

MEETING OF THE
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

March 16, 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 following provides a summary of the discussions that took place on the topics listed on the ACMUI meeting agenda (Enclosure 2):

Dr. Jochem van der Pol of Maastricht University, located in Maastricht, Netherlands, provided an overview of his study on the consequences of radiopharmaceutical extravasation and interventions.

Dr. Katie Tapp provided an overview of the NRC staff's evaluation of patient release considerations associated with temporary brachytherapy devices. The NRC staff is currently developing a draft 10 CFR 35.1000 licensing guidance for the Alpha DaRT and plans to provide to the ACMUI for review in summer 2021.

Dr. Larry DeWerd from the University of Wisconsin provided a presentation on calibration procedures for brachytherapy sources and current standards as determined by the American Association of Physicists in Medicine.

The ACMUI agreed that the current structure of reporting directly to the Office of Nuclear Material Safety and Safeguards, Division of Materials Safety, Security, State, and Tribal Programs is appropriate and continues to function effectively. The ACMUI also agreed that its meeting frequency and its annual reporting to the Commission is well-suited for the workload of the Committee. The ACMUI also expressed their desire for in-person meetings to resume, safety permitting, post COVID-19.

The ACMUI tentatively scheduled the fall 2021 meeting for October 4-5, 2021. The alternate meeting date is September 13-14, 2021. A virtual or in-person meeting for fall 2021 is to be determined.

The NRC staff offered an update on the status of a number of staff activities including the limited revision to the Abnormal Occurrence criteria for medical events; the NRC staff's independent evaluation of extravasations; and the Phase 2 revision of Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material." The NRC staff will provide documents in support of the activities to the respective ACMUI subcommittees for review. Public teleconferences on these topics will be scheduled at a later date. Staff also provided an overview of SECY-21-0013, "Rulemaking Plan to Establish Requirements for Rubidium-82 (Rb-82) Generators & Emerging Medical Technologies (EMTs)," which was issued on February 24, 2021.

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

MEETING ATTENDEES

March 16, 2021

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Darlene F. Metter, M.D.	Chairman
Vasken Dilsizian, M.D.	Vice Chairman
Ronald D. Ennis, M.D.	Member
Richard Green	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)
Chris Einberg	Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Kellee Jamerson	Designated Federal Officer and ACMUI Coordinator, MSEB
Said Daibes, Ph.D.	NMSS/MSST/MSEB
Suzanne Dennis	OEDO/AO
Daniel Dimarco	NMSS/MSST/MSEB
Lisa Dimmick	Medical Radiation Safety Team Leader, MSS/MSST/MSEB
Stephanie Dingbaum	OIG/AIGA/NMW
Robin Elliott	R-I/DNMS/MLAB
Monica Ford	R-I/DNMS
Sarah Forster	R-III/DNMS/MLB
Cassandra Frazier	R-III/DNMS/MLB
Robert Gallagher	R-I/DNMS/MLAB
Farrah Gaskins	R-I/DNMS
Anita Gray, Ph.D.	NMSS/MSST/SMPB
Valerie Gray	NMSS/MSST/MSEB
Michelle Hammond	R-IV/DNMS/MLDB
Latischa Hanson	R-IV/DNMS/MLDB
Vincent Holahan, Ph.D.	NMSS/MSST
Donna-Beth Howe, Ph.D.	NMSS/MSST/MSEB
Ian Irvin	OGC/GCLR/RMR
Donna Janda	R-I/DNMS/MLAB
Janelle Jessie	COMM/OCMJB
Cynthia Jones	COMM/OCMAC
Penny Lanzisera	R-I/DNMS/MLAB
Kathy Modes	NMSS/MSST/SLPB
Janice Nguyen	R-I/DNMS/MLAB
Robert Orlikowski	R-III/DNMS/MLB
Vered Shaffer	RES/DSA/RPB
Katherine Tapp, Ph.D.	NMSS/MSST/MSEB

Carolyn Wolf
Weijun Wang
Geoffrey Warren

OCA
RES/DE/SGSEB
R-III/DNMS/MIB

PUBLIC PARTICIPANTS

Christina Arenas
Joaquin Altamirano
Jinsy Babu
Jaime Barnes
Jason Barney
Samapti Barua
David Bierman
Rebecca Branum
Roy Brown
Jeffrey Brunette
Tina Buehner
Mary Burkhart
Paul Burns
Roger Champion
Sean Chapel
Ashley Cockerham
Gilad Cohen
Thomas Conley
Whitney Cox
David Crowley

Bruce Curran
Matt Dennis
Larry DeWerd
Nick Dorrell
Thomas Eiden
William Erwin
Daniel Fass, M.D.
Roger Fenner
Teresa Fisher
Sandy Gabriel
Jennifer Gersman
Ira Goldman
Aaron Goldner
William Gorge
Johnny Graves

Matthew Greenwood
Marc Gregoire
Miguel de la Guardia
Michael Guastella
Tianliang Gu
Michael Hall
Carolyn Halsey
Stanley Hampton

