

MEETING OF THE  
ADVISORY COMMITTEE ON THE  
MEDICAL USES OF ISOTOPES

April 11-12, 2011

**MEETING SUMMARY**

**PURPOSE**

To discuss current rulemaking activities 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://www.nrc.gov/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
Leon S. Malmud, M.D.	Chairman
Steve R. Mattmuller	Member
John H. Suh, M.D.	Member
Orhan H. Suleiman, Ph.D.	Member
Bruce R. Thomadsen Ph.D.	Vice Chairman
William A. Van Decker, M.D.	Member
James S. Welsh, M.D.	Member
Pat Zanzonico, Ph.D	Member

**NRC**

Jim Luehman	Deputy Director, Division of Materials Safety and State Agreements
June Cai	Branch Chief, Radioactive Materials Safety Branch
Michael Fuller	Alternate Designated Federal Officer

Sophie Holiday	Alternate ACMUI Coordinator
Neelam Bhalla	NRC staff
Susan Chidakel	NRC staff
Susan E. Cooper, Ph.D.	NRC staff
Said Daibes, Ph.D.	NRC staff
Sarenee Hawkins	NRC staff
Donna-Beth Howe, Ph.D.	NRC staff
Deborah Jackson	NRC staff
Andrea Kock	NRC staff
Varughese Kurian	NRC staff
Ed Lohr	NRC staff
Julie Marble, Ph.D.	NRC staff
Kevin O'Sullivan	NRC staff
Patricia Pelke	NRC staff
Josephine Piccone, Ph.D.	NRC staff
Gretchen Rivera-Capella	NRC staff
Susan Salter	NRC staff
Glenda Villamar	NRC staff
Shirley Xu	NRC staff

**MEMBERS OF THE PUBLIC:**

Keith Brown	University of Pennsylvania
William Davidson	University of Pennsylvania
Lynne Fairobent	American Association of Physicists in Medicine
Karen Langley	University of Utah
Ralph Lieto	St. Joseph Mercy Hospital
Candi McDowell	Georgetown University
Janette Merrill	Society of Nuclear Medicine
Herbert Mower, Ph.D.	American Association of Physicists in Medicine
Michael Peters	American College of Radiology
Amanda Potter	American Association of Physicists in Medicine
Joe Rodgers	Theragenics
Gloria Romanelli	American College of Radiology
Conor Schmertz	George Washington University
Danny Song, M.D.	American Society for Radiation Oncology
Cindy Tomlinson	American Society for Radiation Oncology
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. ACMUI Badges and Self-Evaluations

### OPEN SESSION

2. Opening Statements
3. Old Business
4. Medical Events Subcommittee Report
5. Purpose of Rulemaking Meeting
6. Overview of Part 35 Expanded Rulemaking
7. Permanent Implant Brachytherapy Rulemaking
8. Permanent Implant Brachytherapy Rulemaking
9. Permanent Implant Brachytherapy Rulemaking
10. Opening Remarks
11. Extending Grandfathering to Certain Certified Individuals Rulemaking
12. Preceptor Attestation Requirements Rulemaking
13. Public Dose Limits for Released Patients; Need for Rulemaking?
14. Public Dose Limits for Released Patients; Need for Rulemaking?
15. Administrative Closing

## **RECOMMENDATIONS AND ACTIONS**

For agenda topic 4, Medical Events Subcommittee Report, Dr. Malmud volunteered to serve as a reviewer to screen I-131 cases for the ACMUI Medical Events Subcommittee.

For agenda topic 6, Overview of Part 35 Expanded Rulemaking, the ACMUI recommends to reserve some time at the Fall ACMUI Meeting for public stakeholders to discuss topics that will be covered during the Part 35 Public Workshops. The recommendation did not pass with three favorable votes, one abstention, and seven opposing votes.

Also for agenda topic 6, Overview of Part 35 Expanded Rulemaking, the ACMUI recommends a minimum of 3 month for the NRC to provide notice for future Public Stakeholder Meetings in the medical area, in order to provide stakeholders with ample time for planning. The recommendation passed unanimously with eleven favorable votes.

Also for agenda topic 6, Overview of Part 35 Expanded Rulemaking, the ACMUI recommends NRC Staff hold the second Public Stakeholder Workshop in August in order to better accommodate public stakeholders, with the plan that the ACMUI Permanent Implant Brachytherapy Subcommittee Report will be finalized by the Fall ACMUI Meeting.

For agenda topic 7, Permanent Implant Brachytherapy Rulemaking, the ACMUI endorses ASTRO's approach to Permanent Implant Brachytherapy (handout) as the most appropriate approach for patient welfare. The ACMUI recommended that the NRC require Post-Implant dosimetry following brachytherapy treatment. The ACMUI also believes that prostate brachytherapy is a unique subset of brachytherapy and should therefore require a separate set of rules from non-prostate brachytherapy. The recommendation passed unanimously with eleven favorable votes.

For agenda topic 12, Preceptor Attestation Requirements Rulemaking, the ACMUI recommends to eliminate the written attestation for board certification pathway, regardless of date of certification. The recommendation passed unanimously with eleven favorable votes.

Also for agenda topic 12, Preceptor Attestation Requirements Rulemaking, the ACMUI recommends the attestation to be revised to say ... "has received the requisite training and experience in order to fulfill the radiation safety duties required by the licensee." The recommendation passed unanimously with eleven favorable votes.

Also for agenda topic 12, Preceptor Attestation Requirements Rulemaking, the ACMUI supports the statement that residency program directors can sign attestation letters, representing consensus of residency program faculties, if at least one member of the faculty is an authorized user (AU) in the same category as that designated by the applicant seeking authorized status, and that AU did not disagree with the approval. The recommendation passed unanimously with eleven favorable votes.

For agenda topic 13, Public Dose Limits for Released Patients; Need for Rulemaking?, the ACMUI continued to assert that the current regulations are based on a per release limit. ACMUI does not recommend any change to the regulation and does not recommend the NRC consider this topic during the current rulemaking process, as there is no clinical advantage or advantage to members of the public for using an annual limit. The recommendation passed unanimously with eleven favorable votes.

For agenda topic 15, Administrative Closing, the ACMUI has planned to hold the Fall 2011 ACMUI Meeting on September 22 - 23, 2011. The back-up date is October 27 - 28, 2011. The alternate back-up date is October 31 -November 1, 2011