

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

September 22-23, 2011

MEETING SUMMARY

PURPOSE

To discuss current rulemaking activities and other 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://www.nrc.gov/reading-rm/doc-collections/acmui/meeting-slides/>

ATTENDEES

ACMUI

Milton S. Guiberteau, M.D.	Member
Susan M. Langhorst, Ph.D.	Member
Leon S. Malmud, M.D.	Chairman
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
William A. Van Decker, M.D.	Member
Laura Weil	Member
James S. Welsh, M.D.	Member
Pat Zanzonico, Ph.D	Member

NRC

Jim Luehman	Acting Director, Division of Materials Safety and State Agreements
Chris Einberg	Designated Federal Officer

Michael Fuller	Alternate Designated Federal Officer
Ashley Cockerham	Alternate Designated Federal Officer and ACMUI Coordinator
Sophie Holiday	Alternate ACMUI Coordinator
Susan Abrahams	NRC staff
Neelam Bhalla	NRC staff
Susan Chidakel	NRC staff
Said Daibes, Ph.D.	NRC staff
Kerstun Day	NRC staff
Joseph E. DeCicco	NRC staff
Jonathan Evans	NRC staff
Donna-Beth Howe, Ph.D.	NRC staff
Deborah Jackson	NRC staff
Krista Juris	NRC staff
Varughese Kurian	NRC staff
Gary Langlie	NRC staff
Ed Lohr	NRC staff
Angela McIntosh	NRC staff
Kevin O'Sullivan	NRC staff
Patricia Pelke	NRC staff
Michael Radford	NRC staff
Gretchen Rivera-Capella	NRC staff
John Szabo	NRC staff
Duane White	NRC staff
Shirley Xu	NRC staff

MEMBERS OF THE PUBLIC:

Armin Ansari, Ph.D.	Centers for Disease Control and Prevention
Karen Bishop	Johns Hopkins Hospital
Art Chang	Centers for Disease Control and Prevention
Peter Crane	<i>Unknown Affiliation</i>
Andrea Cuzmanes	Johns Hopkins Hospital
William Davidson	University of Pennsylvania
Lynn Evans, Ph.D.	Centers for Disease Control and Prevention
Lynne Fairbent	American Association of Physicists in Medicine
Marc Garland, Ph.D.	Department of Energy
Michael Hagan, M.D.	Department of Veterans' Affairs
Traci Hoon	Johns Hopkins Hospital
Faiz Hussain	Johns Hopkins Hospital
Albert Hyacinth	Centers for Disease Control and Prevention
Frances Jensen, M.D.	CMS/HHS
Robert Jones, Ph.D.	Centers for Disease Control and Prevention
Ira Krefting, Ph.D.	Food and Drug Administration
Alex Lima	Johns Hopkins Hospital
Kathy Lising	Johns Hopkins Hospital
Mary McCormick, Ph.D.	Johns Hopkins Hospital
Janette Merrill	Society of Nuclear Medicine
George Mills, M.D.	Paraxel
Thalia Mills, Ph.D.	Food and Drug Administration
Adrian Nunn, Ph.D.	Bracco Research

Michael Peters	American College of Radiology
Dennis Phillips	Department of Energy
Satish Pillai, Ph.D.	Centers for Disease Control and Prevention
Michelle Podgonik	Centers for Disease Control and Prevention
Courtney Radcliffe	Johns Hopkins Hospital
Dwaine Rieves, Ph.D.	Food and Drug Administration
Gloria Romanelli	American College of Radiology
Wolfgang Runde, Ph.D.	Department of Energy
David Saunders	Centers for Disease Control and Prevention
Joseph Shonka, Ph.D.	Centers for Disease Control and Prevention
Laura Sierra	Alston & Bird
Cindy Tomlinson	American Society for Radiation Oncology
Ann Warbick-Cerone	MDS Nordion
Robert Whitcomb , Ph.D.	Centers for Disease Control and Prevention
Jenna M. Wilkes	American Society of Nuclear Cardiology
Gary E. Williams	Veterans Affairs National Health Physics Program
Lucie Yang, Ph.D.	Food and Drug Administration

AGENDA TOPICS

CLOSED SESSION

1. ACMUI Badges
2. Escort Training
3. Ethics Training
4. Allegation Training
5. Information Security (INFOSEC) Awareness Training
6. Security Briefing

OPEN SESSION

7. Opening Statements
8. Old Business
9. Methods of ACMUI and ACRS Reporting
10. Status of Commission Paper on Data Collection Regarding Patient Release
11. Electronic Signatures
12. Strontium/Rubidium Discussion – FDA Perspective
13. Strontium/Rubidium Discussion – NRC Perspective
14. ACMUI's 2008 Recommended Revision to the Medical Event Abnormal Occurrence Language
15. Medical Related Events
16. NRC Rulemaking Workshop
17. Permanent Implant Brachytherapy Subcommittee Discussion
18. Part 35 Rulemaking Update
19. Administrative Closing

RECOMMENDATIONS AND ACTIONS

For agenda topic 8, Old Business, Dr. James Welsh asked that NRC staff resend the NRC's response to Congressman Markey regarding patient release to the ACMUI.

For agenda topic 9, Methods of ACMUI and ACRS Reporting, Dr. Welsh asked NRC staff if ACRS members are considered Special Government Employees (SGE's). If so, given the number of committee and subcommittee meetings, how many days and hours do they work a year? Also for agenda topic 9, Mr. Steve Mattmuller asked that NRC staff add the ACMUI to the organizational chart on the Office of Federal and State Materials and Environmental Management Programs (FSME) public website. Lastly, Dr. Susan Langhorst requested that NRC staff 1) place historical documents on the ACMUI website that would give individuals a better understanding of the ACMUI organization and history and 2) that NRC staff add past ACMUI membership information on the ACMUI website.

For agenda topic 11, Electronic Signatures, Dr. Leon Malmud created a subcommittee to address electronic signatures for documents licensees are required to retain in accordance with 10 CFR Part 35. Subcommittee members include: Dr. Bruce Thomadsen (chair), Dr. John Suh, Dr. Christopher Palestro and Dr. James Welsh.

For agenda topic 14, ACMUI's 2008 Recommended Revision to the Medical Event Abnormal Occurrence (AO) Language, the ACMUI tabled the discussion on changes to the AO criteria. The recommendation passed unanimously with twelve favorable votes.

For agenda topic 17, Permanent Implant Brachytherapy Subcommittee Discussion, Dr. Leon Malmud added Dr. John Suh to the Permanent Implant Brachytherapy Subcommittee. Existing subcommittee members include: Dr. James Welsh (chair), Dr. Susan Langhorst, and Dr. Bruce Thomadsen. The Permanent Implant Brachytherapy Subcommittee agreed to revise the subcommittee report and distribute to the full committee for review by October 7, 2011. Furthermore, the ACMUI planned a teleconference for October 18, 2011, 12:00pm – 2:00pm EDT to discuss and finalize the Permanent Implant Brachytherapy Subcommittee Report. Lastly, Dr. William Van Decker recommended NRC staff invite Agreement States to participate in the October 18, 2011 teleconference call because the Agreement State Representative position on the ACMUI is vacant.

For agenda topic 19, Administrative Closing, the ACMUI planned the spring 2012 ACMUI Meeting on April 16-17, 2012, at NRC Headquarters.