

MEETING OF THE  
ADVISORY COMMITTEE ON THE  
MEDICAL USES OF ISOTOPES

April 26-27, 2017

**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, 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 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 (Enclosure 2).

The Committee requested that the recommendations and actions pertaining to the Part 35 rulemaking be reviewed during the fall 2017 ACMUI meeting and that additional time be provided to review each item.

Dr. Alderson formed a subcommittee to review the recommendations from Elekta to consider amending the licensing guidance physical presence requirements for the Elekta Gamma Knife® Icon. Subcommittee membership includes Dr. Suh (Chair), Dr. Ennis, and Ms. Laura Weil.

Dr. Alderson requested an update, from NRC staff, on source security initiatives involving Category 3 sources at the fall 2017 ACMUI meeting.

Dr. Alderson formed a subcommittee to review the SECY Paper on Patient Release. The subcommittee will be comprised of Dr. Zanzonico (Chair), Dr. Langhorst, Dr. Palestro, and Ms. Weil. NRC staff point of contact: Dr. Donna-Beth Howe.

Dr. Alderson formed a subcommittee to review the nursing mother guidelines. The subcommittee charge is to review the radiation exposure from diagnostic and therapeutic radiopharmaceuticals including brachytherapy to the nursing mother and child. The subcommittee will be comprised of Dr. Metter (Chair), Dr. Dilsizian, Dr. Palestro, and Dr. Zanzonico.

The Committee endorsed the Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy Subcommittee Report.

The Committee endorsed the Training and Experience for all Modalities Subcommittee Status Report.

The Patient Intervention Subcommittee will amend its Subcommittee Report and will report at the ACMUI fall 2017 meeting or by teleconference to discuss their amended report.

The Committee recommended to (1) amend the title of Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture report from draft report to interim report, (2) to continue future discussions on this topic, and (3) to endorse the interim report.

The Committee tentatively scheduled the fall 2017 ACMUI meeting for September 11-12, 2017. The back-up dates are October 18-19, 2017.

The NRC staff will provide the Committee with information related to the escalated enforcement actions to medical licensees over a 5-year span.

Enclosures:

1. Attendees
2. Meeting Agenda

The Committee endorsed the Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy Subcommittee Report.

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**ML17131A256**

<b>OFFICE</b>	MSTR/MSEB	MSTR/MSEB
<b>NAME</b>	M. Smethers	D. Bollock
<b>DATE</b>	5/5/2017	5/11/2017

**OFFICIAL RECORD COPY**

## MEETING ATTENDEES

### ACMUI

Philip O. Alderson, M.D.	Chairman
Vasken Dilsizian, M.D.	Member
Ronald D. Ennis, M.D.	Member
Susan M. Langhorst, Ph.D.	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>Non-Voting Member</i>

### NRC

Daniel Collins	Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs (MSTR)
Joseph Nick	Acting 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
Michelle Smethers	Alternate Designated Federal Officer and ACMUI Coordinator
Said Daibes, Ph.D.	NMSS
Michael Fuller	NMSS
Vincent Holahan, Ph.D.	NMSS
Sophie Holiday	NMSS
Esther Houseman	OGC
Donna-Beth Howe, Ph.D.	NMSS
Manuel Jimenez	NRR
Angela McIntosh	NMSS
Minh-Thuy Nguyen	RES
Gretchen Rivera-Capella	NMSS
Katie Tapp, Ph.D.	NMSS
Torre Taylor	NMSS
John Thorp	OIG
Irene Wu	NMSS

## MEMBERS OF THE PUBLIC

Bette Blankenship	American Association of Physicists in Medicine (AAPM)
Alex Flirt	Affiliation unknown
Catherine Gilmore-Lawless	Elekta
Desiree Kennedy	Elekta
Caitlin Kubler	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Susan Lohman	Elekta
Richard Martin	American Association of Physicists in Medicine (AAPM)
Avi Oler	Spectrum Pharmaceuticals
Eric Perry	Kentucky Department for Public Health
Michael Peters	American College of Radiology (ACR)
Josephine Piccone	Independent
Craig Piercy	American Nuclear Society (ANS)
Gloria Romanelli	American College of Radiology (ACR)
Michael Stewart	Walter Reed National Military Medical Center
Robert Thomas	Elekta
Cindy Tomlinson	American Society for Radiation Oncology (ASTRO)

