

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

March 05, 2013

MEETING SUMMARY

PURPOSE

To discuss the draft Advisory Committee on the Medical Uses of Isotopes (ACMUI) subcommittee report on the proposed draft expanded 10 CFR Part 35 Rulemaking.

OUTCOME

The subcommittee provided a draft report for discussion with the full committee. Subcommittee members included: Dr. Susan Langhorst; Mr. Steven Mattmuller; Dr. Bruce Thomadsen; Ms. Laura Weil; Dr. James Welsh; and Dr. Pat Zanzonico (chair). During the meeting, the committee approved several recommendations within the subcommittee report. The U.S. Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the ACMUI. The ACMUI scheduled an additional teleconference on March 12, 2013 to continue discussions on the subcommittee report.

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 MEMBERS

Darice G. Bailey	Member
Milton S. Guiberteau, M.D.	Member
Susan M. Langhorst, Ph.D.	Member
Leon S. Malmud, M.D.	Chairman
Steven R. Mattmuller	Member
Christopher J. Palestro, M.D.	Member
Orhan Suleiman, Ph.D.	Member
Bruce R. Thomadsen Ph.D.	Vice Chairman
William A. Van Decker, M.D.	Member
Laura M. Weil	Member
James S. Welsh, M.D.	Member
Pat Zanzonico, Ph.D.	Member

ACMUI MEMBERS NOT PRESENT

John H. Suh, M.D.	Member
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NRC STAFF

Pamela Henderson	Deputy Director, Division of Materials Safety and State Agreements
Christian Einberg.	Chief, Radioactive Materials Safety Branch and Designated Federal Officer
Ashley Cockerham	Alternate Designated Federal Officer and ACMUI Coordinator
Sophie Holiday	Alternate ACMUI Coordinator
Maryann Abogunde	NRC staff Region I
Hector Bermudez	NRC staff Region I
Neelam Bhalla	NRC staff
Colleen Casey	NRC staff Region III
Susan Chidakel	NRC staff, Office of the General Counsel
Jackie Cook	NRC staff Region IV
Said Daibes, Ph.D.	NRC staff
James Danna	NRC staff
Tremaine Donnell	NRC staff
Sara Forster	NRC staff Region III
Cassandra Frazier	NRC staff Region III
Sandra Gabriel, Ph.D.	NRC staff
Michelle Hammond	NRC staff Region IV
Donna-Beth Howe, Ph.D.	NRC staff
Penny Lanzisera	NRC staff Region I
Ed Lohr	NRC staff
Bryan Parker	NRC staff Region III
Dennis O'Dowd	NRC staff Region III
Patricia Pelke	NRC staff, Region III
Deborah Piskura	NRC staff
Gretchen Rivera-Capella	NRC staff
Michelle Simmons	NRC staff Region IV
Sandra Talley	NRC staff
Jack Whitten	NRC staff Region IV
Ronald Zelac, Ph.D.	NRC staff

MEMBERS OF THE PUBLIC

Sue Bunning – Society of Nuclear Medicine and Molecular Imaging	Richard Peros – NJ Dept. of Environmental Protection
William Davidson – University of Pennsylvania	Michael Peters – Am. College of Radiology
Dawn Edgerton – Council for Certification in Cardiovascular Imaging	Joe Rodgers – Theragenics Corporation
Lynne Fairobent – Am. Assoc. of Physicists in Medicine	Gloria Romanelli – Am. College of Radiology
Thomas Huston – Dept. of Veterans Affairs	Karen Sheehan – Fox Chase Cancer Center
Karen Langley – University of Utah	Michael Sheetz – University of Pittsburgh
Ralph Lieto – St. Joseph Mercy Hospital	Michael Stephens – FL Bureau of Radiation Control
Andrew McKinley – Am. Soc. Of Nuclear Cardiology	Cindy Tomlinson – Am. Soc. for Rad. Onc.

RECOMMENDATIONS AND ACTIONS

The subcommittee discussed the following recommendations in the draft subcommittee report:

1. Page 2, 1-A. ACMUI recommended NRC staff allow use of total source strength as a substitute for total dose for determining medical events for permanent implant brachytherapy until the Part 35 rulemaking is complete. [10 CFR 35.3045]
2. Page 2, 1-C. ACMUI recommended that NRC staff solicit feedback from stakeholders, in Supplementary Information section IV.D, on whether the proposed ME definition for permanent implant brachytherapy would discourage licensees from using this form of therapy. *This recommendation was modified the caveat that NRC may utilize the language that they think is appropriate for gaining this type of information from its stakeholders.* [10 CFR 35.3045]
3. Page 3, 1-D. ACMUI recommended the draft rule re-defining medical events in permanent implant brachytherapy be designated as Compatibility Category B. [10 CFR 35.3045]
4. Page 3, 1-E. ACMUI recommended replacing the phrasing in the literature in terms of support for the 5 cubic centimeters of contiguous normal tissue provision of the ME definition, to the specific reference cited as, Nag, et al 2004. [10 CFR 35.3045]
5. Page 3, 2-B. ACMUI recommended that licensees approved to use generator systems show specific training on the requirement now listed under 35.290 (c)(1)(ii)(G) for those individuals (Authorized Users and others) who are responsible for proper operation and testing of the generator as part of their license conditions. ACMUI further recommended that Authorized Nuclear Pharmacists who have the adequate training and experience (T&E) are able to provide the supervised work experience for Authorized Users on the elution of generators. [10 CFR 35.290]
6. Page 3, 2-C. ACMUI recommended amending the preceptor attestation requirements as follows, "...has satisfactorily fulfilled the T&E requirements consistent with achieving a level of competency sufficient to function independently in the position for which authorization is sought..." *After thorough discussion with the full committee and NRC staff, this recommendation was modified to endorse the language in the proposed rule that states a candidate is able to independently fulfill the radiation safety related duties for which authorization is being sought.* [Multiple sections of 10 CFR Part 35]

The recommendations listed above were unanimously approved by the ACMUI.

The subcommittee agreed to modify the wording on Page 4, 2-D of the subcommittee report in preparation for the teleconference meeting to be held the following week.

ACMUI agreed to reconvene for an additional teleconference meeting to complete discussions and finalize the subcommittee report (ML13059A505) on March 12, 2013 from 2:00PM–5:00PM EST.