MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

May 24-25, 2010

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 ML101480965
http://www.nrc.gov/reading-rm/adams/web-based.html

ATTENDEES

ACMUI

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, acting Chair
William A. Van Decker, M.D.	Member
James S. Welsh, M.D.	Member
Pat Zanzonico, Ph.D	Member

NRC

Rob Lewis	Director, Division of Materials Safety and State Agreements
Chris Einberg	Branch Chief, Radioactive Materials Safety Branch
Ashley Cockerham	ACMUI Coordinator
Mark Banks	NRC staff

NRC Continued

Kathryn Brock	NRC staff
Cathy Colleli	NRC staff
Said Daibes, Ph.D	NRC staff
Kerstun Day	NRC staff
Mark Ferdas	NRC staff
James Firth	NRC staff
Cindy Flannery	NRC staff
Michael Fuller	NRC staff
Sandy Gabriel, Ph.D.	NRC staff
Donna-Beth Howe, Ph.D.	NRC staff
Varughese Kurian	NRC staff
Sophie Le	NRC staff
Angela McIntosh	NRC staff
Kevin Nietmann	NRC staff
Patricia Pelke	NRC staff
Gretchen Rivera-Capella	NRC staff
Leela Sreenivas	NRC staff
Glenda Villamar	NRC staff
Jenny Weil	NRC staff
Ron Zelac, Ph.D.	NRC staff

MEMBERS OF THE PUBLIC:

Amanda Potter	American Association of Physicist in Medicine
Andre Acevedo	Johns Hopkins
Calvin Ditch	Johns Hopkins
Carol Florian	Symetosphere
Cindy Tomlinson	Society of Nuclear Medicine
Curtis Anderson	Mele Associates
Doug Pfeiffer	American Association of Physicist in Medicine
Gary E. Williams	Veterans Affairs National Health Physics Program
Grace Colangeli	Johns Hopkins
Heather Green	Johns Hopkins
Jacob Puka	Johns Hopkins
Janet Bukovcan	MDS Nordion
Janet Schlueter	Nuclear Energy Institute
Jenna M. Wilkes	American Society of Nuclear Cardiology
Jim Nance	Symetosphere
Karen Langley	University of Utah
Louis Potters	North Shore University Hospital and Long Island Jewish Medical Center
Mary Morgan	Johns Hopkins
Melissa Allen	General Electric Hitachi Nuclear Energy
Michael Peters	American College of Radiology
Peter Crane	*Unknown Affiliation*
Phung Nguyen	Johns Hopkins
Rachel Stoehr	Johns Hopkins
Richard J. Martin	American Society for Therapeutic Radiology and Oncology
Roy Brown	Council on Radionuclides and Radiopharmaceuticals

AGENDA TOPICS

CLOSED SESSION

1. ACMUI Badging

OPEN SESSION

2. Opening Statements
3. Old Business
4. Status of Current and Future Rulemaking
5. Patient Release
6. Update on Medical Isotope Shortage
7. Domestic Production of Molybdenum 99
8. Update on Permanent Prostate Brachytherapy Medical Events
9. Permanent Implant Brachytherapy Subcommittee
10. Safety Culture
11. Update on Grandfathering Certified Medical Physicists
12. Revisions to the NRC Radiation Protection Requirements: Potential Impacts to the Medical Community
13. Post-Implant Written Directives for Yttrium 90 Microspheres Procedures
14. Subcommittee Report on Byproduct Materials Events
15. Administrative Closing

RECOMMENDATIONS AND ACTIONS

For agenda topic 5, Patient Release, Dr. Thomadsen created a subcommittee to evaluate patient release issues; to objectively review and analyze data, which may include state regulations and guidance to international recommendations; to provide a statement on the issue; and to provide recommendations for improvements to existing NRC rules and guidance, if necessary, which should include the issue of patient release to hotels. Subcommittee members include: Dr. Susan Langhorst (chair), Dr. Darrell Fisher, Ms. Debbie Gilley, Mr. Steven Mattmuller, Dr. Orhan Suleiman, Dr. Bruce Thomadsen, Dr. James Welsh and Dr. Pat Zanzonico. The subcommittee should report to the full ACMUI at the fall meeting. The recommendation passed with eight favorable votes.

Also for agenda topic 5, the ACMUI fully supports Dr. Darrell Fisher as Patients' Rights Advocate. The Committee expressed their appreciation and honor to serve with him. The recommendation passed with seven favorable votes and one abstention from Dr. Fisher.

For agenda topic 6, Update on Medical Isotope Shortage, the NRC staff should provide optimal staff and support to facilitate the licensing process for new domestic producers of the medical isotope, molybdenum 99. The recommendation passed with eight favorable votes.

For agenda topic 9, Permanent Implant Brachytherapy Subcommittee, the subcommittee will revise the draft subcommittee report and resubmit it to the full ACMUI for an e-mail vote. The ACMUI will submit a final subcommittee report to the NRC. The recommendation passed with eight favorable votes.

For agenda topic 10, Safety Culture, the NRC staff should provide information that describes safety culture problems as contributing factors to violations.

For agenda topic 13, Post-Implant Written Directives for Yttrium 90 Microspheres Procedures, the NRC staff should review the Y-90 microsphere brachytherapy guidance to delete “but before the patient or human research subject leaves the post-procedural recovery area” under item 2 of the written directive section. The recommendation passed with eight favorable votes.

Also for agenda topic 13, the NRC staff should revise the Y-90 microsphere brachytherapy guidance to read (under 1 for written directives) “and, if the procedure was not performed in accordance with the pre-administration written directive”, then 2) “after administration and within 48 hours of the procedure, the signature of an AU.” The recommendation passed with eight favorable votes.

For agenda topic 14, Subcommittee Report on Byproduct Materials Events, the NRC staff should consider the necessity and evaluate options to collect or obtain data for the denominator for medical events to improve the overall value of the medical events subcommittee report.