

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

October 6-7, 2016

MEETING SUMMARY

PURPOSE

To discuss issues related to the implementation of the medical regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, and "Medical Use of Byproduct Material."

OUTCOME

The Advisory Committee on the Medical Uses of Isotopes (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 Web site: <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 (Enclosure 2).

Dr. Philip Alderson requested that the ACMUI discuss the nursing mother guidelines related to cessation of breast feeding by patients receiving radioactive materials during the Spring 2017 ACMUI Meeting.

The Committee recommended that staff issue a generic communication (information notice) regarding tubing issues (kinking, connection, hub etc.) during the administration of Y-90 microspheres brachytherapy.

Dr. Pat Zanzonico stepped down from the Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy Subcommittee and Dr. Alderson appointed Mr. Frank Costello to the Subcommittee. Subcommittee membership includes: Mr. Francis Costello, Dr. Vasken Dilsizian, Dr. Ronald Ennis, Dr. Christopher Palestro, and Dr. John Suh (Chair). Mr. Zoubir Ouhib will be added to the subcommittee once he receives full voting rights. Dr. Katie Tapp is the NRC resource.

Dr. Alderson re-established the Patient Intervention Subcommittee. The subcommittee's new charge is to make a recommendation on what the definition of "patient intervention" should be. Subcommittee membership includes: Mr. Costello, Dr. Dilsizian (Chair), Dr. Ennis, Dr. Suh, and Ms. Laura Weil. Ms. Maryann Abogunde is the NRC resource.

The Committee recommended that Pathway 2 remain for the Y-90 Microsphere Brachytherapy Licensing Guidance. The NRC/Organization of Agreement States working group should determine the requirements for proctoring cases by the manufacturer(s).

The Committee recommended to support the update to the waste disposal section and the review of the Y-90 radiation safety issues in autopsy and cremation in the draft revision of the Y-90 Microsphere Brachytherapy Licensing Guidance.

The following items are recommendations from the NorthStar Medical Radioisotopes LLC (NorthStar) RadioGenix™ Molybdenum-99 (Mo-99)/Technetium-99m (Tc-99m) Generator System Licensing Guidance Subcommittee Report:

The Committee recommended that NorthStar provide a training module video clip showing how the system operates.

Given the unique design and operation of the NorthStar system, the Committee agreed that NorthStar should have sole responsibility for the content of the training course and certification.

The Committee stated that it is important to clarify that a System Administrator can be any individual assigned by the Authorized User (AU) without a specifically defined educational or training background. Given the unique role of the System Administrator, perhaps that individual should be named on the license.

The Committee recommended an explicit statement regarding the System Administrator Designee, although it may not have been intended, one could infer from the description of the system administrator designee that there can be only one designee. Presumably, there can, and should, be multiple System Administrator designees.

The Committee recommended specifying the appropriate time period allotted for training on the “changes” and the responsibility of the vendor/manufacturer to inform and train the applicants on changes in a timely manner.

The Committee recommended that the guidance clarify whether the generator will be “non-operational” until all individuals handling the generator are trained in the changes, including the AU, Radiation Safety Officer, system administrator, etc. or whether it requires only the AU to be trained on the “changes.” If the latter, once the AU is trained on the “changes,” state whether the AU is solely responsible for training all others on these changes.

The Committee recommended using the term, “individual tasks” throughout the document for consistency and to clarify that there is only one protocol and software program with this system.

The Committee recommended that the manufacturer’s procedures be reviewed and incorporated into the Licensing Guidance itself.

The Committee recommended that the term “higher than expected” be defined in terms of a maximum specific exposure or exposure-rate limit which a survey meter should be capable of measuring.

The Committee unanimously endorsed the NorthStar Mo-99/Tc-99m Generator (RadioGenix™) Licensing Guidance Subcommittee Report.

The Committee tentatively scheduled the Spring 2017 Meeting for March 20-21, 2017. The back-up meeting dates are April 25-26, April 26-27, and April 27-28, subject to Commission availability.

