

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

May 8-9, 2014

MEETING SUMMARY

PURPOSE

To discuss current rulemaking activities and other issues related to the implementation of the medical regulations in Title 10, Code of Federal Regulations (CFR), Part 35, and “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 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 NRC’s public website: <http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/>

RECOMMENDATIONS AND ACTIONS

The following recommendations and actions are a result of the discussions that took place on the topics listed on the ACMUI meeting agenda (Attachment 2).

The Committee endorsed the Medical Policy Statement Subcommittee Report. This included a recommendation to make no changes to the current NRC Medical Policy Statement. The recommendation passed unanimously with thirteen favorable votes.

Chairman of the ACMUI, Dr. Thomadsen, formed a subcommittee to review the medical event reporting criteria of the yttrium-90 microspheres (35.1000) guidance. Subcommittee members include: Dr. Guiberteau (chair), Mr. Costello, Dr. Langhorst, Dr. Palestro, Dr. Thomadsen, and Dr. Welsh. The subcommittee will present their recommendations at the fall 2014 meeting. The NRC staff resource is Dr. Howe.

Following the discussion on Medical-Related Events, Dr. Thomadsen added Mr. Francis Costello to the Medical Events Subcommittee.

Following an update on Ga-68 Generators, Dr. Thomadsen formed a subcommittee to provide staff with the background information to justify the recommendation for the regulatory relief from the Decommissioning Funding Plan (DFP) of Ge-68. The subcommittee is specifically charged with evaluating the cost of a DFP for the use of Ge-68, its effect on the future clinical use of new Ga-68 radiopharmaceuticals and how appropriate regulatory relief may be gained. Subcommittee members include Mr. Mattmuller (chair), Dr. Langhorst, Mr. Costello, Dr. Palestro and Dr. Zanzonico. Staff will provide the Ge-68 DFP Subcommittee with the NRC guidelines for developing a Regulatory Basis.

The Committee recommended tabling the discussion on the revisions to the ACMUI Bylaws until summer 2014. The Committee also requested that staff provide the current and proposed bylaws with color coding for staff's proposed changes and the subcommittee's proposed changes. The recommendation passed unanimously with thirteen favorable votes.

Also under the topic of the ACMUI Bylaws, the Committee recommended the following: (1) To maintain the current ACMUI reporting structure and continue to review the reporting structure on an annual basis; (2) To maintain the current two face-to-face meetings at headquarters annually; and (3) To endorse the use of web-based meetings as needed, but not in place of the two annual face-to-face meetings. The recommendation passed unanimously with thirteen favorable votes. This discussion served as the annual discussion on reporting structure for 2014.

The Committee planned to hold the fall 2014 ACMUI Meeting on September 29-30, 2014 at NRC Headquarters. The back-up meeting date is October 20-21, 2014.

Attachments:

Attachment 1: Attendees

Attachment 2: Meeting Agenda

MEETING ATTENDEES

ACMUI

Philip O. Alderson, M.D.	Member
Francis M. Costello	Member
Vasken Dilsizian, M.D.	Member
Milton S. Guiberteau, M.D.	Vice Chairman
Susan M. Langhorst, Ph.D.	Member
Steven R. Mattmuller	Member
Christopher J. Palestro, M.D.	Member
John H. Suh, M.D.	Member
Orhan Suleiman, Ph.D.	Member
Bruce R. Thomadsen Ph.D.	Chairman
Laura M. Weil	Member
James S. Welsh, M.D.	Member
Pat B. Zanzonico, Ph.D	Member

NRC

Michael Weber	Deputy Executive Director of Operations for Materials, Waste, Research, State, Tribal, and Compliance Programs
Brian Holian	Acting Director, Office of Federal and State Materials and Environmental Management Programs (FSME)
Mark Shaffer	Acting Deputy Director, Office of Federal and State Materials and Environmental Management Programs (FSME)
Laura Dudes	Director, Division of Materials Safety and State Agreements (DMSSA)
Pamela Henderson	Deputy Director, Division of Materials Safety and State Agreements (DMSSA)
Douglas Bollock	Acting Chief, Radioactive Materials Safety Branch (RMSB)
Michael Fuller	Medical Radiation Safety Team Leader and Alternate Designated Federal Officer
Sophie Holiday	Alternate Designated Federal Officer and ACMUI Coordinator
Neelam Bhalla	FSME
Susan Chidakel	OGC
Ashley Cockerham	FSME
Jackie Cook	Region IV
Said Daibes, Ph.D.	FSME
Jim Dwyer	Region I
Sara Forster	Region III
Cassandra Frazier	Region III
Sandra Gabriel, Ph.D.	FSME
Joe Giessner	Region III
Michelle Hammond	Region IV
Latischa Hanson	Region IV
Tomas Herrera	FSME
Vincent Holahan, Ph.D.	FSME
Donna-Beth Howe, Ph.D.	FSME
Ed Lohr	FSME
Angela McIntosh	FSME
Kevin Null	Region III
Dennis O'Dowd	Region III
Bryan Parker	Region III
Patty Pelke	Region III

William Reichhold	Region III
Gretchen Rivera-Capella	FSME
Lizette Roldan-Otero, Ph.D.	Region IV
Mohammad Saba	RES
Toye Simmons	Region III
Rebecca Tadesse	RES
Frank Tran	Region III
Lester Tripp	Region I
Shirley Xu	FSME

