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

February 7, 2012

MEETING SUMMARY

PURPOSE

To discuss the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Permanent Implant Brachytherapy Subcommittee Report as it relates to the implementation of the medical regulations in Title 10, Code of Federal Regulations (CFR) Part 35, "Medical Use of Byproduct Material."

OUTCOME

The ACMUI Permanent Implant Brachytherapy Subcommittee (PIBS) provided a draft report for the ACMUI's consideration. During the meeting, the PIBS made recommendations to revise the report, and the revisions were approved by the full committee, as described below. The PIBS draft report was endorsed by the full ACMUI with one dissenting opinion. 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/

Permanent Implant Brachytherapy Rulemaking Final Report (2012) can be found on NRC's public website under "Related Information": http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html

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
Orhan H. Suleiman, Ph.D.	Member
Bruce R. Thomadsen Ph.D.	Vice Chairman
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	Acting Deputy Director, Division of Materials Safety and State Agreements
Michael Fuller	Designated Federal Officer
Ashley Cockerham	Alternate Designated Federal Officer and ACMUI Coordinator
Maria Arribas-Colon	NRC staff
Susan Chidakel	NRC staff
Said Daibes, Ph.D.	NRC staff
Sandra Gabriel, Ph.D.	NRC staff Region I
Latischa Hanson	NRC staff Region IV
Donna-Beth Howe, Ph.D.	NRC staff
Patricia Pelke	NRC staff Region III
Gretchen Rivera-Capella	NRC staff
Lizette Roldan-Otero, Ph.D.	NRC staff Region IV
Ronald Zelac, Ph.D.	NRC staff

MEMBERS OF THE PUBLIC:

Dr. Keith Brown – University of Pennsylvania
Karen Colucci – Albert Einstein Healthcare Network
Robert Dansereau – New York State Department of Health
William Davidson – University of Pennsylvania
Dr. Ronald Ennis – American Society for Radiation Oncology
Lynne Fairobent – American Association of Physicist in Medicine
Peter Goyer – Albert Einstein Healthcare Network
Dr. Thomas Huston – Veterans Health Administration
Dennis Kehoe – Jeppensen Radiation Oncology Center
Ralph Lieto – St. Joseph Mercy Hospital
Janette Merrill - Society of Nuclear Medicine
Dr. Subir Nag – Kaiser Permanente
Michael Peters – American College of Radiology
Dr. Bradley Prestidge – American Brachytherapy Society
Joseph Rodgers – Theragenics Corporation
Gloria Romanelli – American College of Radiology
Karen Sheehan – Fox Chase Cancer Center
Michael Sheetz – University of Pittsburgh
Eric Soltycki – Albert Einstein Healthcare Network
Cindy Tomlinson – American Society for Radiation Oncology

AGENDA TOPIC

Permanent Implant Brachytherapy Subcommittee Report

RECOMMENDATIONS AND ACTIONS

The subcommittee made the following changes to the draft report show in italics below:

1. Page 1, "Recommendations" A.2.a. For neighboring structures (such as the bladder or rectum in prostate implants as an example), the dose to at least 5 *contiguous* cm^3 ~~*(contiguously)*~~ exceeds 150% of the dose prescribed to the CTV or PTV.

2. Page 1, "Recommendations" A.2.b. For intra-target structures (such as the urethra in prostate implants as an example), the dose to at least 5 *contiguous* cm^3 ~~*(contiguously)*~~ exceeds 150% of that structure's expected dose based on the approved pre-implant, dose distribution.

3. Page 2, "Recommendations" B. The Authorized User should provide a statement in this Written Directive Completion attesting that the permanently implanted sources have been placed in accordance with the *final* planned distribution.

The first two changes were unanimously approved by the ACMUI. The third change was approved by the ACMUI; however, Dr. Thomadsen abstained because he did not support the concept of attestations in the Written Directive.

The Draft ACMUI Permanent Implant Brachytherapy Subcommitee Report modified January 2012, (ML12019A196) was approved by the ACMUI with the three changes noted above and one opposing vote. Dr. Thomadsen voted against the current report and stated his continued support for the October 18, 2011 version (ML11292A139). Dr. Thomadsen's comments are summarized in the "Minority Report" section of the current report dated February 7, 2012 (ML12038A279).