Enclosures:

1. Attendees
2. Meeting Agenda

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OFC	MSTR/MSEB	MSTR/MSEB	MSTR/MSEB
NAME	M. Smethers	M. Fuller	D. Bollock
DATE	10/26/2016	10/27/2016	10/31/2016

OFFICIAL RECORD COPY

MEETING ATTENDEES

ACMUI

Philip O. Alderson, M.D.	Chairman
Francis M. Costello	Member
Vasken Dilsizian, M.D.	Member
Ronald D. Ennis, M.D.	Member
Susan M. Langhorst, Ph.D.	Member
Darlene F. Metter, M.D.	Member
Michael D. O'Hara, Ph.D.	Member
Christopher J. Palestro, M.D.	Member
John H. Suh, 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

Daniel Collins	Director, Division of Material Safety, State, Tribal and Rulemaking Programs (MSTR)
Pamela 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
Maryann Abogunde	NMSS
Said Daibes, Ph.D.	NMSS
Cliff Doutt	NRR
Michael Fuller	NMSS
Vincent Holahan, Ph.D.	NMSS
Esther Houseman	OGC
Donna-Beth Howe, Ph.D.	NMSS
Angela McIntosh	NMSS
Gretchen Rivera-Capella	NMSS
Reann Shane	COMM
Michelle Smethers	NMSS
Katie Tapp, Ph.D.	NMSS
Torre Taylor	NMSS
Jenny Weil	OCA

MEMBERS OF THE PUBLIC

Bette Blankenship	American Association of Physicists in Medicine (AAPM)
Kathleen Brill	Spectrum Pharmaceuticals
Sue Bunning	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Brian Carey	Spectrum Pharmaceuticals
Ashley Cockerham	Sirtex
Elaine Crescenzi	Pennsylvania Department of Environmental Protection
Jennifer Cultrera	Florida Cancer Specialists
William Davidson	University of Pennsylvania
Alberto DeJesus	Spectrum Pharmaceuticals
Morton Diamond	NSU Physician Assistant Program (FLL)
Adam Dicker	American Society for Radiation Oncology (ASTRO)
Jennifer Elee	Conference of Radiation Control Program Directors (CRCPD)
Brian Erasmus	BTG
Hugh Evans	Eckert & Ziegler Radiopharma, Inc.
Frank Facchini	BTG
Lynne Fairobent	American Association of Physicists in Medicine (AAPM)
Steven Fein	Miami Cancer Institute, Member of American Society of Hematology
Sandra Gabriel	International Atomic Energy Agency
Wendy Galbraith	University of Oklahoma College of Pharmacy
Munir Ghesani	NYU Medical Center
Ira Goldman	Lantheus Medical Imaging
Michael Guastella	Council on Radionuclides and Radiopharmaceuticals, Inc (CORAR)
Bonnie Hamilton	BTG
James Harvey	NorthStar Medical Radioisotopes, LLC
Georgia Hearn	American Society of Nuclear Cardiology (ASNC)
Nicki Hilliard	University of Arkansas for Medical Sciences
Clare Jennings	Bayer Healthcare
Jason Kelly	Texas Department of State Health Services
Ksenija Kapetanovic	American Society for Radiation Oncology (ASTRO)
Caitlin Kubler	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Joseph R. Mace	Florida Cancer Specialists
Carol Marcus	University of California Los Angeles
Richard Martin	American Association of Physicists in Medicine (AAPM)
Clarine Nardi Riddle	Spectrum Pharmaceuticals
Shahin Nassir Khani	Walter Reed National Military Medical Center
Abraham Oler	Spectrum Pharmaceuticals
Mark Paulson	Wisconsin Department of Health Services
Matthew Miller	Neal R. Gross
Michael Peters	American College of Radiology (ACR)
Devon Reed	United States Army
Gloria Romanelli	American College of Radiology (ACR)

Riad Salem
Karl Schwartz
Michael Sheetz
Rajesh Shrotriya
David Smith
Bruce Thomadsen
Cindy Tomlinson
Karl Von Ahn
Kara Weatherman
Kristina Wittstrom
Andrew Zach

BTG
Patients Against Lymphoma
University of Pittsburgh
Spectrum Pharmaceuticals
Medstar Georgetown University Hospital
Center for the Assessment of Radiological Sciences (CARS)
American Society for Radiation Oncology (ASTRO)
Texas Department of State Health Services
Purdue University
University of New Mexico
House Committee on Energy and Commerce

**MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES**

**October 6-7, 2016
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 06, 2016		
CLOSED SESSION		
7:00 – 8:00	1. Badging and Enrollment	ACMUI
OPEN SESSION		
	2. Opening Remarks Mr. Bollock will formally open the meeting and Mr. Collins will provide opening comments.	D. Bollock, NRC D. Collins, NRC
	3. Old Business Ms. Smethers will review past ACMUI recommendations and provide NRC responses.	M. Smethers, NRC
8:00 – 10:15	4. Open Forum The ACMUI will identify medical topics of interest for further discussion.	ACMUI
	5. Event Reporting Mechanisms Multiple organizations will discuss and share information related to their event reporting databases.	ASTRO/AAPM, CARS, CRCPD, IAEA
10:15 – 10:30	BREAK	
10:30 – 11:30	6. Medical Events Subcommittee Report Dr. Ennis will present the subcommittee's analysis of medical events for fiscal year 2015.	R. Ennis, ACMUI
11:30 – 1:00	LUNCH	
	7. Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy Dr. Suh will discuss the subcommittee's recommendations for the reporting of medical events.	J. Suh, ACMUI
1:00 – 2:30	8. 10 CFR Part 35 Rulemaking Update Ms. Taylor will provide an update on the 10 CFR Part 35 rulemaking effort.	T. Taylor, NRC
	9. NRC Comments on 'Patient Intervention' Mr. Fuller will discuss staff's comments in response to the ACMUI's Patient Intervention Subcommittee Report.	M. Fuller, NRC

2:30 – 3:00

BREAK

CLOSED SESSION

3:00 – 5:00

- 10. Ethics Training**
- 11. INFOSEC Training**
- 12. Allegations Training**

M. Clark, NRC
R. Norman, NRC
S. Hawkins, NRC

Friday, October 07, 2016

OPEN SESSION

8:00 – 10:15

- 13. Yttrium-90 Microspheres Brachytherapy Licensing Guidance**
 Dr. Tapp will provide an overview of the revisions to the Y-90 Microspheres Brachytherapy Licensing Guidance.
 Dr. Metter will provide the subcommittee’s comments on the proposed revisions.

K. Tapp, NRC
D. Metter, ACMUI

- 14. NRC’s Abnormal Occurrence Criteria Policy Statement Update**
 Dr. Oxenberg will provide an update on the proposed revisions to the Abnormal Occurrence Criteria Policy Statement.

T. Oxenberg, NRC

- 15. Training and Experience for All Modalities**
 Dr. Palestro will discuss the subcommittee’s comments on the T&E requirements for authorized individuals in 10 CFR Part 35.

C. Palestro, ACMUI

10:15 – 10:30

BREAK

10:30 – 11:30

- 16. Spectrum Pharmaceuticals Proposal for Training and Experience Requirements**
 Representatives from Spectrum Pharmaceuticals, Inc. will discuss their proposed revisions to the T&E requirements for alpha and beta emitters.

Spectrum Pharmaceuticals, Inc.

11:30 – 1:00

LUNCH

- 17. Worldwide Supply of Molybdenum-99**
 Mr. Green will provide an update of the world’s supply of moly-99.

R. Green, ACMUI

1:00 – 2:30

- 18. NorthStar Generator Licensing Guidance**
 Dr. Howe will provide an overview of the 10 CFR 35.1000 licensing guidance drafted by an NRC/OAS working group.
 Dr. Dilsizian will provide the subcommittee’s comments on the proposed guidance.

DB. Howe, NRC
V. Dilsizian, ACMUI

2:30 – 3:00

BREAK

- 19. Germanium-68/Gallium-68 Medical Use Generator Licensing Guidance**
 Dr. Tapp will provide an overview of the 10 CFR 35.1000 licensing guidance drafted by an NRC/OAS working group.

K. Tapp, NRC

3:00 – 4:00

20. Germanium-68/Gallium-68 Medical Use Generator Decommissioning Funding Plan 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.

21. Enhancing Communications with the Medical Community

P. Alderson, ACMUI

Dr. Alderson will provide an update on the ACMUI's efforts to improve the ACMUI and NRC's communications with various medical professional societies.

22. Administrative Closing

M. Smethers, NRC

Ms. **Smethers will** provide a meeting summary and propose dates for the spring 2017 meeting.

4:00

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