D.	NMSS/MSST/SMPB
Vincent Holahan, Ph.D.	NMSS/MSST
Esther Houseman	OGC/GCLR/RMR
Donna-Beth Howe, Ph.D.	NMSS/MSST/MSEB
Ian Irvin	OGC/GCLR/RMR
Janelle Jessie	COMM/OCMJB
Penny Lanzisera	R-I/DNMS/MLAB
Sarah Lopas	NMSS/MSST/MSEB
Kathy Modes	NMSS/MSST/SLPB
Janice Nguyen	R-I/DNMS/MLAB
Dennis O'Dowd	R-III/DNMS/MIB
Shawn Seeley	R-I/DNMS/MLAB
Vered Shaffer	RES/DSA/RPB
Zahid Sulaiman	R-III/DNMS/MIB
Robert Sun	NMSS/MSST/MSEB
Katherine Tapp, Ph.D.	NMSS/MSST/MSEB
Irene Wu	NMSS/MSST/MSEB

MEMBERS OF THE PUBLIC

Jenna Abbott	Illinois Emergency Management Agency
Sukhjeet Ahuja	Society of Nuclear Medicine and Molecular Imaging
Rex Ayers	Northwest Medical Physics Center
Jamie Barnes	Cook Children's Medical Center
Amy Bolar	Illinois Emergency Management Agency
Keith Brown	University of Pennsylvania
Mary Burkhart	Illinois Emergency Management Agency
Ashley Cockerham	Mercurie Consulting
Susan Corey	Cook Children's Medical Center
Elaine Crescenzi	Pennsylvania Department of Environmental Protection
David Crowley	North Carolina Department of Health and Human Services, Radiation Protection Section
Matt Dennis	CRD Associates, LLC
Terri Dodson	Illinois Emergency Management Agency
Ariel Doucet	Virtua Health
Adam Ekstedt	Illinois Emergency Management Agency
Brian Erasmus	Boston Scientific
Kelsey Everett	University of Pennsylvania
Lynn Fairobent	<i>Unaffiliated</i>
Lisa Forney	Pennsylvania Department of Environmental Protection
Jordan Frengut	<i>Unaffiliated</i>
Mike Fuller	Virginia Department of Health
Sandy Gabriel	<i>Unaffiliated</i>
Debbie Gilley	International Atomic Energy Agency
Miguel de la Guardia	Cook Children's Medical Center
Gary Hall	Fort Bragg Department of Public Health
Matthew Hall	Sirtex
Stanley Hampton	Eli Lilly
Meg Harkins	University of Pennsylvania
James Harvey	NorthStar Medical Radioisotopes
Dan Hill	Cardinal Health
James Hirn	Illinois Emergency Management Agency
Mary Ellen Jafari	Gundersen Health
Janelle Jesikiewicz	University of Pennsylvania
Josh Knowland	Lucerno Dynamics
Todd Lafrenze	Illinois Emergency Management Agency
Ronald Lattanze	Lucerno Dynamics
Georgia Lawrence	American Society of Nuclear Cardiology
Ralph Lieto	St. Joseph Mercy Health System
William Lorenzen	Boston Children's Hospital, Harvard Medical School
Carol Marcus	University of California at Los Angeles
Richard Martin	American Association of Physicists in Medicine
Jeffrey Mason	Department of Veterans Affairs
Trenton Mays	Eli Lilly
Candi McDowell	University of Pennsylvania
Thomas Mohaupt	NorthStar Medical Radioisotopes
Vanessa Mongeon	Boston Scientific
Tom Namsa	BWX Technologies
Jon Neuhoff	U.S. Department of Energy, Isotope Program

Richard Peros
Michael Peters
Deron Robbins
Grace Schoeniger
Katie Scott
Diana Thompson
Cindy Tomlinson
Gibb Vinson
Karamdeep Virk
Joseph Wissing
Melonie Wissing

New Jersey Department of Environmental Protection
American College of Radiology
Illinois Emergency Management Agency
Pennsylvania Department of Environmental Protection
Pennsylvania Department of Environmental Protection
Sirtex
American Society for Radiation Oncology
Illinois Emergency Management Agency
Illinois Emergency Management Agency
St. Joseph Mercy Health System
Department of Veterans Affairs

MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
March 30, 2020
Teleconference/WebEx

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, MARCH 30, 2020
OPEN SESSION

9:30 – 10:45	1. Opening Remarks Mr. Einberg will formally open the meeting and Mr. Layton will provide opening remarks.	C. Einberg, NRC M. Layton, NRC
	2. Old Business Ms. Jamerson will review past ACMUI recommendations and provide NRC responses.	K. Jamerson, NRC
	3. Open Forum The ACMUI will identify medical topics of interest for further discussion.	ACMUI
	4. Trends in Radiopharmaceuticals Dr. Jadvar will provide a presentation on the status of emerging radiopharmaceuticals.	H. Jadvar, ACMUI

10:45 – 11:00 **BREAK**

11:00 – 12:15	5. Patient Intervention Subcommittee Report Mr. Sheetz will discuss the subcommittee's recommendations regarding the definition of patient intervention and other actions exclusive of medical events.	M. Sheetz, ACMUI
	6. NMED Overview Mr. Sun will provide an overview of the NRC's Nuclear Material Events Database.	R. Sun, NRC

12:15 – 1:15 **LUNCH**

1:15 – 2:30	7. ACMUI Reporting Structure Members will discuss the reporting structure of the Committee and provide feedback to the NRC.	K. Jamerson, NRC
	8. ACMUI Bylaws Subcommittee Report Dr. Wolkov will discuss the subcommittee's recommendations for changes to the bylaws, with focus on term limits for the ACMUI Chair and Vice Chair.	H. Wolkov, ACMUI

2:30 – 2:45 **BREAK**

	9. Medical Related Events Dr. Howe will provide an update on recent medical events.	DB. Howe, NRC
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2:45 – 5:00

10. Interventional Radiologist Subcommittee Report

M. Shober, ACMUI

Ms. Shober will discuss the subcommittee's recommendations on the need for an Interventional Radiologist on the ACMUI.

11. Open Forum

ACMUI

The ACMUI will discuss medical topics of interest previously identified.

12. Administrative Closing

K. Jamerson, NRC

Ms. Jamerson will provide a meeting summary and propose dates for the fall 2020 meeting.

5:00

ADJOURN