

MEETING OF THE  
ADVISORY COMMITTEE ON THE  
MEDICAL USES OF ISOTOPES

October 20-21, 2010

**MEETING SUMMARY**

**PURPOSE**

To discuss issues related to the implementation of the medical regulations in 10 Code of Federal Regulations (CFR) Part 35, "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 of the ACMUI meeting can be found on NRC's public website:  
<http://www.nrc.gov/reading-rm/doc-collections/acmui/tr/>

Handouts from the ACMUI meeting can be found on NRC's public website:  
<http://webwork.nrc.gov:300/reading-rm/doc-collections/acmui/meeting-slides/>

**ATTENDEES**

**ACMUI**

Darrell Fisher, Ph.D.	Member
Debbie B. Gilley	Member
Milton S. Guiberteau, M.D.	Representative
Susan M. Langhorst, Ph.D.	Member
Steve R. Mattmuller	Member
Christopher J. Palestro, M.D.	Member
John H. Suh, M.D.	Member
Orhan H. Suleiman, Ph.D.	Member
Bruce R. Thomadsen Ph.D.	Vice Chairman, acting Chair
William A. Van Decker, M.D.	Member
James S. Welsh, M.D.	Member
Pat Zanzonico, Ph.D	Member

**NRC**

Robert Lewis	Director, Division of Materials Safety and State Agreements
Christian Einberg	Branch Chief, Radioactive Materials Safety Branch, Designated Federal Officer

Michael Fuller	Team Leader, Medical Radiation Safety Team, Alternate Designated Federal Officer
Ashley Cockerham	ACMUI Coordinator
Kimyata Morgan Butler, Ph.D.	NRC staff
Mark Banks	NRC staff
Neelam Bhalla	NRC staff
Marc Ferdas	NRC staff
James Firth	NRC staff
Patricia Holahan, Ph.D.	NRC staff
Vincent Holahan, Ph.D.	NRC staff
Sophie Holiday	NRC staff
Donna-Beth Howe, Ph.D.	NRC staff
John Jankovich, Ph.D.	NRC staff
Andrea Kock	NRC staff
Varughese Kurian	NRC staff
Jose Ibarra	NRC staff
Robert Norman	NRC staff
Kevin O'Sullivan	NRC staff
Patricia Pelke	NRC staff
Michael Rodriguez	NRC staff
Maria Schwartz	NRC staff
John Szabo	NRC staff
Catherine Thompson, Ph.D.	NRC staff
Ron Zelac, Ph.D.	NRC staff

**MEMBERS OF THE PUBLIC:**

Dave Adler	American Society for Therapeutic Radiology and Oncology
Curtis M. Anderson	MELE Associates
Peter Crane	No Known Affiliation
James A. Deye	National Institutes of Health
Jennifer Elee	Conference of Radiation Control Program Directors, Inc.
Michael Hagan, M.D.	Dept. of Veterans Affairs National Director of Radiation Oncology Services
Jessica Lloyd	Society of Nuclear Medicine
Michael Peters	American College of Radiology
Gloria Romanelli	American College of Radiology
Eric Soltycki	Albert Einstein Healthcare Network
Bhadrasain Vikram	National Institutes of Health
David Walter	Organization of Agreement States
Ann Warbick-Cerone	MDS Nordion
Jenna M. Wilkes	American Society of Nuclear Cardiology
Gary E. Williams	Veterans Affairs National Health Physics Program

## **AGENDA TOPICS**

### CLOSED SESSION

1. Commission Briefing Preparation

### OPEN SESSION

2. Commission Briefing
3. Group Photo
4. Opening Statements
5. Old Business
6. Conference of Radiation Control Program Directors (CRCPD) H-38 Committee on Radiation Medical Events
7. 10 CFR Part 35 Medical Event Reporting Rule & Implementation Plan
8. Update on Permanent Prostate Brachytherapy Medical Events at the Department of Veterans Affairs Medical Center Philadelphia
9. Permanent Implant Brachytherapy Subcommittee Report
10. Patients' Rights Advocate Responsibilities
11. Emerging Technology – Novel Means of Medical Isotope Production

### CLOSED SESSION

12. Allegation Training
13. Information Security (INFOSEC) Awareness Training
14. Ethics Training
15. Escort Training
16. ACMUI Badges
17. Policy & Procedure – ACMUI Interactions with Staff for Major Medical Policy

### OPEN SESSION

18. 10 CFR Part 37 Rulemaking & Guidance
19. Overview of the NRC's Initiatives on the Use of Cesium-137 Chloride Radiation Sources
20. Patient Release Subcommittee Report
21. Medical Related Events
22. Further Considerations on Options to Revise Radiation Protection Regulations & Guidance
23. Safety Culture Policy Statement
24. Administrative Closing

## **RECOMMENDATIONS AND ACTIONS**

For agenda topic 9, Permanent Implant Brachytherapy Subcommittee Report, the ACMUI endorsed the subcommittee report with the caveat that this is an interim report that may be revised in the future to consider additional input such as that received from stakeholders at public workshops. The recommendation passed unanimously with ten favorable votes.

For agenda topic 17, Policy & Procedure – ACMUI Interactions with Staff for Major Medical Policy, the ACMUI endorsed the draft version of FSME Policy and Procedures 2-5, Revision 0 presented at the meeting. The recommendation passed unanimously with ten favorable votes.

For agenda topic 18, 10 CFR Part 37 Rulemaking & Guidance, Dr. Thomadsen created a subcommittee to prepare a document to guide the December discussion on 10 CFR Part 37. Subcommittee members include: Ms. Debbie Gilley (chair), Dr. Susan Langhorst, and Dr. Darrell Fisher.

Also for agenda topic 18, 10 CFR Part 37 Rulemaking & Guidance, the ACMUI planned a teleconference to discuss 10 CFR Part 37 rulemaking and safety culture on Monday, December 13, 2010, from 1:00pm to 3:00pm Eastern Time. The backup time and date is scheduled for Wednesday, December 15, 2010, from 11:00am to 1:00pm Eastern Time.

For agenda topic 20, Patient Release Subcommittee Report, the subcommittee will incorporate the comments made during the meeting to revise the draft subcommittee report and will resubmit the report to the full ACMUI for an e-mail vote. The ACMUI will submit a final subcommittee report to the NRC in the near future.

Also for agenda topic 20, Patient Release Subcommittee Report, Mr. Steve Mattmuller, Dr. Bruce Thomadsen, and Dr. Susan Langhorst offered to provide support to respond to the letter dated October 20, 2010, to Chairman Jaczko from Congressman Markey regarding patient release.