

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

October 8-9, 2015

MEETING SUMMARY

PURPOSE

To discuss 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 recommended to make the following change to the Patient Intervention Subcommittee Recommendation Issue II:

Unintentional Treatment outcome due to anatomic or physiologic anomaly and/or imaging uncertainty falls into the category "the Art of Medical Practice" provided that the standards of medical practice are met.

The Committee endorsed the Patient Intervention Subcommittee Report with the caveat that the revision be made to issue II (referenced immediately above).

The Committee recommended that staff issue a Generic Communication (i.e. Information Notice or Regulatory Issue Summary) to licensees to inform them of the interpretation of "patient intervention."

Dr. Thomadsen, ACMUI Chairman, charged the Training and Experience (T&E) for Alpha and Beta Emitters Subcommittee with establishing a recommendation for the total number of hours of T&E for authorized users of such emitters that is necessary for safety. This subcommittee will present its recommendation(s) at the spring 2016 meeting.

Dr. Ennis recommended that the individual who implants the source for radioactive seed localization be the authorized user only - and not an individual under the supervision of an authorized user. [Note: The motion did not pass.]

The Committee recommended that the individual who implants the source for radioactive seed localization procedures can do so under the supervision of an authorized user.

The Committee endorsed the Radioactive Seed Localization Subcommittee Report.

The Committee endorsed the Yttrium-90 (Y-90) Microspheres Subcommittee Report. This report supported the proposed revisions to the (Y-90) licensing guidance.

The Committee planned to hold the spring 2016 ACMUI Meeting on March 17-18, 2016 at NRC Headquarters. The back-up meeting date is March 3-4, 2016.

The Committee endorsed the 2015 Abnormal Occurrence Criteria Subcommittee Report with the caveat that the report be amended to include an introductory paragraph that provides the rationale for the recommendations, as well as a summary paragraph to state that the Committee desires that the recommendations be incorporated into this revision of the NRC's Abnormal Occurrence Criteria Policy Statement.

The Committee endorsed the NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses," Subcommittee Report.

Dr. Thomadsen formed a subcommittee to propose the appropriate criteria for Medical Event Reporting for events other than permanent implant brachytherapy. Subcommittee members include: Dr. Dilsizian, Dr. Ennis, Mr. Ouhib, Dr. Palestro, Dr. Suh (Chair), and Dr. Zanzonico. The subcommittee will present its recommendations at the Spring 2016 meeting.

Attachments:

- Attachment 1: Attendees
- Attachment 2: Meeting Agenda

MLXXXXXXXXXXXXXXX

OFC	MSTR/MSEB	MSTR/MSEB
NAME	S. Holiday	D. Bollock
DATE	10/15/2015	10/16/2015

MEETING ATTENDEES

ACMUI

Philip O. Alderson, M.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
Bruce R. Thomadsen Ph.D.	Chairman
Laura M. Weil	Member
Pat B. Zanzonico, Ph.D	Member
<i>Darlene F. Metter M.D.</i>	<i>Member-elect (non-voting)</i>
<i>Zoubir Ouhib</i>	<i>Member-elect (non-voting)</i>

NRC

Stephen G. Burns	Chairman, U.S. Nuclear Regulatory Commission
Josie Piccone, Ph.D.	Director, Division of Material Safety, State, Tribal and Rulemaking Programs (MSTR)
Chris Einberg	Acting 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
Maryann Abogunde	NMSS
Bernice Ammon	OGC
Steven Baggett	COMM/OCM
Tamara Bloomer	COMM/OCMWO
Ashley Cockerham	NMSS
Jackie Cook	Region IV
Said Daibes, Ph.D.	NMSS
Anthony Delamotte	NMSS
Cassandra Frazier	Region III
Michael Fuller	NMSS
Sarenee Hawkins	NMSS
Tomas Herrera	NMSS
Eliza Hilton	NMSS (<i>on rotation to</i>)
Vinh Hoang	OGC
Vincent Holahan, Ph.D.	NMSS
Esther Houseman	OGC
Donna-Beth Howe, Ph.D.	NMSS
Tom Lourenco	OCFO
Angela McIntosh	NMSS
Joyce Merilos	OGC
Eric Michel	OGC
Johari Moore	COMM/OCM
Rob Norman	NSIR
Jan Nguyen	RI
Kevin Null	RIII
Diane Render, Ph.D.	NRR

Attachment 1

Nilda Rivera	NSIR
Gretchen Rivera-Capella	NMSS
Alex Sapountzis	NSIR
Julian Sessoms	NMSS
JoAnn Simpson	OCFO
Zahid Sulaiman	RIII
Jeremy Suttenger	OGC
Torre Taylor	NMSS
Charles Teal	NSIR
Lester Tripp	RI
John Walker	OCFO
Sheena Whaley	NMSS

