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

January 06, 2016

MEETING SUMMARY

PURPOSE

To discuss the Advisory Committee on the Medical Uses of Isotopes (ACMUI) subcommittee report on the ACMUI review of and comments on the draft final rule for Title 10 Code of Federal Regulations (CFR), Part 35, "Medical Use of Byproduct Material."

OUTCOME

The subcommittee provided a draft report for discussion with the full Committee. Subcommittee members included: Mr. Francis Costello, Dr. Ronald Ennis, Dr. Susan Langhorst, Mr. Steven Mattmuller, Ms. Laura Weil and Dr. Pat Zanzonico (Chair). During the meeting, the Committee unanimously approved the draft report with the modifications listed below. The U.S. Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the ACMUI. The final report will be submitted to the NRC staff, and the staff will consider the ACMUI's recommendations 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.

A full transcript and handout for the ACMUI teleconference meeting can be found on NRC's public website at http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/

The draft and final ACMUI Subcommittee report on the draft final rule is 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 Subcommittee Report on the Review and Comments of the Draft Final Rule for Title 10 Code of Federal Regulations (CFR), Part 35, "Medical Use of Byproduct Material."

RECOMMENDATIONS AND ACTIONS

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

1. Page 1: The Sub-Committee endorses that component of the current proposed rule re-defining medical events in permanent implant brachytherapy in terms of activity (i.e. source strength rather than radiation dose).

The recommendation was unanimously approved by the ACMUI.

2. Page 1: The Sub-Committee endorses, with reservation, designating the current proposed rule re-defining medical events in permanent implant brachytherapy as

Compatibility Category C, with activity-based medical event metrics defined as an essential program element.

The recommendation was unanimously approved by the ACMUI.

3. Page 1: The Sub-Committee recommends changing the language for a “wrong-location” medical event in permanent implant brachytherapy *from* the current proposed language,

> ”Sealed source(s) implanted directly into a location where the radiation from the source(s) will not contribute dose to the treatment site, as defined in the written directive,” *to*
>
> “Sealed source(s) implanted directly into a location discontiguous from the treatment site, as defined in the written directive.”

The recommendation was unanimously approved by the ACMUI.

4. Page 2: The Sub-Committee recommends revising the passage in lines 4182-4186 on page 167 in the Draft Final Rule as follows, thereby eliminating the dose-based criteria for a leaking source” medical event:

> “3) An administration that includes the wrong radionuclide; the wrong individual or human research subject; a leaking sealed source; or a sealed source or sources implanted into a location discontiguous from the treatment site, as defined in the written directive.”

The recommendation was unanimously approved by the ACMUI.

5. Page 2: The Sub-Committee endorses the elimination of the preceptor-statement requirement for Board-certified individuals for an individual seeking regulatory authorization as an authorized user, authorized medical physicist, Radiation Safety Officer, or authorized nuclear pharmacist.

The recommendation was unanimously approved by the ACMUI.

6. Page 2: With respect to the amended requirements for preceptor attestation for an individual seeking regulatory authorization as an authorized user, authorized medical physicist, Radiation Safety Officer, or authorized nuclear pharmacist through the alternate pathway, the Sub-Committee endorses changing the language for the preceptor attestation *from*

> the individual “…has achieved a level of competency to function independently…” for the authorization *to*
>
> the individual can “…independently fulfill the radiation safety-related duties…” associated with the authorization being requested.

The recommendation was unanimously approved by the ACMUI.

7. Page 2: The Sub-Committee recommends that the date of recognition by the NRC of a certifying board should *not* impact individuals seeking to be named as an authorized user, authorized medical physicist, Radiation Safety Officer, or authorized nuclear pharmacist through the certification pathway.

During the discussion, this recommendation was modified as follows:

The Sub-Committee recommends that NRC Staff consider providing guidance in the NUREG-1556, Volume 9 update to licensees on the ways individuals with board certifications prior to NRC's board recognition date may seek authorization.

The revised recommendation was unanimously approved by the ACMUI.

8. Page 2: The Sub-Committee recommends that the NRC adopt the parent-breakthrough limits for radioisotope generators specified in the relevant FDA-approved package inserts.

During the discussion, the Committee recommended to *eliminate* this recommendation and instead, revise the general comments section of the report to suggest that NRC consider, in *future* rulemaking, establishing conformity with the FDA breakthrough-limit regulations.

The recommendation passed; however, Dr. Langhorst opposed.

9. Page 2: The Sub-Committee does *not* endorse the new requirement in the Draft Final Rule that licensees report to the NRC as well as to the manufacturer/vendor generator elutions with out-of-tolerance parent-breakthrough but, instead, recommends a single reporting requirement to the manufacturer/vendor.

The recommendation was unanimously approved by the ACMUI.

10. Page 3: The Sub-Committee endorses allowing Associate Radiation Safety Officers (ARSO) to be named on a medical license.

The recommendation was unanimously approved by the ACMUI.

11. Page 3: The Sub-Committee recommends that the designation of a board-certified authorized user, authorized medical physicist, or authorized nuclear pharmacist as the RSO or as an ARSO requires their board certification to include the designation, "RSO Eligible."

