

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

September 29-30, 2014

MEETING SUMMARY

PURPOSE

To discuss current rulemaking activities and other issues related to the implementation of the medical regulations in Title 10, Code of Federal Regulations (CFR), Part 35, and “Medical Use of Byproduct Material.”

OUTCOME

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

RECOMMENDATIONS AND ACTIONS

The following recommendations and actions are a result of the discussions that took place on the topics listed on the ACMUI meeting agenda (Attachment 2).

The Committee endorsed the Y-90 Microsphere Brachytherapy Medical Event Criteria Subcommittee Report. This included the following recommendations:

- 1) Specification of an “acceptable” GI tract and lung dose/activity in the written directive prior to performance of the Y-90 microsphere embolization procedure should NOT be required. Instead, the total treatment activity of Y-90 microspheres to be administered should be the required compliance measure for organs and tissues other than the treatment site;
- 2) The implantation of the microsphere brachytherapy sources is considered to be in accordance with the written directive if the total administered/infused activity does not vary from the activity prescribed in the written directive by 20% or more; except on situations in which the activity administered is limited by the termination of procedure due to stasis; and
- 3) The above recommendations be incorporated into the NRC guidance for Y-90 microsphere brachytherapy, and that NRC staff, in consultation with ACMUI, compose and disseminate explanation of these recommended revisions in a manner best suited to both the NRC as well as to AUs and other stakeholders tasked with compliance.

The recommendations passed unanimously by the Committee with thirteen favorable votes.

The Committee endorsed the revisions to the ACMUI Bylaws presented, which includes the proposed language in section 1.3.5 and 3.1 and changes to reflect the new office structure.

Chairman of the ACMUI, Dr. Thomadsen, tasked Dr. Langhorst and Mr. Costello with creating a proposal to present to the Committee and staff regarding the costs and logistics for an additional

face-to-face meeting and/or a medical regulatory information conference. They will present this proposal at the spring 2015 meeting. The NRC staff resource is Dr. Daibes.

Dr. Thomadsen tasked Dr. Suh and Dr. Welsh to work with the American Society for Radiation Oncology for their proposed changes to the language in the Draft FY15 Water and Energy Bill. Dr. Ennis will serve as a consultant to Drs. Suh and Welsh until he assumes the role of the ACMUI's Brachytherapy Radiation Oncologist in February 2015. Dr. Ennis and Dr. Suh will present the language to the Committee at the spring 2015 meeting.

Dr. Thomadsen formed a subcommittee to review the advanced notice of proposed rulemaking for Title 10 Code of Federal Regulations Part 20, "Standards for Protection Against Radiation." Subcommittee members include: Dr. Langhorst (chair), Mr. Costello, Dr. Dilsizian, Mr. Mattmuller, and Dr. Zanzonico. The subcommittee will present their recommendations at a future teleconference.

The Committee planned to hold the spring 2015 ACMUI Meeting on March 19-20, 2015 at NRC Headquarters. The back-up meeting date is either March 23-24, 2015 or April 13-14, 2015.

Attachments:

Attachment 1: Attendees

Attachment 2: Meeting Agenda

MEETING ATTENDEES

ACMUI

Philip O. Alderson, M.D.	Member
Francis M. Costello	Member
Vasken Dilsizian, M.D.	Member
Milton S. Guiberteau, M.D.	Vice Chairman
Susan M. Langhorst, Ph.D.	Member
Steven R. Mattmuller	Member
Christopher J. Palestro, M.D.	Member
John H. Suh, M.D.	Member
Orhan Suleiman, Ph.D.	Member
Bruce R. Thomadsen Ph.D.	Chairman
Laura M. Weil	Member
James S. Welsh, M.D.	Member
Pat B. Zanzonico, Ph.D	Member

NRC

Brian Holian	Acting Director, Office of Federal and State Materials and Environmental Management Programs (FSME)
Raymond Lorson	Acting Deputy Director, Office of Federal and State Materials and Environmental Management Programs (FSME)
Laura Dudes	Director, Division of Materials Safety and State Agreements (DMSSA)
Pamela Henderson	Deputy Director, Division of Materials Safety and State Agreements (DMSSA)
Susan Abraham	Acting Deputy Director, Division of Materials Safety and State Agreements (DMSSA)
Douglas Bollock	Acting Chief, Radioactive Materials Safety Branch (RMSB)
Michael Fuller	Medical Radiation Safety Team Leader and Alternate Designated Federal Officer
Sophie Holiday	Alternate Designated Federal Officer and ACMUI Coordinator
Maryann Abogunde	FSME
Luis Benevides, Ph.D.	RES
Susan Chidakel	OGC
Ashley Cockerham	FSME
Jackie Cook	Region IV
Said Daibes, Ph.D.	FSME
Gina Davis	FSME
Sara Forster	Region III
Cassandra Frazier	Region III
Sandra Gabriel, Ph.D.	FSME
Joseph Gilman	OGC
Latischa Hanson	Region IV
Michelle Hammond	Region IV
Vincent Holahan, Ph.D.	FSME
Donna-Beth Howe, Ph.D.	FSME
Angela McIntosh	FSME
Joyce Merilos	OGC
Robert Norman	NSIR

Kevin Null
Patty Pelke
Brooke Poole
Gretchen Rivera-Capella
Katie Tapp, Ph.D.

Region III
Region III
OGC
FSME
RES

MEMBERS OF THE PUBLIC

Debra Bensen
Jennifer Elee

Ronald Ennis, M.D.

