

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

April 16-17, 2012

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

Darice G. Bailey	Member
Milton S. Guiberteau, M.D.	Member
Susan M. Langhorst, Ph.D.	Member
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.	Acting Chairman
William A. Van Decker, M.D.	Member
Laura Weil	Member
James S. Welsh, M.D.	Member
Pat Zanzonico, Ph.D	Member

NRC

Pamela Henderson	Acting Deputy 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 Augustus	NRC staff
Neelam Bhalla	NRC staff
Tammy Bloomer	NRC staff
Anne Boland	NRC staff
Susan Chidakel	NRC staff
Jackie Cook	NRC staff
Said Daibes, Ph.D.	NRC staff
Sandra Gabriel, Ph.D.	NRC staff
Latischa Hanson	NRC Staff
Donna-Beth Howe, Ph.D.	NRC staff
Harriet Karagiannis	NRC staff
Ed Lohr	NRC staff
Aaron McCraw	NRC staff
Patricia Pelke	NRC staff
Gretchen Rivera-Capella	NRC staff
Shirley Xu	NRC staff

MEMBERS OF THE PUBLIC:

Scott Bertetti	Bayer Healthcare Pharmaceuticals
Colin Biggin, Ph.D.	Algeta ASA
Jeff Bova	Bayer Healthcare Pharmaceuticals
Darrell Brown	Fox Chase Cancer Center
Keith Brown	University of Pennsylvania
Peter Crane	<i>Unknown Affiliation</i>
Robert Dansereau	New York State Department of Health
William Davidson	University of Pennsylvania
Mohan Doss, Ph.D.	Fox Chase Cancer Center
Bryan Edwards	Fox Chase Cancer Center
Lynne Fairobent	American Association of Physicists in Medicine
Maria Garrigan	Bayer Healthcare Pharmaceuticals
Juergen Gay, Ph.D.	Bayer Healthcare Pharmaceuticals
Joseph Germino, Ph.D.	Bayer Healthcare Pharmaceuticals
Shaemus Gleason	Cardinal Health
Traci Hollingshead	Avera McKennan
Deepika Jalota	Bayer Healthcare Pharmaceuticals
Ralph Lieto	St. Joseph Mercy Hospital
Peter Luhrs	Bayer Healthcare Pharmaceuticals
Gary Lunger	<i>Unknown Affiliation</i>
Andrew McKinley	American Society of Nuclear Cardiology
Janette Merill	Society of Nuclear Medicine
Erik Merten, Ph.D.	Bayer Healthcare Pharmaceuticals

MEMBERS OF THE PUBLIC (continued):

Mary E. Moore	Philadelphia Veterans' Affair Medical Center
Donna Mosley	Fox Chase Cancer Center
Michael Peters	American College of Radiology
Sobha Phillips	Fox Chase Cancer Center
Kathryn Pryor	Health Physics Society
Willie Regits	Cardinal Health
Joe Rodgers	Theragenics
Gloria Romanelli	American College of Radiology
Gerhard Schuleter	Bayer Healthcare Pharmaceuticals
Karen Sheehan	Fox Chase Cancer Center
Michael Sheetz	University of Pittsburgh
Jeff Siegel, Ph.D.	Nuclear Physics Enterprises
Michael N. Stephens	Florida Department of Health
Rose Talarico	Bayer Healthcare Pharmaceuticals
John Talian, Ph.D.	Bayer Healthcare Pharmaceuticals
Cindy Tomlinson	American Society for Radiation Oncology
Christopher Vascoe	Bayer Healthcare Pharmaceuticals
Richard Vetter, Ph.D.	Health Physics Society
Dimitris Voliotis, M.D.	Bayer Healthcare Pharmaceuticals
Mona Wahba	Bayer Healthcare Pharmaceuticals
Evan Western	Cardinal Health
Gary E. Williams	Veterans Affairs National Health Physics Program
David Williamson	University of Pennsylvania

AGENDA TOPICS

CLOSED SESSION

1. Commission Meeting Preparation

OPEN SESSION

2. Opening Statements
3. Old Business
4. Fundamental Concepts in Patient Advocacy
5. Electronic Signatures Subcommittee
6. Medical Events Subcommittee Report
7. Permanent Implant Brachytherapy
8. Status of Commission Paper on Patient Release
9. Radiation Therapy Implications from Anomalous Variations of the Nuclear Decay Law
10. Medical Use of Radium-223 Chloride – Bayer Healthcare Pharmaceuticals
11. Medical Use of Radium-223 Chloride – ACMUI
12. Strontium/Rubidium Update – NRC Perspective
13. Strontium/Rubidium Update – FDA Perspective
14. Administrative Closing

RECOMMENDATIONS AND ACTIONS

For agenda topic 5, Electronic Signatures Subcommittee, the ACMUI recommended to approve the Electronic Signatures Subcommittee Report. The recommendation passed unanimously with eleven favorable votes.

For agenda topics 10 and 11, Medical Use of Radium-223 Chloride, Dr. Bruce Thomadsen created a subcommittee to provide a recommendation on licensing for alpha-emitters, including Ra-223. The subcommittee will submit its report to the full committee by June 15, 2012. Subcommittee members include: Dr. Pat Zanzonico (chair), Ms. Darice Bailey, Dr. Susan Langhorst, Mr. Steve Mattmuller, Dr. Christopher Palestro, Dr. Orhan Suleiman, Dr. Bruce Thomadsen, and Dr. James Welsh. The NRC staff resource person will be Ms. Ashley Cockerham.

For agenda topic 14, Administrative Closing, the ACMUI planned the fall 2012 ACMUI Meeting on October 18-19, 2012, at NRC Headquarters. The back-up date is September 20-21, 2012.