MEMBERS OF THE PUBLIC

David Allard	Pennsylvania Bureau of Radiation Protection
Maxwell Amurao	Columbia University Medical Center
Sarah Bender	National Nuclear Security Administration
Lisa Bruedigan	Texas Department of State Health Services
Sue Bunning	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Jessica Clements	Texas Health Resources
Peter Crane	<i>unaffiliated</i>
Robert Dansereau	New York State Department of Health
Ray Dielman	Florida Department of Health
Lynne Fairobent	American Association of Physicists in Medicine (AAPM)
Karen Flanigan	New Jersey Department of Environmental Protection
Cindi Gilbert	North Carolina Nuclear Medicine Technologists, Inc.
Brian Goretzki	Arizona Radiation Regulatory Agency
Georgia Hearn	American Society of Nuclear Cardiology (ASNC)
Angela Hill	Arkansas Department of Health
Caitlin Kubler	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Ralph Lieto	St. Joseph Mercy Hospital
Jose Morales	Hima San Pablo
Vicki Morris	University of Cincinnati
Elizabeth Peetz	Mallinckrodt Pharmaceuticals
Michael Peters	American College of Radiology (ACR)
Gloria Romanelli	American College of Radiology
Daniel Snyder	Geisinger Health System
William Sones	Mallinckrodt Pharmaceuticals
Tod Speer	Willmar Regional Cancer Center
Parrish Staples	National Nuclear Security Administration
Michael Stephens	Florida Bureau of Radiation Control
Joy Stephenson	Florida Bureau of Radiation Control
Glenn Sturchio	Mayo Clinic
Julie Timins	<i>unaffiliated</i>
Cindy Tomlinson	American Society for Radiation Oncology (ASTRO)
Paul Yurko	Veterans Health Administration

**MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES**

**May 8-9, 2014
Two White Flint North Building (T2-B3), Rockville, Maryland**

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.

Thursday, May 08, 2014 CLOSED SESSION		
7:30 – 8:30	1. Badging and Enrollment	S. Holiday, NRC
OPEN SESSION		
8:30 – 8:45	2. Opening Statements Mr. Fuller will formally open the meeting and Ms. Dudes will provide opening comments.	M. Fuller, NRC L. Dudes, NRC
8:45 – 9:00	3. Old Business Ms. Holiday will review past ACMUI recommendations and provide NRC responses.	S. Holiday, NRC
9:00 – 9:45	4. Commission Direction on Part 35 Rulemaking Activities Dr. Howe will discuss the tasking from the Commission related to the 10 CFR Part 35 Rulemaking.	DB. Howe, NRC
B R E A K		
9:45 – 10:00		
10:00 – 11:00	5. NRC Medical Policy Statement Dr. Thomadsen and Ms. Cockerham will lead discussions about whether or not the NRC should revise the Medical Policy Statement.	A. Cockerham, NRC B. Thomadsen, ACMUI
11:00 – 11:45	6. Medical Related Events Dr. Howe will provide the latest update on medical-related events	DB. Howe, NRC
11:45 – 12:00	7. Update on Ga-68 Generators Mr. Mattmuller will provide an update on the developments associated with the Ge-68/Ga-68 generators.	S. Mattmuller, ACMUI
L U N C H		
12:00 – 1:30		
1:30 – 3:00	8. Amendments to the ACMUI Bylaws Dr. Zanzonico will discuss the amendments to the ACMUI Bylaws	P. Zanzonico, ACMUI
B R E A K		
CLOSED SESSION		
3:00 – 3:30		
3:30 – 5:30	9. ACMUI Subcommittee Meeting	ACMUI

Friday, May 09, 2014
CLOSED SESSION

- 7:30 – 8:00 **10. Security Briefing**
8:00 – 9:00 **11. Escort Training**

OPEN SESSION

- 9:00 – 11:00 **12. Commission Briefing** **ACMUI**
The ACMUI will brief the Commission on various topics in the Commissioners Hearing Room.
- 11:00 – 11:30 **13. Group Photo**
The ACMUI will take a group photo.

LUNCH

- 1:00 – 2:00 **14. Research on the Release of Patients Following Iodine-131 Administration** **M. Saba, NRC**
P. Zanzonico, ACMUI
Mr. Saba will provide a status update on the research being conducted for patients who are released following the administration of iodine-131. Dr. Zanzonico will discuss the presentation given during the Commission Meeting.
- 2:00 – 2:45 **15. NNSA's Efforts on Reducing HEU in Molybdenum-99 Production** **R. Hamilton, NNSA**
P. Staples, NNSA
Dr. Staples and Ms. Hamilton will provide a status update on NNSA's efforts to reduce HEU during the production of molybdenum-99.
- 2:45 – 3:00 **16. Administrative Closing** **S. Holiday, NRC**
Ms. Holiday will provide a meeting summary and propose dates for the Fall 2014 meeting.

BREAK

CLOSED SESSION

- 3:30 – 3:45 **17. eTravel Training** **S. Holiday, NRC**
3:45 – 4:00 **18. HRMS Training** **S. Holiday, NRC**

4:00 **ADJOURN**