Lynne Fairbent
Debbie Gilley
Steven Goetsch, Ph.D.
Caitlin Kubler

Michael Peters
Gloria Romanelli
Cindy Tomlinson
C. Gibb Vinson
Mark Williams
Paul Yurko

Elekta
Conference for Radiation Control Program Directors,
Louisiana Department of Environmental Quality
American Society for Radiation Oncology (ASTRO), Mount
Sinai Roosevelt Hospital
American Association of Physicists in Medicine (AAPM)
American Association of Physicists in Medicine (AAPM)
Dade Moeller Health
Society of Nuclear Medicine and Molecular Imaging
(SNMMI)
American College of Radiology (ACR)
American College of Radiology
American Society for Radiation Oncology (ASTRO)
Illinois Emergency Management Agency
Tripler Army Medical Center
Veterans Health Administration

MEETING AGENDA ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

September 29-30 2014
Two White Flint North Building (T2-B3), Rockville, Maryland

NOTE: Sessions of the meeting may be closed pursuant to 5 U.S.C. 552(b) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACMUI; information the release of which would constitute a clearly unwarranted invasion of personal privacy; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and disclosure of information which would risk circumvention of an agency regulation or statute.

Monday, September 29, 2014

OPEN SESSION

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| 8:30 – 8:45 | 1. Opening Statements
Mr. Fuller will formally open the meeting and Ms. Dudes will provide opening comments. | M. Fuller, NRC
L. Dudes, NRC |
| 8:45 – 9:00 | 2. Old Business
Ms. Holiday will review past ACMUI recommendations and provide NRC responses. | S. Holiday, NRC |
| 9:00 – 9:45 | 3. Physical Presence Requirements for Perfexion™
Dr. Suh and Dr. Howe will discuss the existing physical presence requirements for the Leksell Gamma Knife® Perfexion™ licensed under 10 CFR 35.1000. | J. Suh, ACMUI
D. Howe, NRC |
| 9:45 – 10:00 | B R E A K | |
| 10:00 – 10:30 | 4. Licensing Under 10 CFR 35.1000
Ms. Holiday will provide information on how NRC determines which emerging medical technologies are licensed under 35.1000 and how licensing guidance is developed. | S. Holiday, NRC |
| 10:30 – 11:30 | 5. Y-90 Microspheres ME Subcommittee Report
Dr. Guiberteau will discuss the subcommittee's recommendations regarding the current medical event reporting criteria for yttrium-90 microspheres. | M. Guiberteau, ACMUI |
| 11:30 – 1:00 | L U N C H | |
| 1:00 – 1:30 | 6. FDA's Role in the Global Mo-99 Shortage
Dr. Suleiman will discuss the FDA's role related to the global shortage of molybdenum-99. | O. Suleiman, ACMUI |
| 1:30 – 1:45 | 7. ACMUI Bylaws
Dr. Zanzonico will discuss the proposed revisions to the ACMUI bylaws. | P. Zanzonico, ACMUI |
| 1:45 – 2:20 | 8. Release of Patients Administered Radionuclides
Dr. Howe will provide an update on the staff's efforts related to the release of patients administered radioactive material. | D. Howe, NRC |
| 2:20 – 2:30 | 9. Follow-up to the May 2014 ACMUI Commission Meeting
Ms. Holiday will discuss the direction received from the Commission | S. Holiday, NRC |

following its meeting with the ACMUI on May 9, 2014.

2:30 – 3:00 **10. Safety Culture: Interactions Between Licensees and Regulators** **S. Langhorst, ACMUI**
 Dr. Langhorst will expand upon the discussion from the May 9, 2014 ACMUI Commission Meeting regarding safety culture.

3:00 – 3:30 **B R E A K**

3:30 – 4:15 **11. Enhancing Interactions Between the NRC and the Medical Community** **S. Langhorst, ACMUI**
Dr. Langhorst will discuss possible mechanism to enhance the relationship and interactions between the NRC and the medical community.

4:15 – 5:00 **12. Medical Events Subcommittee Report** **J. Welsh, ACMUI**
 Dr. Welsh will discuss the subcommittee report on medical events for fiscal year 2013.

Tuesday, September 30, 2014

OPEN SESSION

8:00 – 9:30 **13. Event Reporting Mechanisms** **ASTRO/AAPM, CRCPD, ROIR, SAFRON**
 Multiple organizations will discuss and share information related to their event reporting databases.

9:30 – 10:00 **14. Publicly Available NMED** **A. McIntosh, NRC**
 Ms. McIntosh will discuss the public availability of the NRC's event reporting database system; the Nuclear Materials Event Database (NMED).

10:00 – 10:15 **B R E A K**

10:15 – 10:30 **15. Special Presentation to Dr. Welsh** **B. Holian, NRC**
 Mr. Holian will make a special presentation to Dr. Welsh for his years of service on the ACMUI and to the NRC.

10:30 – 10:45 **16. Remarks from Dr. Welsh** **J. Welsh, ACMUI**
 Dr. Welsh will provide his perspectives about serving on the ACMUI.

10:45 – 11:00 **17. Administrative Closing** **S. Holiday, NRC**
 Ms. Holiday will provide a meeting summary and propose dates for the next meeting.

11:00 – 12:30 **L U N C H**

CLOSED SESSION

12:30 – 1:00 **18. Allegations** **J. Gilman, NRC**

1:00 – 1:30 **19. Ethics Training** **J. Merilos, NRC**

1:30 – 2:00 **20. INFOSEC Training** **S. Hawkins, NRC**
R. Norman, NRC

2:00 **A D J O U R N**