

MEETING OF THE  
ADVISORY COMMITTEE ON THE  
MEDICAL USES OF ISOTOPES

September 9-10, 2013

**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/>

**ATTENDEES**

**ACMUI**

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
William A. Van Decker, M.D.	Member
Laura M. Weil	Member
James S. Welsh, M.D.	Member
Pat B. Zanzonico, Ph.D	Member

**NRC**

Laura Dudes	Acting Deputy Director, Office of Federal and State Materials and Environmental Management Programs (FSME)
Brian McDermott	Director, Division of Materials Safety and State Agreements (DMSSA)
Pamela Henderson	Deputy Director, Division of Materials Safety and State Agreements (DMSSA)
Christian Einberg	Chief, Radioactive Materials Safety Branch (RMSB)

Michael Fuller	Medical Radiation Safety Team Leader and Alternate Designated Federal Officer
Sophie Holiday	ACMUI Coordinator
Ashley Cockerham	Alternate Designated Federal Officer
Bernice Ammon	Office of General Counsel (OGC)
Neelam Bhalla	FSME
June Cai	FSME
Susan Chidakel	OGC
Michael Clark	OGC
Donald Cool, Ph.D.	FSME
Said Daibes, Ph.D.	FSME
Cindy Flannery	FSME
Sara Forster	Region III
Cassandra Frazier	Region III
Sandra Gabriel, Ph.D.	FSME
Joseph Gilman	OGC
Michelle Hammond	Region IV
Latischa Hanson	Region IV
Vincent Holahan	FSME
Donna-Beth Howe, Ph.D.	FSME
Ed Lohr	FSME
Angela McIntosh	FSME
Tamara Powell	FSME
Gretchen Rivera-Capella	FSME
Bern Stapleton	FSME
Jeremy Suttenger	OGC
Shirley Xu	FSME
Ronald Zelac, Ph.D.	FSME

## **MEMBERS OF THE PUBLIC**

Sue Bunning – Society of Nuclear Medicine and Molecular Imaging (SNMMI)	Michael Peters – American College of Radiology (ACR)
Robert Dansereau – NY State Dept of Health	Joe Rodgers – Theragenics
William Davidson – University of Pennsylvania	Jesse Schoolnik – Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Lynne Fairbrent – American Association of Physicists in Medicine (AAPM)	Megan Shoer – Wisconsin Radiation Protection Section
Debbie Gilley – American Association of Physicists in Medicine (AAPM)	Michael Stephens – FL Bureau of Radiation Control
Karen Langley – University of Utah	Cindy Tomlinson – American Society for Radiation Oncology (ASTRO)
Ralph Lieto – St. Joseph Mercy Hospital	Gary E. Williams – Veterans Health Administration
Andrew McKinley – American Society of Nuclear Cardiology (ASNC)	

## **AGENDA TOPICS**

### **CLOSED SESSION**

1. Amendments to the ACMUI Bylaws
2. Ethics Training
3. Information Security Training

#### 4. Allegations Training

#### OPEN SESSION

5. Opening Statements
6. Old Business
7. What is the ACMUI?
8. Group Photo
9. 10 CFR Part 35 Rulemaking Update
10. NRC and Safety Culture
11. Interim Enforcement Policy for Permanent Implant Brachytherapy Programs
12. Enforcement Guidance Memorandum for Rb-82 Generators
13. Medical Events Subcommittee Report

#### CLOSED SESSION

14. Commission Briefing Preparation

#### OPEN SESSION

15. ACMUI Reporting Structure
16. ViewRay™ System Licensing Guidance
17. Iodine-123 mIBG Imaging: New Frontiers in Nuclear Cardiology With Cardiac Sympathetic Innervation Imaging
18. Regulatory Aspects of Germanium-68/Gallium-68 Generators
19. Status Update of 10 CFR Part 20
20. Status of Revisions to NUREG-1556, Volume 9
21. Special Presentation to Dr. Van Decker
22. Administrative Closing

#### **RECOMMENDATIONS AND ACTIONS**

For agenda topic 1, Amendments to the ACMUI Bylaws, Dr. Thomadsen created a subcommittee to review the proposed amendments to the ACMUI Bylaws. The recommendations will be presented during the spring 2014 meeting. Subcommittee members include: Mr. Steve Mattmuller, Dr. Christopher Palestro, Dr. John Suh, Dr. Orhan Suleiman, Ms. Laura Weil, and Dr. Pat Zanzonico (chair).

For agenda topics 6, Old Business, Dr. Thomadsen added Dr. Christopher Palestro to the Medical Events Subcommittee. Dr. Palestro will review the I-131 medical events.

For agenda topic 14, Commission Briefing Preparation, the ACMUI recommended reestablishing the Rulemaking Subcommittee to review and address staff's response to the subcommittee's recommendations for the draft proposed expanded 10 CFR Part 35 Rulemaking.

For agenda topic 15, ACMUI Reporting Structure, Dr. Thomadsen tasked the ACMUI Bylaws Subcommittee with the following additional tasks: 1) Discuss, address, and making a recommendation for the ACMUI reporting structure (MSSA director versus the Commission); 2) Discuss, address, and make a recommendation for the consideration of budgeting for an additional face-to-face meeting at Headquarters and; 3) Consider the feasibility of conducting meetings using the Go-To-Meeting or Go-To-Webinar function.

Also for agenda topic 15, ACMUI Reporting Structure, Dr. Thomadsen requested that staff provide the full Committee with the SECY Paper that was transmitted to the Commission in 2011 regarding the reporting structure of the ACMUI.

For agenda topic 16, ViewRay™ System Licensing Guidance, the ACMUI recommended to add the physical presence requirements for Authorized Users for the Gamma Knife® Perfexion™ to the spring 2014 agenda. The recommendation passed unanimously with ten favorable votes.

For agenda topic 22, Administrative Closing, the ACMUI planned to hold the spring 2014 ACMUI Meeting on May 8-9, 2014 at NRC Headquarters. The back-up meeting date is May 12-13, 2014.