

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

April 15-16, 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

Darice G. Bailey	Member
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
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

Allison Macfarlane, Ph.D.	Chairman, U.S. Nuclear Regulatory Commission
Mark Satorius	Director, Office of Federal and State Materials and Environmental Management Programs (FSME)
Brian McDermott	Director, Division of Materials Safety and State Agreements (DMSSA)
Christian Einberg	Chief, Radioactive Materials Safety Branch (RMSB)
Sandra Gabriel, Ph.D.	Acting Medical Radiation Safety Team Leader

Ashley Cockerham	Alternate Designated Federal Officer and ACMUI Co-Coordinator
Sophie Holiday	ACMUI Co-Coordinator
Neelam Bhalla	NRC staff, FSME
Stephanie Bush-Goddard, Ph.D.	NRC staff, RES
Susan Chidakel	NRC staff, OGC
Said Daibes, Ph.D.	NRC staff, FSME
Jim Dwyer	NRC staff, Region I
Sara Forster	NRC staff, Region III
Cassandra Frazier	NRC staff, Region III
Michael Fuller	NRC staff, OCM
Latischa Hanson	NRC staff, Region IV
Vincent Holahan	NRC staff, FSME
Deborah Jackson	NRC staff, FSME
Ed Lohr	NRC staff, DILR
Angela McIntosh	NRC staff, FSME
Kimyata Morgan-Butler, Ph.D.	NRC staff, FSME
Kevin Null	NRC staff, Region III
Patty Pelke	NRC staff, Region III
Gretchen Rivera-Capella	NRC staff, FSME
Mohammad Saba	NRC staff, RES
Sami Sherbini, Ph.D.	NRC staff, RES
Ronald Zelac, Ph.D.	NRC staff, FSME

MEMBERS OF THE PUBLIC

Paul Bessette – ViewRay™	Michael Peters – American College of Radiology (ACR)
David Breuning - ViewRay™	Joe Rodgers – Theragenics
Robert Dansereau – NY State Dept of Health	Gloria Romanelli – American College of Radiology (ACR)
William Davidson – University of Pennsylvania	Michael Sheetz – University of Pittsburgh
Dr. James Dempsey – ViewRay™	Dr. Parrish Staples – National Nuclear Security Administration (NNSA)
Dr. Daniel Duvall – Center for Medicare and Medicaid Services (CMS)	Michael Stephens – FL Bureau of Radiation Control
Lynne Fairobert – American Association of Physicists in Medicine (AAPM)	Cindy Tomlinson – American Society for Radiation Oncology (ASTRO)
Rilla Hamilton – National Nuclear Security Administration (NNSA)	Nancy Wersto – U.S. Food and Drug Administration (FDA)
Karen Langley – University of Utah	Paul Yurko – Veterans Health Administration
Andrew McKinley – American Society of Nuclear Cardiologists (ASNC)	

AGENDA TOPICS

CLOSED SESSION

1. HRMS Training
2. eTravel Training
3. Biennial Evaluations and Discussions

OPEN SESSION

4. Opening Statements
5. Special Presentation
6. Old Business
7. ACMUI Webpage Update
8. Draft Guidance for 10 CFR Part 35 Rulemaking
9. Medical Related Events
10. Abnormal Occurrence (AO) Subcommittee Report
11. 10 CFR Part 35 Rulemaking Update
12. Status of Data Collection on Patient Release
13. The NNSA's Efforts to Minimize the Use of Highly Enriched Uranium in Molybdenum-99 Production
14. The Federal Government's Center for Medicare and Medicaid Service's (CMS) 2013 Reimbursement Policy for non-HEU Produced Medical Isotopes
15. Status of Licensing Guidance for ViewRay™ System
16. Thyroid Cancer Survivors' Conference
17. Germanium-68/Gallium-68 Generator, Clinical Uses and Regulatory Issues
18. Administrative Closing

RECOMMENDATIONS AND ACTIONS

For agenda topic 3, Biennial Evaluations and Discussion, the ACMUI recommended tabling the amendments to the ACMUI Bylaws to the fall 2013 ACMUI meeting. The recommendation passed unanimously with twelve favorable votes.

For agenda topics 4 and 5, Opening Statements and Special Presentation, NRC Chairman Allison Macfarlane made a special presentation to Dr. Malmud to thank him for his eleven years of service and leadership to the ACMUI. Brian McDermott, Director of the Division of Materials Safety and State Agreements, announced Dr. Bruce Thomadsen as the new ACMUI Chair and Dr. Milton Guiberteau as the new ACMUI Vice Chair.

For agenda topic 8, Draft Guidance for 10 CFR Part 35 Rulemaking, Dr. Langhorst requested if NRC staff could add the Draft Guidance for the Draft Expanded Part 35 Rulemaking into the same docket number as the Rulemaking document. If this is not possible, she requests that the location (docket number) of the draft guidance be clearly identified in the Draft Expanded Part 35 Rulemaking docket (and vice versa).

For agenda topic 9, Medical Related Events, the ACMUI scheduled a teleconference on June 18, 2013 from 2-4pm EDT to discuss the Medical Events Subcommittee analysis of yttrium-90 microspheres medical events. The back-up teleconference meeting date is June 20, 2013 from 2-4pm EDT.

For agenda topic 10, Abnormal Occurrence (AO) Subcommittee Report, the ACMUI endorsed the AO Criteria Subcommittee Report. The recommendation passed unanimously with twelve favorable votes.

For agenda topic 16, Thyroid Cancer Survivors' Conference, Dr. Guiberteau requested that NRC staff provide a link to the abstract cited in Ms. Weil's presentation to the full ACMUI.

For agenda topic 17, Germanium-68/Gallium-68 Generator, Clinical Uses and Regulatory Issues, the ACMUI recommended that NRC provide regulatory relief from the decommissioning funding plan requirements for the use of a Germanium-68/Gallium-68 generator. The recommendation passed with eight favorable votes and four abstentions.

For agenda topic 18, Administrative Closing, the ACMUI planned to hold the fall 2013 ACMUI Meeting on September 9-10, 2013 at NRC Headquarters. The back-up meeting date is September 16-17, 2013.