

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

June 24, 2016

MEETING SUMMARY

PURPOSE

To discuss the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Subcommittee on Radioactive Seed Localization (RSL Subcommittee) response to the NRC working group draft “Low Activity Radioactive Seeds Used for Localization of Non-palpable Lesions and Lymph Nodes Guidance” and the potential rulemaking to expand the financial assurance requirements to include Category 1 and 2 radioactive sealed sources tracked in the National Source Tracking System.

OUTCOME

The ACMUI RSL Subcommittee provided their final report for discussion with the full Committee. Subcommittee members included: Dr. Ronald Ennis (Chair), Mr. Frank Costello, Dr. Darlene Metter, and Dr. Pat Zanzonico. During the meeting, the Committee unanimously approved the draft report with the modifications listed below. The ACMUI RSL Subcommittee commented on the more substantive changes where they do not align with the current working group draft. Additionally, U.S. Nuclear Regulatory Commission (NRC) staff discussed the potential rulemaking to expand the financial assurance requirements in 10 CFR 30.35 for certain radioactive byproduct material. The ACMUI made recommendations on revisions to the draft RSL guidance and the NRC staff gained a better understanding of the views and opinions of the ACMUI for further consideration by the NRC.

Full transcripts and handouts from the ACMUI meeting can be found on NRC’s public website:
<http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/>

The draft and final ACMUI RSL Subcommittee reports are available on NRC’s public website under “ACMUI Subcommittee Reports”:
<http://www.nrc.gov/reading-rm/doc-collections/acmui/reports/>

AGENDA TOPIC

Discuss the ACMUI RSL Subcommittee report.

RECOMMENDATIONS AND ACTIONS

The RSL Subcommittee discussed the following recommendations in their report:

1. Page 1: The subcommittee agreed with the elimination of the written directive with the understanding that there will be documentation in the medical record pre-procedure and post-procedure that would allow regulators to determine whether a medical event occurred.

The recommendation was unanimously approved by the ACMUI.

2. Page 2: The subcommittee agreed with the third pathway in which a radiologist could become an authorized user with the listed 80-hours of training and experience. However, the subcommittee did not support surgeons or others without a significant background in radiation (from a residency or other similarly intense education and practical experience) becoming Authorized Users for RSL with only 80 hours of training.

The recommendation was unanimously approved by the ACMUI.

3. Page 2: The subcommittee supports the modified definition of medical events (MEs) with the caveat that such an outcome would not be an ME if “the physician makes the determination not to explant the seed for various patient conditions (e.g. doing so would jeopardize the patient’s well-being).” The subcommittee accepts this change and supports exclusion from an ME under circumstances in which the physician deems removal would not be in the best interest of the patient. Additionally, the subcommittee supports the position that an ME has not occurred if the patient fails to return for the surgical removal procedure, considering this to be an instance of “patient intervention,” provided the patient has been properly counseled about the importance of returning for the procedure and the risk of radiation exposure if the sources are not removed. Documentation of this counseling should be made in the patient’s medical record.

The recommendation was unanimously approved by the ACMUI.

4. Pages 2-3: The subcommittee recommended inclusion of the following in the Draft Guidance:

“Patient should be advised not to breast feed from a breast into which one or more radioactive seeds been implanted and not yet removed. Breast feeding is, of course, permissible once the seed(s) has(ve) been removed. In the event of seed rupture within the breast, the subcommittee recommends the patient be advised to never breast feed from the effected breast for this child.”

During the discussion, this recommendation was modified as follows:

*“Patient should be advised not to breast feed from a breast into which one or more radioactive seeds been implanted and not yet removed. Breast feeding is, of course, permissible once the seed(s) has(ve) been removed. In the event of seed rupture within the breast, the subcommittee recommends the patient be advised to never breast feed from **either** breast for this child.”*

The revised recommendation was unanimously approved by the ACMUI.

Attachments:

1. List of Attendees
2. Agenda

ML16201A163

OFC	MSTR/MSEB	MSTR/MSEB	MSTR/MSEB
NAME	M. Smethers	M. Fuller	D. Bollock
DATE	07/14/2016	07/18/2016	07/18/2016

MEETING ATTENDEES

ACMUI

Philip O. Alderson, M.D.	Chairman
Francis M. Costello	Member
Vasken Dilsizian, M.D.	Member
Ronald D. Ennis, M.D.	Member
Steven R. Mattmuller	Member
Darlene F. Metter, M.D.	Member
Michael D. O'Hara, Ph.D.	Member
Christopher J. Palestro, M.D.	Member
Laura M. Weil	Member
Pat B. Zanzonico, Ph.D	Vice Chairman
<i>Zoubir Ouhib</i>	<i>Non-Voting Member</i>
<i>Richard Green</i>	<i>Non-Voting Member</i>

NRC

Pam Henderson	Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs (MSTR)
Douglas Bollock	Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Sophie Holiday	Alternate Designated Federal Officer and ACMUI Coordinator
Colleen Casey	RIII
Said Daibes, Ph.D.	NMSS
Michael Fuller	NMSS
Robert Gallagher	RI
Latischa Hanson	RIV
Donna-Beth Howe, Ph.D.	NMSS
Erin Kennedy	RIII
Gretchen Rivera-Capella	NMSS
Jim Shaffner	NMSS
Toye Simmons	RIII
Michelle Smethers	NMSS
Katie Tapp, Ph.D.	NMSS
Ryan Whited	NMSS
Jack Whitten	RIV

MEMBERS OF THE PUBLIC

Dave Adler	American Society of Radiation Oncology (ASTRO)
Jeffrey Brunette	Mayo Clinic
David Close	National Physics
Robert Danseareau	New York State Department of Health
Scott Dube	Baycare
Hugh Evans	Eckert & Ziegler Radiopharma, Inc.
Jordan Fahle	Alpine Group
Sandra Gabriel	International Atomic Energy Agency
Philip Griffin	Utah Division of Radiation Control
Eric Haviland	Baystate Health
Stanley Hampton	Eli Lilly and Company
Jim Harvey	NorthStar Medical Technologies, LLC
Gregory Hodges	Overlook Medical Center
Linda Kroger	University of California Davis Health System

Attachment 1

Karen Langley
Ralph Lieto
Steve Marsh
Richard Martin
Matthew Miller
Michael Oumano
Andrea Ravard
Gloria Romanelli
Michael Sheetz
Debby Steva

University of Utah
St. Joseph Hospital
Baystate Health
American Association of Physicists in Medicine (AAPM)
unaffiliated
Baystate Health
Cedar Sinai Medical Center
American College of Radiology
University of Pittsburgh
University of Virginia

**Advisory Committee on the Medical Uses of Isotopes
TELECONFERENCE AGENDA
Friday, June 24, 2016
3:00 PM – 5:00 PM (ET)**

OPEN SESSION

3:00 – 4:00 pm

Discuss the Draft ACMUI Radioactive Seed Localization Subcommittee Report

4:00 – 5:00 pm

Discuss Potential Rulemaking to Expand the Financial Assurance Requirements for Some Radioactive Byproduct Material in Title 10 *Code of Federal Regulations* Section 30.35