

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

September 20-21, 2012

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, "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

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

Brian McDermott	Director, Division of Materials Safety and State Agreements
Pamela Henderson	Deputy Director, Division of Materials Safety and State Agreements
Christian Einberg	Chief, Radioactive Materials Safety Branch
Michael Fuller	Alternate Designated Federal Officer and Medical Radiation Safety Team Leader
Ashley Cockerham	Alternate Designated Federal Officer and ACMUI Coordinator
Sophie Holiday	Alternate ACMUI Coordinator
Susan Abrahams	NRC staff, Office of Nuclear Security and Incident Response
Bernice Ammon	NRC staff, Office of the General Counsel
Neelam Bhalla	NRC staff, Rulemaking Branch B
Susan Chidakel	NRC staff, Office of the General Counsel
Sean Croston	NRC staff, Office of the General Counsel
Jackie Cook	NRC staff, Region IV
Donald Cool, Ph.D.	NRC staff, Division of Intergovernmental Liaison and Rulemaking
Said Daibes, Ph.D.	NRC staff, Radioactive Materials Safety Branch
Sara Forster	NRC staff, Region III
Sandra Gabriel, Ph.D.	NRC staff, Radioactive Materials Safety Branch
Joseph Gilman	NRC staff, Office of the General Counsel
Latischa Hanson	NRC staff, Region IV
Patricia Hirsch	NRC staff, Office of the General Counsel
Vincent Holahan	NRC staff, Division of Materials Safety and State Agreements
Anthony Huffert	NRC staff, Office of Nuclear Regulatory Research
Andrea Kock	NRC staff, Office of the Commission, Commissioner William Ostendorff
Angela McIntosh	NRC staff, Radioactive Materials Safety Branch
Robert Norman	NRC staff, Office of Nuclear Security and Incident Response
Andrew Pessin	NRC staff, Office of the General Counsel
Josephine Piccone, Ph.D.	NRC staff, Director, Division of Intergovernmental Liaison and Rulemaking
Tamara Powell	NRC staff, Intergovernmental Liaison Branch
Lizette Roldan	NRC staff, Region IV
Mohammad Saba	NRC staff, Office of Nuclear Regulatory Research
Jeremy Suttentberg	NRC staff, Office of the General Counsel
John Szabo	NRC staff, Office of the General Counsel
Duane White	NRC staff, Radioactive Materials Safety Branch
Ronald Zelac, Ph.D.	NRC staff, Radioactive Materials Safety Branch

MEMBERS OF THE PUBLIC

Scott Bertetti - Bayer	Maria Favorito – Cohn & Wolfe
Jeffrey Bova – Bayer	Maria Garrigan - Bayer
Uwe Budde - Bayer	Juergen Gay - Bayer
Robert Dansereau – NY State Dept of Health	Dr. Joseph Germino – Bayer
William Davidson – University of Pennsylvania	Robert Gorsuch – Johns Hopkins University
Dr. Lothar Everz – Bayer	Kelli Hayashi – Johns Hopkins University
Lynne Fairobent – Am. Assoc. of Physicists in Medicine	Dr. Deepika Jalota – Bayer
	Karen Langley – Univeristy of Utah

Ralph Lieto – Trinity Health
Dr. Peter Luehrs – Bayer
Angel McCullough – Johns Hopkins University
Andrew McKinley – Am. Soc. of Nuc. Card.
Janette Merrill – Society of Nuclear Medicine
and Molecular Imaging
Michael Noska – U.S. Food and Drug Admin.
Jatinder Palia – Veterans Health Administration
Michael Peters – Am. College of Radiology
Dr. Dennis Phillips – U.S. Dept. of Energy

Joe Rodgers – Theragenics
Gloria Romanelli – Am. College of Radiology
Ruth Schukman-Dakotas – Univ. of Kansas
Hospital
Michael Sheetz – University of Pittsburgh
Dr. Jeffry Siegel – Nuclear Physics Enterprises
Cindy Tomlinson – Am. Soc. for Rad. Onc.
Dr. Mona Wahba - Bayer
Gary Williams – Veterans Health Administration
Nancy Young – Xcenda

AGENDA TOPICS

CLOSED SESSION

1. Ethics Training
2. eTravel Training
3. Time Training
4. Allegations Training
5. Information Security Training

OPEN SESSION

6. Opening Statements
7. Old Business
8. ACMUI Group Photo
9. Use of Dose Calibrators in Medicine
10. Licensing of Radium-223 Dichloride/Radium-223 Dichloride Subcommittee Report
11. Status of Data Collection on Patient Release
12. 10 CFR Part 35 Rulemaking Update
13. Update on Proposed Regulatory Changes for Permanent Implant Brachytherapy Programs
14. ACMUI Reporting Structure
15. Abnormal Occurrence Criteria
16. Reducing Occupational Dose Limits
17. Update on Domestic Production of Molybdenum-99
18. Administrative Closing

RECOMMENDATIONS AND ACTIONS

For agenda topic 9, Use of Dose Calibrators in Medicine, Dr. Leon Malmud asked NRC staff to find data on events in which the radiopharmacy has dispensed the incorrect amount of a radiopharmaceutical or the incorrect radiopharmaceutical.

For agenda topic 10, Licensing of Radium-223 Dichloride/Radium-223 Dichloride Subcommittee Report, the ACMUI recommended that Ra-223 dichloride be licensed under 10 CFR 35.300 and recommended (but not recommend requiring) direct measurement of activity before/after administration. The recommendation passed unanimously with twelve favorable votes.

Also for agenda topic 10, Licensing of Radium-223 Dichloride/Radium-223 Dichloride Subcommittee Report, the ACMUI endorsed the subcommittee report submitted on July 16, 2012 with the following changes: 1) recommend licensing of Ra-223 dichloride under 10 CFR 35.300 and recommend (but not require) direct measurement of activity before/after administration; 2) remove statement regarding applicability of report for all future alpha-emitting particles; and 3) remove statement regarding Ra-223 dichloride significantly prolonging survival. The ACMUI will submit a report to NRC staff with the aforementioned changes. The recommendation passed unanimously with 12 favorable votes.

For agenda topic 14, ACMUI Reporting Structure, the ACMUI requested that the reporting structure reviews remain on an annual basis.

For agenda topic 15, Abnormal Occurrence Criteria, Dr. Leon Malmud created a subcommittee to review the refined Abnormal Occurrence criteria and to provide recommendations to NRC staff. Subcommittee members include: Dr. Susan Langhorst (chair), Ms. Darice Bailey, Mr. Steve Mattmuller, Dr. Christopher Palestro, Dr. Bruce Thomadsen, Ms. Laura Weil, and Dr. James Welsh. The NRC staff resource person will be Ms. Angela McIntosh.

Also for agenda topic 15, Abnormal Occurrence Criteria, Dr. Susan Langhorst asked NRC staff to provide direction as to whether or not the trigger criteria needs to be a part of the Abnormal Occurrence criteria or if the trigger criteria could be used separately.

For agenda topic 18, Administrative Closing, the ACMUI planned the spring 2013 ACMUI Meeting on April 15-16, 2013, at NRC Headquarter. The back-up date is April 29-30, 2013. The ACMUI will meet separately with the Commission, if requested.