

MEETING OF THE  
ADVISORY COMMITTEE ON THE  
MEDICAL USES OF ISOTOPES

September 11-12, 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 NRC staff will engage in discussions with the Organization of Agreement States (OAS) to find a way to centralize event reporting from the Agreement States.

The Committee endorsed the Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture Draft Report, as amended to support the concept of the pilot program with the total number of sites and duration to be determined at a later date and to include the Patient Intervention Subcommittee recommendations as an addendum. The recommendation passed unanimously with nine votes.

The Committee will hold a public teleconference in the near future to discuss the amended Nursing Mothers Guidelines Subcommittee Report. Amendments will include, but are not limited to: (1) a suggested time frame for providing written and oral instructions to patients who will stop breastfeeding altogether and (2) consideration to revise the radionuclides to be non-pharmaceutical specific.

The Committee endorsed the Patient Release SECY Paper Subcommittee Report. The recommendation passed unanimously with nine votes.

The Committee will hold a public teleconference in the near future to discuss the amended Physical Presence Requirements for the Leksell Gamma Knife Icon Subcommittee Report. Amendments will include (1) the distinction between "an" or "the" AU or AMP;" (2) AU presence for re-initiation of procedure following interruption; (3) possible incorporation of changes to the physical presence requirements for the Leksell Gamma Knife Perfexion; and (4) whether the physical presence requirements will be limited to the frame-based or frameless-based option for the Leksell Gamma Knife Icon.

The Committee tentatively scheduled the spring 2018 Meeting for March 1-2, 2018. The back-up meeting dates are March 14-15, 2018, subject to Commission availability.

Enclosures:

1. Attendees
2. Meeting Agenda

**SUBJECT:** SUMMARY OF THE SEPTEMBER 11-12, 2017 MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

**MLXXXXXXXXX**

<b>OFC</b>	MSTR/MSEB	MSTR/MSEB	MSTR/MSEB
<b>NAME</b>	SHoliday	LDimmick	DBollock
<b>DATE</b>	10/08/2017	10/10/2017	10/11/2017

**OFFICAL 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**

Marc Dapas	Director, Office of Nuclear Material Safety and Safeguards
Daniel Collins	Director, Division of Material Safety, State, Tribal and Rulemaking Programs (MSTR)
Kevin Williams	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
Lisa Dimmick	Medical Radiation Safety Team Leader and Alternate Designated Federal Officer
Sophie Holiday	Alternate Designated Federal Officer and ACMUI Coordinator
Maryann Ayoade	NMSS
Colleen Casey	RIII
Jackie Cook	RIV
Said Daibes, Ph.D.	NMSS
Ashley Ferguson	NRO
Sara Forster	RIII
Cassandra Frazier	RIII
Michelle Hammond	RIV
Latischa Hanson	RIV
Esther Houseman	OGC
Donna-Beth Howe, Ph.D.	NMSS
Kevin Null	RIII
Dennis O'Dowd	RIII
Bryan Parker	RIII
Patty Pelke	RIII
Gretchen Rivera-Capella	NMSS
Katie Tapp, Ph.D.	NMSS
Torre Taylor	NMSS
Frank Tran	RIII
Lester Tripp	RI
Irene Wu	NMSS

**MEMBERS OF THE PUBLIC**

Bette Blankenship	American Association of Physicists in Medicine (AAPM)
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Ashley Cockerham  
Wanda Costello  
Peter Crane  
Robert Dansereau  
Michael Fuller  
Paul Gunter  
Desiree Kennedy  
Caitlin Kubler

Richard Martin  
Michael Peters  
Josephine Piccone  
Craig Piercy  
Michael Sheetz  
Robert Thomas  
Cindy Tomlinson

SirTex Medical Technologies  
*Unaffiliated*  
*Unaffiliated*  
New York State Department of Health  
*Unaffiliated*  
Beyond Nuclear  
Elekta, Inc.  
Society of Nuclear Medicine and Molecular Imaging  
(SNMMI)  
American Association of Physicists in Medicine (AAPM)  
American College of Radiology (ACR)  
*Unaffiliated*  
American Nuclear Society (ANS)  
University of Pittsburgh  
Elekta, Inc.  
American Society for Radiation Oncology (ASTRO)