MEMBERS OF THE PUBLIC

Bette Blankenship	American Association of Physicists in Medicine (AAPM)
Andrew Buchan	Siemens Medical Solutions USA, Inc.
Brian Carey	Spectrum Pharmaceuticals
Bonnie Clarke	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Charles Coleman	Virginia Department of Health
Peter Crane	<i>unaffiliated</i>
Jennifer Cultrera	Spectrum Pharmaceuticals
Robert Danseareau	New York State Department of Health
William Davidson	University of Pennsylvania
Karen Flanigan	NJ Department of Environmental Protection
James Harvey	NorthStar Medical Technologies, LLC
Yungmi Kim	Spectrum Pharmaceuticals
Caitlin Kubler	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Karen Langley	University of Utah
Josh Mailman	NorCal CarciNET
Richard Martin	American Association of Physicists in Medicine (AAPM)
Candi McDowell	University of Pennsylvania
Gene Menendez	Spectrum Pharmaceuticals
Clarine Nardi Riddle	Spectrum Pharmaceuticals
Richard Peros	NJ Department of Environmental Protection
Michael Peters	American College of Radiology (ACR)
Gloria Romanelli	American College of Radiology (ACR)
Angelique Rowley	Spectrum Pharmaceuticals
Daniel Samson	New York State Department of Health
Karen Sheehan	Fox Chase Cancer Center
Michael Sheetz	University of Pittsburgh
Cindy Tomlinson	American Society for Radiation Oncology (ASTRO)
Ed Truskowski	NJ Department of Environmental Protection
Allen Yang	Spectrum Pharmaceuticals

MEETING AGENDA ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

October 8-9, 2015

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.

Thursday, October 08, 2015		
CLOSED SESSION		
7:30 – 8:30	1. Badging and Enrollment	ACMUI
OPEN SESSION		
8:30 – 8:45	2. Opening Statements Mr. Bollock will formally open the meeting and Dr. Piccone will provide opening comments.	D. Bollock, NRC J. Piccone, NRC
8:45 – 9:00	3. Old Business Ms. Holiday will review past ACMUI recommendations and provide NRC responses.	S. Holiday, NRC
9:00 – 9:15	4. Open Forum The ACMUI will identify medical topics of interest for further discussion.	ACMUI
9:15 – 10:00	5. Patient Intervention Subcommittee Report Dr. Dilsizian will discuss the subcommittee's recommendation for the definition of patient intervention.	V. Dilsizian, ACMUI
10:00 – 10:15	BREAK	
10:15 – 11:00	6. Training and Experience for Alpha and Beta Emitters Subcommittee Report Dr. Palestro will discuss the subcommittee's comments on the existing 700 hour T&E requirements for authorized users of alpha and beta emitters.	C. Palestro, ACMUI
11:00 – 11:30	7. Radioactive Seed Localization Subcommittee Report Dr. Ennis will discuss the revisions to the subcommittee's report.	R. Ennis, ACMUI
11:30 – 1:00	LUNCH	
1:00 – 1:30	8. GARS Working Group Mr. Herrera will provide an overview of the working group's objectives and activities.	T. Herrera, NRC
1:30 – 2:00	9. Yttrium-90 Microspheres Licensing Guidance Dr. Palestro will provide the subcommittee's comments on the proposed revisions to the Y-90 microspheres brachytherapy licensing guidance.	C. Palestro, ACMUI

Attachment 1

2:00 – 2:30 **10. Germanium/Gallium-68 Medical Use Generator Update** **S. Daibes, NRC**
Dr. Daibes will provide an update on staff's efforts to address the decommissioning funding issues related to the germanium/gallium-68 medical use generator.

2:30 – 3:00 **BREAK**

CLOSED SESSION

3:00 – 3:30 **11. ETHICS Training** **J. Merilos, NRC**
3:30 – 4:00 **12. INFOSEC Training** **R. Norman, NRC**
4:00 – 5:00 **13. E2 Travel Training** **OCFO Staff, NRC**
5:00 – 5:30 **14. Allegations Training** **S. Hawkins, NRC**

Friday, October 09, 2015
OPEN SESSION

8:00 – 8:45 **15. Medical Events Subcommittee Report** **R. Ennis, ACMUI**
Dr. Ennis will present the subcommittee's analysis of medical events for fiscal year 2015.

8:45 – 9:45 **16. ACMUI Comments on NUREG-1556, Volume 9** **S. Langhorst, ACMUI**
Dr. Langhorst will discuss the Committee's comments on the proposed revisions to NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses."

9:45 – 10:00 **17. Special Presentation to Dr. Thomadsen** **Chairman S. Burns, NRC**
Chairman Burns will make a special presentation to Dr. Thomadsen.

10:00 – 10:15 **18. 10 CFR Part 35 Rulemaking Update** **S. Whaley, NRC**
Ms. Whaley will provide an update on the 10 CFR Part 35 rulemaking effort.

10:15 – 10:30 **BREAK**

10:30 – 11:00 **19. Patient Release Workshops** **DB. Howe, NRC**
Dr. Howe will provide an update of the patient release project, as well as the upcoming patient release workshops.

11:00 – 11:30 **20. Abnormal Occurrence Criteria Subcommittee Report**
Dr. Langhorst will provide the subcommittee's comments on the proposed revisions to the NRC's Abnormal Occurrence Criteria Policy Statement.

11:30 – 1:00 **LUNCH**

1:00 – 1:45 **21. Thoughts on Leaving the ACMUI** **B. Thomadsen, ACMUI**
Dr. Thomadsen will provide his farewell remarks to the Committee and to staff.

Attachment 1

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| 1:45 – 2:30 | 22. NorthStar Generator
Dr. Harvey will provide an overview of NorthStar®'s approach to the production of molybdenum-99. | J. Harvey, NorthStar |
| 2:30 – 3:15 | 23. Additional Medical Meeting
Mr. Costello and Dr. Langhorst will discuss various options for an additional medical-related meeting. | S. Langhorst, ACMUI |
| 3:15 – 3:45 | 24. Open Forum
The ACMUI will discuss medical topics of interest previously identified. | ACMUI |
| 3:45 – 4:00 | 25. Administrative Closing
Ms. Holiday will provide a meeting summary and propose dates for the spring 2016 meeting. | S. Holiday, NRC |
| 4:00 | ADJOURN | |