

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

September 20-21, 2018

MEETING SUMMARY

PURPOSE

To discuss issues related to Title 10 of the *Code of Federal Regulations* (10 CFR) part 35, "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 NRC 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 the ACMUI Meetings Web page, located on NRC's public Web site: <http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/>

RECOMMENDATIONS AND ACTIONS

The following recommendations and actions resulted from the discussions that took place on the topics listed on the ACMUI meeting agenda (Enclosure 2):

The Committee endorsed the report of the Subcommittee on the Nursing Mother Guidelines for the Medical Administration of Radioactive Materials with added language that this document reflects the FDA approved radiopharmaceuticals on the market at this time and that licensees are obligated to carefully evaluate radiopharmaceuticals that are not encompassed in this report to keep exposures ALARA to patients, staff, and members of the public. The recommendation passed unanimously with thirteen votes.

The Committee endorsed the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance Subcommittee Report. The recommendation passed unanimously with thirteen votes.

The NRC staff will provide the Committee with a copy of the Briefing on Results of the Agency Action Review Meeting presentation slides on Yttrium-90 microspheres; SECY-18-0048, "Annual Report to the Commission on Licensee Performance in the Nuclear Materials and Waste Safety Program Fiscal Year 2017," which includes a discussion on medical events involving Yttrium-90 microsphere brachytherapy; and the Strategic Programmatic Overview of the Fuel Facilities and Nuclear Materials Users Business Lines Commission meeting slides related to Yttrium-90.

Dr. Palestro amended the membership of the Training and Experience for All Modalities Subcommittee. Subcommittee membership now includes Dr. Metter (chair), Dr. Ennis, Dr. Schleipman, Ms. Weil, Ms. Shober, and Mr. Sheetz. The NRC staff resource continues to be Ms. Maryann Ayoade.

Dr. Palestro formed a subcommittee to review the Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance. Subcommittee membership includes Ms. Shober (chair), Dr. Metter, Mr. Sheetz, and Ms. Martin. The NRC staff resource is Dr. Said Daibes.

Dr. Palestro formed a subcommittee to review the revisions to Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material." Subcommittee membership includes Mr. Sheetz (chair), Ms. Shober, Dr. Dilsizian, Dr. Schleipman, Ms. Martin, and Ms. Weil. The NRC staff resource is Dr. Said Daibes.

Dr. Palestro formed a subcommittee to review the Yttrium-90 Microspheres Brachytherapy Sources and Devices TheraSphere® and SIR_Spheres® Licensing Guidance. Subcommittee membership includes Dr. O'Hara (chair), Dr. Dilsizian, Mr. Ouhib, Ms. Marin, Dr. Metter, and Dr. Schleipman. The NRC staff resource is Dr. Katie Tapp.

Dr. Palestro formed a subcommittee to review and update the ACMUI Bylaws as needed, including a review of the role of the ACMUI Chair and his or her participation on subcommittees. Subcommittee membership includes Ms. Weil (chair), Dr. Schleipman, Ms. Shober, and Mr. Sheetz. The NRC staff resource is Ms. Sophie Holiday.

Dr. Palestro formed a subcommittee to review the appropriateness of the required elements of medical event reporting, the adherence to these requirements, and recommend actions to improve reporting. Subcommittee membership includes Dr. Ennis (chair), Ms. Weil, Ms. Martin, Mr. Ouhib, Dr. Dilsizian, and Ms. Shober. The NRC staff resource is Ms. Lisa Dimmick.

The Committee recommended for the NRC to draft an Information Notice on the best practices that could help prevent medical events.

The Committee requested a list of all the current ACMUI members, their contact information, information regarding each member's term, and the subcommittee(s) they serve on. The Committee also requested that the NRC staff create a web page that lists the active subcommittees and subcommittees that have been sunset, their members with term expiration, NRC staff resource, and the specific charge of the subcommittee.

The Committee tentatively scheduled the spring 2019 meeting for April 15-16, 2019. The alternate meeting dates are April 3-4, 2019, subject to Commission availability.

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

MEETING ATTENDEES

ACMUI

Vasken Dilsizian, M.D.	Member
Ronald D. Ennis, M.D.	Member
Richard L. Green	Member
Melissa Martin	Member
Darlene F. Metter, M.D.	Vice Chairman
Michael D. O'Hara, Ph.D.	Member
Zoubir Ouhib	Member
Christopher J. Palestro, M.D.	Chairman
A. Robert Schleipman, M.D.	Member
Michael Sheetz	Member
Megan L. Shober	Member
John H. Suh, M.D.	Member
Laura M. Weil	Member

