

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

March 19-20, 2015

MEETING SUMMARY

PURPOSE

To discuss 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 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 Web site: <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).

Mr. Costello and Dr. Langhorst will distribute questions to the Committee regarding the proper platform, expected and necessary participants and the feasibility of conducting an additional “Medical Meeting.”

Chairman of the ACMUI, Dr. Thomadsen, formed a subcommittee to review and evaluate the phrase “patient intervention.” Subcommittee members include: Dr. Dilsizian (chair), Dr. Alderson, Mr. Costello, Dr. Ennis, Dr. Suh and Ms. Weil. The NRC staff resource contact is Dr. Gabriel. The subcommittee will present their report at the fall 2015 ACMUI Meeting.

Dr. Thomadsen formed a subcommittee to review and make recommendations for revisions to the existing 10 CFR 35.1000 licensing guidance for radioactive seed localization. Subcommittee members include: Dr. Ennis (chair), Dr. Alderson, Mr. Costello, Dr. Mettler (pending security clearance) and Dr. Zanzonico. The NRC staff resource contact is Ms. Holiday. The subcommittee will present their report during a summer teleconference.

Dr. Thomadsen added Dr. Ennis, Dr. O'Hara and Dr. Zanzonico to the standing ACMUI Medical Events Subcommittee. Subcommittee members include: Dr. Ennis (chair), Dr. Langhorst, Mr. Mattmuller, Dr. O'Hara, Dr. Palestro, Dr. Suh, Dr. Thomadsen and Dr. Zanzonico.

Dr. Thomadsen has tasked the existing Ge/Ga-68 subcommittee with (1) estimating the number of potential Ge/Ga-68 generator licensees and (2) making a recommendation to the Committee on which route of action it believes NRC should pursue to address the decommissioning funding plan issue. Subcommittee members include: Mr. Mattmuller (Chair), Mr. Costello, Dr. Langhorst, Dr. Palestro, and Dr. Zanzonico. The NRC staff resource contact is Ms. Holiday. The subcommittee will present their report during a summer teleconference.

Dr. Thomadsen will draft a letter to the Commission addressing the miswording of the intention of the Committee's recommendation for the ME Compatibility Category. The Committee's recommendation was to address the compatibility category for permanent implant brachytherapy only.

The Committee requested that staff transmit the Committee's clarification for their recommendation for events in which radiation is administered to an embryo/fetus or a nursing child. Specifically, the Committee recommended that that a human exposure to radiation from licensed material should be an Abnormal Occurrence if an unintended dose to an embryo/fetus or a nursing child resulted in a significant adverse health impact to the embryo/fetus or nursing child, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State. The Committee now wants to amend the proposed Abnormal Occurrence (AO) criterion I.A.4 to state, "These criteria [in section I.A.] do not apply to medical events defined in 10 CFR 35.3045 or 10 CFR 35.3047 and included in AO criteria III.C., 'Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects.

The Committee planned to hold the fall 2015 ACMUI Meeting on October 08-09, 2015 at NRC Headquarters. The back-up meeting date is September 10-11, 2015.

Attachments:

Attachment 1: Attendees

Attachment 2: Meeting Agenda

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OFC	MSTR/MSEB	MSTR/MSEB
NAME	S. Holiday	D. Bollock
DATE	04/02/2015	04/02/2015

MEETING ATTENDEES

ACMUI

Philip O. Alderson, M.D.	Vice Chairman
Francis M. Costello	Member
Vasken Dilsizian, M.D.	Member
Ronald D. Ennis, M.D.	Member
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
Pat B. Zanzonico, Ph.D	Member
<i>Fred Mettler, Jr., M.D.</i>	<i>Member-elect (non-voting)</i>

NRC

Laura Dudes	Director, Division of Material Safety, State, Tribal and Rulemaking Programs (MSTR)
Pamela Henderson	Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs (MSTR)
Douglas Bollock	Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Sophie Holiday	Alternate Designated Federal Officer and ACMUI Coordinator
Maryann Abogunde	NMSS
Maria Arribas-Colon	NMSS
Luis Benevides, Ph.D.	RES
Michael Blair	OIG
Marcia Carpentier	OGC
Ashley Cockerham	NMSS
Jackie Cook	Region IV
Said Daibes, Ph.D.	NMSS
Sara Forster	Region III
Cassandra Frazier	Region III
Sandra Gabriel, Ph.D.	NMSS
Joseph Gilman	OGC
Latischa Hanson	Region IV
Michelle Hammond	Region IV
Vincent Holahan, Ph.D.	NMSS
Esther Houseman	OGC
Donna-Beth Howe, Ph.D.	NMSS
Cardelia Maupin	NMSS
Angela McIntosh	NMSS
Tony McMurtray	NMSS