**MEETING AGENDA  
 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES  
 September 11-12, 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>Monday, September 11, 2017</b>		
<b>CLOSED SESSION</b>		
7:30 – 8:30	<b>1. Badging and Enrollment</b>	<b>ACMUI</b>
<b>OPEN SESSION</b>		
	<b>2. Opening Remarks</b> Mr. Bollock will formally open the meeting and Mr. Collins will provide opening comments.	<b>D. Bollock, NRC D. Collins, NRC</b>
	<b>3. Old Business</b> Ms. Holiday will review past ACMUI recommendations and provide NRC responses.	<b>S. Holiday, NRC</b>
8:30 – 10:00	<b>4. Open Forum</b> The ACMUI will identify medical topics of interest for further discussion.	<b>ACMUI</b>
	<b>5. Medical Events Subcommittee Report</b> Dr. Ennis will present the subcommittee’s analysis of medical events for fiscal year 2016.	<b>R. Ennis, ACMUI</b>
10:00 – 10:30	<b>BREAK</b>	
	<b>6. Medical Event Reporting and its Impacts on Safety Culture Subcommittee Report</b> Dr. Langhorst will discuss the subcommittee’s comments on how NRC’s medical event reporting criteria under 10 CFR 35.3045 impacts safety culture at medical institutions.	<b>S. Langhorst, ACMUI</b>
10:30 – 11:45	<b>7. Patient Intervention Subcommittee Report</b> Dr. Dilsizian will discuss the subcommittee’s recommendation for the definition of patient intervention.	<b>V. Dilsizian, ACMUI</b>
11:45 – 1:00	<b>LUNCH</b>	
	<b>8. Nursing Mother Guidelines Subcommittee Report</b> Dr. Metter will discuss the subcommittee’s comments on the nursing mother guidelines for exposure from diagnostic and therapeutic radiopharmaceuticals.	<b>D. Metter, ACMUI</b>
1:00 – 3:00	<b>9. Patient Release Project Update</b> Dr. Howe will provide an update on the patient release project.	<b>DB. Howe, NRC</b>
	<b>10. ACMUI Comments on Patient Release Commission Paper</b> Dr. Zanzonico will discuss the subcommittee’s comments on the Patient Release Commission Paper.	<b>P. Zanzonico, ACMUI</b>
3:00 – 3:30	<b>BREAK</b>	

**CLOSED SESSION**

3:30 – 5:00	<b>11. Ethics Training</b> <b>12. INFOSEC Training</b> <b>13. Allegations Training</b>	<b>M. Clark, NRC</b> <b>R. Norman, NRC</b> <b>S. Hawkins, NRC</b>
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**Tuesday, September 12, 2017**

**OPEN SESSION**

8:30 – 10:00	<b>14. NRC Online Resources</b> Ms. Holiday will provide an overview of the resources available on the NRC Website and Medical Toolkit.	<b>S. Holiday, NRC</b>
8:30 – 10:00	<b>15. Status Update on Source Security and Accountability Initiatives</b> Ms. Wu will provide an overview of source security initiatives and a status update on the evaluation of Category 3 source security and accountability.	<b>I. Wu, NRC</b>  <b>J. Suh, ACMUI</b>
10:00 – 10:30	<b>16. Physical Presence Requirements for the Leksell Gamma Knife® Icon™ Subcommittee Report</b> Dr. Suh will discuss the subcommittee’s recommendations on the physical presence requirements for the Leksell Gamma Knife® Icon™.	<b>J. Suh, ACMUI</b>
10:00 – 10:30	<b>BREAK</b>	<b>K. Tapp, NRC</b>
10:30 – 11:30	<b>17. Yttrium-90 Microspheres Brachytherapy Licensing Guidance</b> Dr. Tapp will provide an update on the Y-90 Microspheres Brachytherapy Licensing Guidance.	<b>K. Tapp, NRC</b>
10:30 – 11:30	<b>18. Enhancing Communications with the Medical Community</b> Dr. Alderson, Dr. Metter and Dr. Palestro will provide an update on ACMUI’s efforts to improve communications with various medical professional societies.	<b>P. Alderson, ACMUI</b> <b>D. Metter, ACMUI</b> <b>C. Palestro, ACMUI</b>
11:30 – 1:00	<b>LUNCH</b>	
1:00 – 2:00	<b>19. Special Presentation for Mr. Francis (Frank) Costello</b> NRC Staff and Dr. Alderson will make a special presentation in memory of Mr. Costello, former Agreement State Representative on the ACMUI.	<b>NRC</b> <b>P. Alderson, ACMUI</b>
1:00 – 2:00	<b>20. Special Presentation to Dr. Susan (Sue) Langhorst</b> Mr. Dapas will make a special presentation to Dr. Langhorst.	<b>M. Dapas, NRC</b>
2:00 – 2:30	<b>21. Thoughts on Leaving the ACMUI</b> Dr. Langhorst will share her thoughts on leaving the ACMUI.	<b>S. Langhorst, ACMUI</b>
2:00 – 2:30	<b>BREAK</b>	
2:30 – 3:15	<b>22. Open Forum</b> The ACMUI will discuss medical topics of interest previously identified.	<b>ACMUI</b>
2:30 – 3:15	<b>23. Administrative Closing</b> Ms. Holiday will provide a meeting summary and propose dates for the spring 2018 meeting.	<b>S. Holiday, NRC</b>
3:15	<b>ADJOURN</b>	