# MEETING AGENDA ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

**April 26-27, 2017**  
**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.

<b>Wednesday, April 26, 2017</b>		
<b>CLOSED SESSION</b>		
7:30 – 8:00	• <b>Badging and Enrollment</b>	<b>ACMUI</b>
<b>OPEN SESSION</b>		
8:00 – 10:15	<ul style="list-style-type: none"> <li>• <b>Opening Remarks</b> Mr. Bollock will formally open the meeting and Mr. Collins will provide opening comments.</li> </ul>	<b>D. Bollock, NRC</b> <b>D. Collins, NRC</b>
	<ul style="list-style-type: none"> <li>• <b>Old Business</b> Ms. Smethers will review past ACMUI recommendations and provide NRC responses.</li> </ul>	<b>M. Smethers, NRC</b>
	<ul style="list-style-type: none"> <li>• <b>Open Forum</b> The ACMUI will identify medical topics of interest for further discussion.</li> </ul>	<b>ACMUI</b>
	<ul style="list-style-type: none"> <li>• <b>Physical Presence Requirements</b> Representatives from Elekta will discuss the physical presence requirements for the Leksell Gamma Knife® Icon™.</li> </ul>	<b>S. Lohman, Elekta</b>
10:15 – 10:30	<ul style="list-style-type: none"> <li>• <b>Status Update on Source Security and Accountability Initiatives</b> Ms. Wu will provide an overview of source security initiatives and provide a status update on the evaluation of Category 3 source security and accountability.</li> </ul>	<b>I. Wu, NRC</b>
	<b>BREAK</b>	
10:30 – 11:45	<ul style="list-style-type: none"> <li>• <b>Medical Related Events</b> Dr. Howe and Dr. Langhorst will provide an update on recent medical events and events at medical institutions.</li> </ul>	<b>DB. Howe, NRC &amp; S. Langhorst, ACMUI</b>
<b>LUNCH</b>		
1:00 – 2:30	<ul style="list-style-type: none"> <li>• <b>Training and Experience for All Modalities</b> Dr. Palestro will discuss the subcommittee’s comments on the training and experience requirements for authorized individuals in 10 CFR Part 35.</li> </ul>	<b>C. Palestro, ACMUI</b>
	<ul style="list-style-type: none"> <li>• <b>Patient Release Project Update</b> Dr. Howe will provide an update on the patient release project.</li> </ul>	<b>DB. Howe, NRC</b>

2:30 – 3:00	<b>BREAK</b> (Public portion ends)	
3:00 – 5:00	• <b>ACMUI Working Preparatory Session</b>	<b>ACMUI</b>
<b>Thursday, April 27, 2017 OPEN SESSION</b>		
8:00 – 9:30	• <b>Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy</b> Dr. Suh will discuss the subcommittee’s final recommendations for the reporting of medical events.	<b>J. Suh, ACMUI</b>
	• <b>Patient Intervention Subcommittee Report</b> Dr. Dilsizian will discuss the subcommittee’s recommendations on the definition of patient intervention.	<b>V. Dilsizian, ACMUI</b>
9:30 – 10:00	<b>BREAK</b>	
10:00 – 12:00	• <b>Commission Briefing</b> The ACMUI will participate in a public meeting with the Commission.	<b>ACMUI</b>
	• <b>Group Photo</b> The ACMUI will take a group photo with and without the Commission.	<b>ACMUI</b>
12:00 – 1:00	<b>LUNCH</b>	
1:00 – 2:30	• <b>10 CFR Part 35 Rulemaking Status</b> Ms. Taylor will provide an update on the 10 CFR Part 35 rulemaking effort.	<b>T. Taylor, NRC</b>
	• <b>Medical Event Reporting and Impact on Safety Culture</b> Dr. Langhorst will discuss the subcommittee’s report on Medical Event Reporting and Impact on Safety Culture.	<b>S. Langhorst, ACMUI</b>
	• <b>Annual Reporting Structure</b> Members will discuss the reporting structure of the Committee and provide feedback to NRC staff.	<b>M. Smethers, NRC</b>
2:30 – 3:00	<b>BREAK</b>	
3:00 – 3:45	• <b>Open Forum</b> The ACMUI will discuss medical topics of interest previously identified.	<b>ACMUI</b>
	• <b>Administrative Closing</b> Ms. Smethers will provide a meeting summary and propose dates for the fall 2017 meeting.	<b>M. Smethers, NRC</b>
3:45	<b>ADJOURN</b>	