

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

October 19-20, 2009

MEETING SUMMARY

PURPOSE

To discuss issues related to the implementation of the medical regulations in 10 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 in NRC's Agencywide Documents Access and Management System (ADAMS) using Accession Number ML092960075:
<http://www.nrc.gov/reading-rm/adams/web-based.html>

ATTENDEES

ACMUI

Leon S. Malmud, M.D.	Chairman
Douglas F. Eggli, M.D.	Member
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
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

NRC

Charlie Miller, Ph.D.	Director, Office of Federal and State Materials and Environmental Management Programs
Rob Lewis	Director, Division of Materials Safety and State Agreements
James Luehman	Deputy Director, Division of Materials Safety and State Agreements

NRC continued

Chris Einberg	Designated Federal Officer
Cindy Flannery	Alternate Designated Federal Officer
Ashley Cockerham	ACMUI Coordinator
Neelam Bhalla	NRC staff
Andrew Bramnik	NRC staff
Stuart Easson	NRC staff
Ossy Font	NRC staff
Cassandra Frazier	NRC staff
Sandy Gabriel	NRC staff
Merri Horn	NRC staff
Donna-Beth Howe, Ph.D.	NRC staff
Jennifer Rand	NRC staff
Gretchen Rivera-Capella	NRC staff
Carrie Safford	NRC staff
Glenda Villamar	NRC staff
Jenny Weil	NRC staff
Darrel Wiedeman	NRC staff
Michael Zeitler	NRC staff
Ron Zelac, Ph.D.	NRC staff

MEMBERS OF THE PUBLIC:

Melissa Allen (phone)	General Electric
Cindy Tomlinson	Society of Nuclear Medicine
Curtis Anderson	Mele Associates
David Burton	Walter Reed Army Medical Center
David Dodoo-Amoo	Associates in Medical Physics
Eiping Quang	Walter Reed Army Medical Center
George Wesley	Veterans Affairs, Office of the Inspector General
Gloria Romanelli	American College of Radiology
Ira Schneider (phone)	State of California
James Ross (phone)	General Electric Hitachi Nuclear Energy
John Creasy	Mele Associates
Joseph Goldstein	<i>Unknown Affiliation</i>
Josh Goldstein	Philadelphia Inquirer
Karen Langley (phone)	State of Utah
Lin Clegg	Veterans Affairs, Office of the Inspector General
Lynne Fairobent	American Association of Physicist in Medicine
Mary Moore	Philadelphia Veterans Affairs Medical Center
Melissa Martin	American Association of Physicist in Medicine
P. Yorke	Veterans Affairs National Health Physics Program
Parker Moore	Beveridge & Diamond, PC
Randall Snow	Veterans Affairs, Office of the Inspector General
Richard Martin	American Society for Radiation Oncology
Roberty Massey	Walter Reed Army Medical Center
Virgil Dickson	FDAnews

AGENDA TOPICS

CLOSED SESSION

1. Opening Statements
2. Ethics Training
3. Information Security (INFOSEC) Training
4. Allegations Training
5. 2009 Evaluations

OPEN SESSION

6. Opening Statements
7. Old Business
8. Summary of the Enforcement Process and Enforcement Actions Against Medical Licensees
9. Update on Medical Isotope Shortage
10. Medical Related Events
11. Update on Permanent Prostate Brachytherapy Medical Events
12. International Commission on Radiological Protections (ICRP) Publication 103 Subcommittee Report and Discussion
13. New Security Regulations – 10 CFR Part 37
14. Potential Changes to 10 CFR Part 35
15. Medical Uses of Radium-223
16. Regulatory Responsibilities of the U.S. Food and Drug Administration
17. Outgoing Member Presentation
18. Administrative Closing

RECOMMENDATIONS AND ACTIONS

For agenda topic 10, Medical Related Events, Dr. Malmud added three temporary members to the medical events subcommittee: Dr. Welsh (chair), Dr. Langhorst, and Mr. Mattmuller. Existing subcommittee members include: Ms. Gilley, Dr. Suleiman, and Dr. Thomadsen.

For agenda topic 14, Potential Changes to 10 CFR Part 35, ACMUI recommended that NRC staff delete the phrase "at a medical institution" from 10 CFR 35.2, 35.490(b)(1)(ii), 35.491(b)(2) and 35.690(b)(1)(ii). The recommendation passed with nine favorable votes and one abstention.

Also for agenda topic 14, ACMUI recommended that NRC staff revise 10 CFR 35.41(a) by adding "(3) If the administration is not in accordance with the written directive, a determination of whether it resulted in a reportable medical event will be made in a timely manner." Five members opposed the recommendation, two members were in favor, and two abstained. One member was not present and, therefore, did not vote. The recommendation did not pass.