

MEETING OF THE
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

September 21-22, 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 webpage, located at: <https://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/>.

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/>.

- The ACMUI endorsed the Medical Events Subcommittee report and its recommendations, as presented.

The recommendation passed unanimously with thirteen favorable votes.

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

- Dr. David Hamby, Renaissance Code Development, LLC, provided a presentation on the dosimetry methodology update for the Phase 2 revision of Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material." The ACMUI Regulatory Guide 8.39 Subcommittee will have the opportunity to review the preliminary draft Phase 2 update when it becomes available. This presentation was informational and requires no action of the ACMUI.
- Mr. Frank Lutterodt, U.S. Food & Drug Administration (FDA), provided a presentation on the FDA's process for new drug development and labeling. This presentation was informational and requires no action from the ACMUI.

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

- At the conclusion of the report of Non-Medical Events, the ACMUI recommended that the National Materials Program evaluate the issue of detection of short-lived medical isotopes in municipal waste (waste from nuclear medicine patients that could possibly be triggering the landfill alarms) and provide some level of guidance, best practices, or additional instructions.

The recommendation passed unanimously with thirteen favorable votes.

- The ACMUI tentatively scheduled its spring 2021 meeting for March 15-16, 2021. The alternate meeting date is March 22-23, 2021. A virtual or in-person meeting for spring 2021 is to be determined.

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

MEETING ATTENDEES

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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 Shober	Member
Harvey B. Wolkov, M.D.	Member

NRC STAFF

Kevin Williams	Director, Division of Materials Safety, Security, State, and Tribal Programs (MSST)
Jacob Zimmerman	Acting Deputy Director, 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
Stephanie Bush-Goddard	RES/DSA
Theresa Clark	NMSS/REFS
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
Sarah Forster	R-III/DNMS/MLB
Robert Gallagher	R-I/DNMS/MLAB
Anita Gray, Ph.D.	NMSS/MSST/SMPB
Valerie Gray	NMSS/MSST/MSEB
Michelle Hammond	R-IV/DNMS/MLDB
Vincent Holahan, Ph.D.	NMSS/MSST
Esther Houseman	OGC/GCLR/RMR
Donna-Beth Howe, Ph.D.	NMSS/MSST/MSEB
Ian Irvin	OGC/GCLR/RMR
Penny Lanzisera	R-I/DNMS/MLAB
Sarah Lopas	NMSS/MSST/MSEB
Kathy Modes	NMSS/MSST/SLPB
Jan Nguyen	R-I/DNMS/MLAB
Robert Orlikowski	R-III/DNMS/MLB
Vered Shaffer	RES/DSA/RPB
Zahid Sulaiman	R-III/DNMS/MIB
Robert Sun	NMSS/MSST/MSEB

Katherine Tapp, Ph.D.
Elizabeth Tindle-Engelman
John Tomon
Duncan White

NMSS/MSST/MSEB
R-I/DNMS/MLAB
RES/DSA/RPB
NMSS/MSST/SLPB

PUBLIC PARTICIPANTS

Alex Bakken
Jaime Barnes
Rebecca Branum
Haley Brown
Keith Brown
Janet Bukovcan
Mary Burkhart
Paul Burns
Ashley Cockerham
Thomas Conley
Whitney Cox
Elaine Crescenzi
Corey Creveling
David Crowley

Bruce Curran
Matt Dennis
Newbegin Devaraj
Nick Dorrell
Ariel Doucet
Dawn Edgerton
Brian Erasmus
Teresa Fisher
John Follette
Lisa Forney
Sandy Gabriel
Debbie Gilley
Richard Granberg
Carl Granlund
Johnny Graves

Miguel de la Guardia
Michael Guastella
Michael Hall
David Hamby, PhD.
Stanley Hampton
Kathleen Hintenlang
Rachel Houseman
Josh Knowland
Joseph Koshy
Sasikala Krishnasarma