Kevin Null	Region III
Patty Pelke	Region III
Josie Piccone, Ph.D.	NMSS
Lymari Sepulveda	NMSS
Sami Sherbini, Ph.D.	NMSS
Toye Simmons	Region III
Jaclyn Storch	OIG
Katie Tapp, Ph.D.	RES

MEMBERS OF THE PUBLIC

Bette Blankenship	American Association of Physicists in Medicine (AAPM)
Sue Bunning	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Peter Crane	<i>unaffiliated</i>
Robert Danseareau	New York State Department of Health
William Davidson	University of Pennsylvania
Lynne Fairbent	American Association of Physicists in Medicine (AAPM)
Catherine Gilmore-Lawless	Elekta
Per Kjall	Elekta
Caitlin Kubler	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Richard Martin	American Association of Physicists in Medicine (AAPM)
Michael Peters	American College of Radiology (ACR)
Dhereen Prasad	Roswell Park Cancer Center
Cara Santillo	Elekta
Michael Sheetz	University of Pittsburgh
Robert Thomas	Elekta
Cindy Tomlinson	American Society for Radiation Oncology (ASTRO)
Bin Wang	Walter Reed National Military Medical Center

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

**March 19-20, 2015
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, March 19, 2015 OPEN SESSION		
8:30 – 8:45	1. 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	2. Old Business Ms. Holiday will review past ACMUI recommendations and provide NRC responses.	S. Holiday, NRC
9:00 – 9:15	3. Open Forum The ACMUI will identify any medical topics of interest.	ACMUI
9:15 – 10:00	4. Additional Medical Meeting Mr. Costello and Dr. Langhorst will discuss various options for an additional medical-related meeting.	F. Costello, ACMUI S. Langhorst, ACMUI
10:00 – 10:15	BREAK	
10:15 – 10:45	5. Patient Release Tasks Ms. Cockerham and Dr. Howe will provide an update on the staff's efforts related to the release of patients administered radioactive material.	A. Cockerham, NRC DB. Howe, NRC
10:45 – 11:30	6. Patient Intervention Dr. Gabriel will provide the history and background of the term "patient intervention." Mr. Costello will provide the perspective from an Agreement State inspector point of view.	S. Gabriel, NRC F. Costello, ACMUI
11:30 – 1:00	LUNCH	
1:00 – 2:00	7. ACMUI Comments on NUREG-1556, Volume 9 Ms. Cockerham will lead discussions on the proposed changes to NUREG-1556, Volume 9.	A. Cockerham, NRC

2:00 – 3:00	8. Medical Related Events Dr. Howe will provide the latest update on medical-related events.	DB. Howe, NRC
3:00 – 3:30	BREAK	
3:30 – 4:15	9. Radioactive Seed Localization Mr. Sheetz and Dr. Langhorst will lead discussions on proposed changes to the existing 35.1000 licensing guidance for radioactive seed localization.	M. Sheetz, Univ. of Pittsburgh S. Langhorst, ACMUI
4:15 – 5:00	10. Ge/Ga-68 Subcommittee Report Mr. Mattmuller will discuss the subcommittee's recommendations regarding the decommissioning funding plan for Ge/Ga-68 generators.	S. Mattmuller, ACMUI

Friday, March 20, 2015
OPEN SESSION

8:30 – 9:00	11. Yttrium-90 Microspheres and Radionuclides in Cadavers Dr. Zanzonico will discuss the handling and disposal of yttrium-90 microspheres and other radionuclides found in cadavers.	P. Zanzonico, ACMUI
9:00 – 9:45	12. Compatibility Category for Permanent Brachytherapy Reportable Medical Events Mr. Costello will discuss the compatibility category for permanent brachytherapy medical events from an Agreement State perspective.	F. Costello, ACMUI
9:45 – 10:15	13. Status of the Abnormal Occurrence Criteria Dr. Tapp will provide a status update on the proposed changes to the Abnormal Occurrence Criteria.	K. Tapp, NRC
10:15 – 10:30	BREAK	
10:30 – 11:00	14. Perfexion Gamma Knife and AU Physical Presence A representative from Elekta will provide an overview of the Perfexion Gamma Knife and discuss the need for AU physical presence.	Elekta
11:00 – 11:15	15. 10 CFR Part 35 Rulemaking Update Mr. Danna will provide an update on the status of rulemaking for 10 CFR Part 35.	J. Danna, NRC
11:15- 11:30	16. Committee Reporting Structure Members will discuss the reporting structure of the	S. Holiday, NRC

Committee and provide feedback to NRC staff.

11:30 – 12:00

17. Open Forum

The ACMUI will discuss any medical topics of interest.

ACMUI

12:00 – 12:15

18. Administrative Closing

Ms. Holiday will provide a meeting summary and propose dates for the Fall 2015 meeting.

S. Holiday, NRC

12:15

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