

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

March 17-18, 2016

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 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 NRC staff will provide data to the ACMUI for medical events reported over a five-year span for trending purposes.

Dr. Alderson, ACMUI Chairman, formed a subcommittee to: 1) explore the impact of medical event (ME) reporting and its impact on self-reporting (safety culture); 2) identify potential ways to improve the effectiveness of self-reporting in support of a culture of safety; and 3) suggest ways to share ME reports and lessons learned with the medical community to promote safety. This subcommittee will present its recommendation(s) at the fall 2016 meeting. Subcommittee members include: Mr. Costello, Dr. Dilsizian, Dr. Ennis, Dr. Langhorst (Chair), and Ms. Weil. Mr. Ouhib will serve as a consultant to the subcommittee pending security clearance. The NRC staff resource is Dr. Katie Tapp.

The NRC staff will provide the ACMUI with the draft final 10 CFR 35.1000 licensing guidance for the Leksell Gamma Knife Perfexion and Leksell Gamma Knife Icon. Interested members will be encouraged to provide comments to the Working Group.

Dr. Langhorst requested that NRC staff provide the ACMUI with the total number of medical use licensees within the United States, for both NRC and Agreement States.

The Committee will contact their respective professional organizations to request and encourage interactions between the NRC and the ACMUI at their organizational meetings.

The Committee planned to hold the fall 2016 ACMUI Meeting on October 6-7, 2016 at NRC Headquarters. The back-up meeting date is September 1-2, 2016.

Attachments:

- Attachment 1: Attendees
- Attachment 2: Meeting Agenda

MLXXXXXXXXXXXXXX

OFC	MSTR/MSEB	MSTR/MSEB	MSTR/MSEB
NAME	S. Holiday	M. Fuller	D. Bollock
DATE	04/25/2016	04/26/2016	04/27/2016

MEETING ATTENDEES

ACMUI

Philip O. Alderson, M.D.	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
Darlene F. Metter, M.D.	Member
Michael D. O'Hara, Ph.D.	Member
Christopher J. Palestro, M.D.	Member
John H. Suh, M.D.	Member
Laura M. Weil	Member
Pat B. Zanzonico, Ph.D	Vice Chairman
<i>Zoubir Ouhib</i>	<i>Non-Voting Member</i>
<i>Richard Green</i>	<i>Member-elect</i>

NRC

Scott Moore	Acting Director, Office of Nuclear Material Safety and Safeguards (NMSS)
Daniel Collins	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
Said Daibes, Ph.D.	NMSS
Anthony Delamotte	Nuclear Safety Authority (ASN) assignee working for NMSS
Michael Fuller	NMSS
Esther Houseman	OGC
Donna-Beth Howe, Ph.D.	NMSS
Angela McIntosh	NMSS
Anthony McMurtray	NMSS
Gretchen Rivera-Capella	NMSS
Katie Tapp, Ph.D.	NMSS
Torre Taylor	NMSS

MEMBERS OF THE PUBLIC

Debbie Bensen	Elekta, Inc.
Bette Blankenship	American Association of Physicists in Medicine (AAPM)
Sue Bunning	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Robert Danseareau	New York State Department of Health
William Davidson	University of Pennsylvania
Lynne Fairobent	American Association of Physicists in Medicine (AAPM)
Sandra Gabriel	International Atomic Energy Agency
Catherine Gilmore-Lawless	Elekta, Inc.
Caitlin Kubler	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Richard Martin	American Association of Physicists in Medicine (AAPM)
Carl Mellerby	Nordea

Attachment 1

Eric Perry
Michael Peters
Craig Piercy
Karen Sheehan
Michael Sheetz
Robert Thomas
Cindy Tomlinson

Kentucky Department for Public Health
American College of Radiology (ACR)
Elekta, Inc.
Fox Chase Cancer Center
University of Pittsburgh
Elekta, Inc.
American Society for Radiation Oncology (ASTRO)

MEETING AGENDA ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

March 17-18, 2016

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 17, 2016		
CLOSED SESSION		
7:30 – 9:30	1. Badging and Enrollment	ACMUI
OPEN SESSION		
9:30 – 11:30	2. Commission Briefing The ACMUI will participate in a public meeting with the Commission.	ACMUI
	3. Group Photo The ACMUI will take a group photo with the Commission.	ACMUI
	LUNCH	
11:30 – 1:00		
1:00 – 2:30	4. Opening Remarks Mr. Bollock will formally open the meeting and Mr. Collins will provide opening comments.	D. Bollock, NRC D. Collins, NRC
	5. Old Business Ms. Holiday will review past ACMUI recommendations and provide NRC responses.	S. Holiday, NRC
	6. Open Forum The ACMUI will identify medical topics of interest for further discussion.	ACMUI
	7. Medical Related Events Dr. Howe will provide the latest update on medical-related events.	DB. Howe, NRC
2:30 – 3:00	BREAK	
3:00 – 5:00	8. Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy Dr. Suh will discuss the subcommittee's comments on the reporting of medical events.	J. Suh, ACMUI
	9. NUREG-1556, Volume 9 Update Dr. Tapp will provide an update on the proposed revisions to NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses."	K. Tapp, NRC
	10. Committee Reporting Structure Members will discuss the reporting structure of the Committee and provide feedback to NRC staff.	S. Holiday, NRC
	11. Status Update for Yttrium-90 Microspheres Brachytherapy Licensing Guidance Dr. Tapp will provide an update on the proposed revisions to the Y-90 licensing guidance.	K. Tapp, NRC

Friday, March 18, 2016

CLOSED SESSION

7:30 – 8:30

12. Enrollment of HSPD-12 Badges**ACMUI****OPEN SESSION**

8:00 – 10:30

13. Staff Response to OIG Audit of NRC's Oversight of Medical Uses of Nuclear Material**D. Bollock, NRC**

Mr. Bollock will discuss staff actions in response to the OIG Audit Report issued on October 08, 2015.

14. Leksell Gamma Knife Icon Licensing Guidance**S. Holiday, NRC****E. Perry, KY**

Ms. Holiday and Mr. Perry will provide an overview of the 10 CFR 35.1000 licensing guidance drafted by an NRC/OAS working group.

15. Germanium-68/Gallium-68 Medical Use Generator Update**S. Daibes, NRC**

Dr. Daibes will provide an update on staff's efforts to address the decommissioning funding issues related to the germanium/gallium-68 medical use generator

16. Special Presentation to Mr. Mattmuller**S. Moore, NRC**

Mr. Moore will make a special presentation to Mr. Mattmuller.

17. Thoughts on Leaving the ACMUI**S. Mattmuller, ACMUI**

Mr. Mattmuller will provide his farewell remarks to the Committee and to staff.

10:30 – 10:45

BREAK

10:45 – 11:30

18. Open Forum**ACMUI**

The ACMUI will discuss medical topics of interest previously identified.

19. Administrative Closing**S. Holiday, NRC**

Ms. Holiday will provide a meeting summary and propose dates for the spring 2016 meeting.

11:30

ADJOURN**CLOSED SESSION**

12:00 – 1:00

20. Training on NRC Rules, Guidance and Generic Communications Development**E. Houseman, NRC**

Ms. Houseman will provide training to the members related to each of these processes.