Kevin Kunder
Ronald Lattanze

Niowave, Inc.
Cook Children's Medical Center
CRD Associates
Emory University
University of Pennsylvania
Boston Scientific
Illinois Emergency Management Agency
Mount Sinai
Mercurie Consulting
University of Kansas Health System
Illinois Emergency Management Agency
Pennsylvania Department of Environmental Protection
State of Nevada, Radiation Control Program
North Carolina Department of Health and Human Services,
Radiation Protection Section
VCU Health System
CRD Associates, LLC
National Institutes of Health
University of Virginia
Virtua Health
American Society of Nuclear Cardiology
Boston Scientific
National Institutes of Health
State of Nevada, Radiation Control Program
Pennsylvania Department of Environmental Protection
Unaffiliated
International Atomic Energy Agency
NorthStar
Johns Hopkins University
Tennessee Department of Environment and Conservation,
Division of Radiological Health
Cook Children's Medical Center
CORAR
Emory University
RCD Radiation Protection Association
Eli Lilly
American College of Radiology
SHINE Medical Technologies
Lucerno Dynamics
Pennsylvania Department of Environmental Protection
Tennessee Department of Environment and Conservation,
Division of Radiological Health
Florida Department of Health, Bureau of Radiation Control
Lucerno Dynamics

Ralph Lieto
Frank Lutterodt
Carol Marcus, MD, PhD.
Richard Martin
Candi McDowell
Tara Medich
Christopher Mitchell
Thomas Mohaupt
Vanessa Mongeon
Jennifer Noll
Ron Parsons

Michael Peters
Andrea Ravard
Erin Reynolds
Tracy Scherer
Grace Schoeniger
Katie Scott
Michael Semon
Meredith Semon-Pomposelli
Michael Stabin
Carol Wen
Neil Whiteside
Colin Whitney
Melonie Wissing
John Witkowski

St. Joseph Mercy Health System
U.S. Food and Drug Administration
University of California at Los Angeles
American Association of Physicists in Medicine
University of Pennsylvania
Massachusetts General Hospital
Kettering Health Network
NorthStar Medical Radioisotopes
Boston Scientific
Pennsylvania Department of Environmental Protection
Tennessee Department of Environment and Conservation,
Division of Radiological Health
American College of Radiology
Radiation Protection & Training
Pennsylvania Department of Environmental Protection
Pennsylvania Department of Environmental Protection
Pennsylvania Department of Environmental Protection
Pennsylvania Department of Environmental Protection
Monongahela Valley Hospital
Monongahela Valley Hospital
NV5
Christiana Care
Yale New Haven Hospital
ASTRO
Department of Veterans Affairs
UPPI

MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
September 21-22, 2020
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, September 21, 2020
OPEN SESSION

- | | | |
|---------------|--|-------------------------|
| 10:00 – 11:30 | 1. Opening Remarks
Mr. Einberg will formally open the meeting and provide opening remarks. | C. Einberg, NRC |
| | 2. Old Business
Ms. Jamerson will review past ACMUI actions and recommendations and provide NRC responses. | K. Jamerson, NRC |
| | 3. Open Forum
The ACMUI will identify medical topics of interest for further discussion. | ACMUI |
| | 4. Medical Events Subcommittee Report
Dr. Ennis will provide an analysis of FY19 medical events. | R. Ennis, ACMUI |

11:30 – 12:15 **BREAK/LUNCH**

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|--------------|--|--|
| 12:15 – 2:00 | 5. Non-Medical Events
Mr. Sheetz will provide an analysis of FY19 non-medical events reported by medical use facilities and commercial pharmacies. | M. Sheetz, ACMUI |
| | 6. New Drug Development and Labeling
Mr. Lutterodt will discuss the U.S. Food and Drug Administration's regulatory process for new drug development and labeling. | F. Lutterodt, FDA |
| | 7. Dosimetry Methodology Update for Regulatory Guide 8.39, Phase 2 Revision
Dr. Hamby will discuss the dosimetry methodology update for the Regulatory Guide 8.39, Phase 2 revision. | D. Hamby,
RCD Radiation
Protection Assoc. |

2:00 **ADJOURN FOR THE DAY**

Tuesday, September 22, 2020
CLOSED SESSION

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|---------------|---------------------------------|------------------------|
| 10:00 – 12:00 | 8. INFOSEC Training | R. Norman, NRC |
| | 9. Ethics Training | C. Safford, NRC |
| | 10. Allegations Training | S. Hawkins, NRC |

12:00 – 12:15 **BREAK**

Tuesday, September 22, 2020
OPEN SESSION

11. Medical Team Updates

L. Dimmick, NRC

Ms. Dimmick will provide an update on Medical Radiation Safety Team activities.

12:15 – 1:45

12. Open Forum

ACMUI

The ACMUI will discuss medical topics of interest previously identified.

13. Administrative Closing

K. Jamerson, NRC

Ms. Jamerson will provide a meeting summary and propose dates for the spring 2021 meeting.

1:45

ADJOURN