Society of Nuclear Medicine and Molecular Imaging
Memorial Sloan Kettering Cancer Center
Department of Veterans' Affairs
Cook Children's Medical Center
University of Kansas Health System
Society of Nuclear Medicine and Molecular Imaging
Memorial Sloan Kettering Cancer Center
CRD Associates
Curium Pharma
Mayo Clinic
Rush Medical Center
Illinois Emergency Management Agency
Mount Sinai
Maryland Department of the Environment
Boston Scientific
Mercurie Consulting
Memorial Sloan Kettering Cancer Center
University of Kansas Health System
Illinois Emergency Management Agency
North Carolina Department of Health and Human Services,
Radiation Protection Section
VCU Health System
CRD Associates, LLC
University of Wisconsin
University of Virginia
Atomic Alchemy
UT MD Anderson Cancer Center
Princeton Healthcare Alliance
Tennessee Department of Environment and Conservation
National Institutes of Health
Unaffiliated
Northwestern Medicine
Lantheus
U.S. Senate Committee on Appropriations
Halcyon Strategy Group
Tennessee Department of Environment and Conservation,
Division of Radiological Health
Tennessee Department of Environment and Conservation
ABK Biomedical
Cook Children's Medical Center
CORAR
UT Health Center at Houston
Emory University
Veterans' Affairs
Eli Lilly

Kathleen Hintenlang	Ohio State University
Neal Holter	Mount Nittany Medical Center
Sean Hoyt	Ohio Health
Mary Ellen Jafari	Atlantic Health
Janelle Jesikiewicz	University of Pennsylvania
Josh Knowland	Lucerno Dynamics
Linda Kroger	UC Davis
Kevin Kunder	Florida Department of Health, Bureau of Radiation Control
Norman LaFrance	Jubilant Radiopharma
Ronald Lattanze	Lucerno Dynamics
Christopher Lease	RWJ Barnabas Health
Ralph Lieto	St. Joseph Mercy Health System
Cindi Luckett-Gilbert	Curium Pharma
Josh Mailman	NorCal Carcinet
Carol Marcus, MD, PhD.	University of California at Los Angeles
Richard Martin	American Association of Physicists in Medicine
Roberto Maass-Moreno	National Institutes of Health
Mary McCormack	CNMT
Candi McDowell	University of Pennsylvania
Josh McIlvain	Diagnostic Technology Consultants
Scott McKee	U.S. House Committee on Appropriations
Ashley Mishoe	Novartis
Christopher Mitchell	Kettering Health Network
Jeff Moirano	University of Washington
William Ostertag	U.S House Committee on Appropriations
Jade Parisey	Veterans' Affairs
Ron Parsons	Tennessee Department of Environment and Conservation, Division of Radiological Health
Michael Peters	American College of Radiology
Carmine Plott	Novant Health
Kavya Prasad	Memorial Sloan Kettering
Gloria Romanelli	American College of Radiology
Manar Sakalla	MedStar Georgetown
Brian Serencsits	Memorial Sloan Kettering
Brian Shen	University of Michigan
Dominic Siewko	Jubilant Radiopharma
Eugenio Silvestrini	North Shore University Hospital
Mike Stephens	Florida Department of Health, Bureau of Radiation Control
Tishara Stewart	Maryland Department of the Environment
Allyson Stout	Kentucky Radiation Health Department
Diana Thompson	Sirtex
Michelle Thompson	UPPI
Cindy Tomlinson	ASTRO
Adam Turner	Turner Medical Consulting
Jochem van der Pol, M.D.	Maastricht University Medical Centre
David Vassy	Spartanburg Regional Healthcare System
Paul Wallner	ACR
Chu Wang	Duke University
Nancy Wersto	US FDA
Matthew Williamon	Memorial Sloan Kettering
Matthew Williams	MedStar Georgetown

John Witkowski
Brandi Woods
Pat Zanzonico

UPPI
ABK Biomedical
Memorial Sloan Kettering Cancer Center

MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
March 16, 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.

TUESDAY, MARCH 16, 2021
OPEN SESSION

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|---------------|--|--|
| 10:00 – 12:30 | <p>1. Opening Remarks
Mr. Einberg will formally open the meeting and Mr. Williams will provide opening remarks.</p> <p>2. Old Business
Ms. Jamerson will review past ACMUI recommendations and provide NRC responses.</p> <p>3. Extravasations in Nuclear Medicine
Dr. Jochem van der Pol will provide an overview of his study on the consequences of radiopharmaceutical extravasation and therapeutic interventions.</p> <p>4. Open Forum
The ACMUI will identify medical topics of interest for further discussion.</p> <p>5. Patient Release Evaluation of Emerging Brachytherapy Sources
Dr. Tapp will provide an overview of the current status of the NRC's evaluation of patient release following administration of new emerging brachytherapy sources.</p> | <p>C. Einberg, NRC
K. Williams, NRC</p> <p>K. Jamerson, NRC</p> <p>J. van der Pol, MD,
Maastricht
University Medical
Centre</p> <p>ACMUI</p> <p>K. Tapp, PhD, NRC</p> |
| 12:30 – 1:00 | BREAK | |
| 1:00 – 3:00 | <p>6. ACMUI Reporting Structure
Ms. Jamerson will provide an overview of the current reporting structure. Members will discuss the reporting structure of the Committee and provide feedback to the NRC.</p> <p>7. Calibration Procedures for Brachytherapy Sources
Dr. Larry DeWerd will provide a presentation on the calibration procedures for existing brachytherapy sources and considerations for emerging manual brachytherapy sources.</p> <p>8. Open Forum
The ACMUI will continue discussion on medical topics of interest.</p> | <p>K. Jamerson, NRC</p> <p>L. DeWerd, PhD,
University of
Wisconsin</p> <p>ACMUI</p> |

9. Administrative Closing

K. Jamerson, NRC

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

3:00

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