The recommendation was unanimously approved by the ACMUI.

12. Page 3: The Sub-Committee does *not* endorse establishing a separate category of Authorized Users for parenteral administration of alpha-emitting radiopharmaceuticals but, instead, recommends deleting § 35.390(b)(1)(ii)(G)(4) in the current Draft Final Rule and revising the pertinent passage in § 35.390(b)(1)(ii)(G)(3) as follows,

> "Parenteral administration of any radioactive drug for which a written directive is required."

The recommendation was unanimously approved by the ACMUI.

13. Page 3: The Sub-Committee endorses the elimination of the requirement to submit copies of NRC Form 313, Application for Material License, or a letter containing information required by NRC Form 313 when applying for a license, an amendment, or renewal.

    The recommendation was unanimously approved by the ACMUI.

14. Page 3: The Sub-Committee recommends changing the "medical-events" language in lines 5531-5532 (page 232) of the Draft Final Rule *from*,

    > "A licensee shall report as a medical event, any administration requiring a written directive, except for an event that results from patient intervention…," *back to the language in the current Draft Final Rule,*
    >
    > "A licensee shall report any event, except for an event that results from patient intervention…"

During the discussion, the recommendation was modified as follows:

The Sub-Committee recommends changing the "medical-events" language in lines 5531-5532 (page 232) of the current version of the Draft Final Rule *from*,

"A licensee shall report any event, except for an event that results from patient intervention…" back to the language published in the Proposed Rule as presented for public comment,

"A licensee shall report as a medical event, any administration requiring a written directive, except for an event that results from patient intervention…,"

The recommendation was unanimously approved by the ACMUI.

The Draft Comments on the Draft Final Rule for 10 CFR Parts 30, 32, and 35 Subcommittee Report (ML15357A469) was unanimously approved by the full ACMUI. The Final Comments on the Draft Final Rule for 10 CFR Parts 30, 32, and 35 Report (ML16007A771) is posted on the ACMUI Subcommittee Report Webpage.

Attachments:

List of Attendees

MEETING ATTENDEES

ACMUI

Philip O. Alderson, M.D.	Chairman
Pat B. Zanzonico, Ph.D.	Vice Chairman
Francis M. Costello	Member
Vasken Dilsizian, M.D.	Member
Ronald D. Ennis, M.D.	Member
Susan M. Langhorst, Ph.D.	Member
Steven R. Mattmuller	Member
Michael D. O'Hara, Ph.D.	Member
Christopher J. Palestro, M.D.	Member
John H. Suh, M.D.	Member
Laura M. Weil	Member
Darlene F. Metter, M.D.	Non-Voting Member
Zoubir Ouhib	Non-Voting Member

NRC

Pamela Henderson	Acting Director, Division of Material Safety, State, Tribal and Rulemaking Programs (MSTR)
Douglas Bollock	Branch Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Sophie Holiday	Alternate Designated Federal Officer/ACMUI Coordinator
Michael Fuller	Medical Radiation Safety Team Leader
Maryann Abogunde	NMSS
Neelam Bhalla	NMSS
Jennifer Bishop	RIII
Jackie Cook	RIV
Said Daibes, Ph.D.	NMSS
Anthony Delamotte	NMSS
Sara Forster	RIII
Farrah Gaskins	RI
Vincent Holahan, Ph.D.	NMSS
Esther Houseman	OGC
Donna-Beth Howe, Ph.D.	NMSS
Erin Kennedy	RIII
Jan Nguyen	RI
Patty Pelke	RIII
Gretchen Rivera-Capella	NMSS
Lizette Roldan-Otero	NMSS
Vered Schaffer	RIII
Alexa Sieracki	NMSS
Toye Simmons	RIII
Katherine Tapp, Ph.D.	NMSS
Torre Taylor	NMSS
Roberto Torres	RIV
Lester Tripp	RI
Duncan White	NMSS

MEMBERS OF THE PUBLIC

Robert Dansereau	New York State Department of Health
Miguel de la Guardia	Cook Children's Health Care System
Susan Elliott	Arkansas Department of Health
Sandra Gabriel	*unaffiliated*
Michael Guastella	Council on Radionuclides and Radiopharmaceuticals
Angie D. Hall	Arkansas Department of Health
Yungmi Kim	Spectrum Pharmaceuticals, Inc.
Caitlin Kubler	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Karen Langley	University of Utah
Ralph Lieto	St. Joseph Mercy Health System
Sam Leveritt	Cardinal Health
Gary Lunger	Bayer
Steve Mack	Arkansas Department of Health
Michael Miller	Spectrum Pharmaceuticals, Inc.
Michael Peters	American College of Radiology (ACR)
Josephine Piccone	*unaffiliated*
Amy Schoppman	Webster Chamberlain & Bean LLP
Michael Sheetz	University of Pittsburgh
David Stephens	Arkansas Department of Health
Bruce Thomadsen	University of Wisconsin
Jared Thompson	Arkansas Department of Health
Cindy Tomlinson	American Society of Radiation Oncology (ASTRO)
Michael Welling	Virginia Department of Health