TELECONFERENCE MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

January 5, 2011

MEETING SUMMARY

PURPOSE

To discuss issues related to the implementation of the medical regulations in 10 Code of Federal Regulations (CFR) Part 35, "Medical Use of Byproduct Material," including patient release; the Advisory Committee on the Medical Uses of Isotopes (ACMUI) reporting structure; rulemaking and implementation guidance for physical protection of byproduct material; and the impacts of the draft safety culture policy statement for medical licensees.

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 on these topics. The staff will consider these views in its continuing effort to make 10 CFR Parts 35 and 37 and the draft safety culture policy statement 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

Darrell Fisher, Ph.D.	Member
Debbie B. Gilley	Member
Milton S. Guiberteau, M.D.	Representative
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
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
Pat Zanzonico, Ph.D	Member

NRC

Rob Lewis	Director, Division of Materials Safety and State Agreements
Chris Einberg	Designated Federal Officer
Mike Fuller	Alternate Designated Federal Officer
Ashley Cockerham	ACMUI Coordinator
Neelam Bhalla	NRC staff
James Biggins	NRC staff
Elva Bowden Berry	NRC staff
Lisa Dimmick	NRC staff
James Firth	NRC staff
Sophie Holiday	NRC staff
Donna-Beth Howe, Ph.D.	NRC staff
Ed Lohr	NRC staff
Maria Schwartz	NRC staff
Diane Sieracki	NRC staff
Dave Solorio	NRC staff
Catherine Thompson, Ph.D.	NRC staff
Ron Zelac, Ph.D.	NRC staff

MEMBERS OF THE PUBLIC

Dave Adler	American Society for Therapeutic Radiology and Oncology
Curtis M. Anderson	MELE Associates
James D. Albright	NCDENR
David J. Allard	Pennsylvania Department of Environmental Protection
Christofer Alston	Georgetown University Hospital
Maxwell Amurao	Georgetown University Hospital
Sue Bunning	Society of Nuclear Medicine
Robert E. Dansereau	New York State Department of Health
William Davidson	University of Pennsylvania
Deirdre Elder	University of Colorado Hospital
Nancy Farrington	Iowa Department of Public Health
Dr. Thomas Huston	Department of Veterans Affairs
Karen Langley	University of Utah
Andrew Mauer	Nuclear Energy Institute
Candi McDowell	Georgetown University Hospital
Herb Mower	Lahey
Joseph Och	Geisinger Medical Center
Mike Peters	American College of Radiology
Melanie Rasmusson	Iowa Department of Public Health
Gloria Romanelli	American College of Radiology
Dr. George Segall	Society of Nuclear Medicine
Michael Sheetz	University of Pittsburgh
Cindy Tomlinson	American Society for Radiation Oncology
Dr. Richard Vetter	Health Physics Society
Michelle White	DMS Health Technologies
Jenna Wilkes	Society of Nuclear Medicine
Sandy Wolff	Sentara

AGENDA TOPICS

1. Patient Release
2. ACMUI Reporting Structure
3. Rulemaking and Implementation Guidance for Physical Protection of Byproduct Material
4. Impacts of the Draft Safety Culture Policy Statement for Medical Licensees

RECOMMENDATIONS AND ACTIONS

For agenda topic 1, Patient Release, the ACMUI endorsed the draft response to NRC comments, as reflected in the meeting handout (ML110600249). The recommendation passed with nine favorable votes and one abstention. ACMUI agrees that if NRC believes the release criteria should be changed from a per release criteria to an annual criteria, this change would require new rulemaking, as stated in Regulatory Issue Summary (RIS) 2008-07. ACMUI recommends rulemaking to clarify that the release under 35.75 is per release and not per year.

Note: The NRC position stated in RIS 2008-07 is that the current rule is per release and rulemaking would be needed to eliminate the ambiguity in the language of the rule.

For agenda topic 2, ACMUI Reporting Structure, the ACMUI recommended the NRC maintain the current reporting structure; however, the motion was tabled for further discussion at the January 12, 2011 ACMUI teleconference.

For agenda topic 3, Rulemaking and Implementation Guidance for Physical Protection of Byproduct Material, the ACMUI endorsed the draft comments on proposed 10 CFR Part 37, as reflected in the meeting handout (ML110600261). The recommendation passed unanimously with ten favorable votes.

For agenda topic 4, Impacts of the Draft Safety Culture Policy Statement for Medical Licensees, the ACMUI endorsed the Draft Safety Culture Policy Statement. The recommendation passed with nine favorable votes and one abstention. Ms. Debbie Gilley abstained because the policy statement is not enforceable, which means it is open for interpretation by the Agreement States.