NRC

Marc Dapas	Director, Office of Nuclear Material Safety and Safeguards (NMSS)
Sabrina Atack	Acting Deputy Director, Division of Materials Safety, State, and Tribal Programs (MSST)
Douglas Bollock	Chief, Medical Safety and Events Assessment Branch and Designated Federal Officer
Lisa Dimmick	Medical Radiation Safety Team Leader and Alternate Designated Federal Officer
Maryann Ayoade	NMSS/MSST
Russell Chazell	Office of the Secretary
Said Daibes, Ph.D.	NMSS/MSST
Christian Einberg	NMSS/MSST
Vincent Holahan, Ph.D.	NMSS/MSST
Sophie Holiday	Office of Enforcement
Esther Houseman	Office of the General Counsel (OGC)
Donna-Beth Howe, Ph.D.	NMSS/MSST
Ian Irvin	OGC
Janelle Jessie	Office of Commissioner Jeff Baran
Kathy Modes	NMSS/MSST
Katie Tapp, Ph.D.	NMSS/MSST
Irene Wu	NMSS/MSST

MEMBERS OF THE PUBLIC

Philip O. Alderson, M.D.	<i>Unaffiliated</i>
Bette Blankenship	American Association of Physicists in Medicine (AAPM)
Ashley Cockerham	Sirtex Medical Limited
Munir Ghesani, M.D.	Society for Nuclear Medicine & Molecular Imaging (SNMMI)

Michael Guastella	Council on Radionuclides and Radiopharmaceuticals (CORAR)
Caitlin Kubler	SNMMI
Akio Hori	Japan Nuclear Regulation Authority
Susan Lohman	Elekta
Richard Martin	AAPM
Michael Peters	American College of Radiology (ACR)
Aria Razmaria, M.D.	SNMMI
Gloria Romanelli	ACR
Daichi Saito	Japan Nuclear Regulation Authority
Cindy Tomlinson	American Society for Radiation Oncology (ASTRO)

MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
September 20–21, 2018

One White Flint North Building (Commission Hearing Room), 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, September 20, 2018
CLOSED SESSION

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| 7:30 – 10:30 | <ul style="list-style-type: none">• Badging and Enrollment• INFOSEC Training• Ethics Training• Allegations Training | PERSEC, NRC
R. Norman, NRC
J. Suttenger & J. Ezell, NRC
D. Willis, NRC |
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10:30 – 11:00 **BREAK**

OPEN SESSION

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| 11:00 – 11:45 | <ul style="list-style-type: none">• Opening Remarks
Mr. Bollock will formally open the meeting and Ms. Atack will provide opening comments.• Old Business
Ms. Dimmick will review past ACMUI recommendations and provide NRC responses.• Open Forum
The ACMUI will identify medical topics of interest for further discussion. | D. Bollock & S. Atack, NRC

L. Dimmick, NRC

ACMUI |
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11:45 – 12:45 **LUNCH**

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| 12:45 – 2:30 | <ul style="list-style-type: none">• Medical Events Subcommittee Report
Dr. Ennis will present the subcommittee's analysis of medical events for fiscal year 2017.• Non-Medical Events
Mr. Sheetz will did non-medical events reported by medical use facilities and commercial pharmacies.• ABS Medical Event Case Study Program
Mr. Ouhib will discuss the American Brachytherapy Society's effort to reach out to the brachytherapy community for creative corrective actions regarding events that have taken place. | R. Ennis, ACMUI

M. Sheetz, ACMUI

Z. Ouhib, ACMUI |
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2:30 – 2:45 **BREAK**

- 2:45 – 5:00
- **T&E for All Modalities Subcommittee Update** **D. Metter, ACMUI**
Dr. Metter will provide an update on the actions of the training and experience for all modalities subcommittee and the planned path forward.
 - **T&E Stakeholder Outreach Plan** **M. Ayoade, NRC**
Ms. Ayoade will present the staff's outreach plan for the continued evaluation of training and experience.
 - **ACMUI-SNMMI Session at the 2018 SNMMI Annual Meeting** **C. Palestro, ACMUI**
Dr. Palestro will provide an overview of the topics discussed by ACMUI at the 2018 SNMMI meeting in Philadelphia, PA.
 - **Nursing Mother Guidelines Subcommittee Report** **D. Metter, ACMUI**
Dr. Metter will discuss the subcommittee's final report on the nursing mother guidelines for exposure from diagnostic and therapeutic radiopharmaceuticals.
 - **ACMUI Comments on the Draft Revision of the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance** **J. Suh, ACMUI**
Dr. Suh will discuss the subcommittee's comments on the draft revision of the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ licensing guidance.

Friday, September 21, 2018
OPEN SESSION

- 8:30 – 10:15
- **Special Presentation to Dr. Suh** **M. Dapas, NRC**
Mr. Dapas will make a special presentation to Dr. Suh.
 - **Dr. Suh's Thoughts on Leaving ACMUI** **J. Suh, ACMUI**
Dr. Suh will share his thoughts on leaving the ACMUI.
 - **Special Presentation to Dr. Alderson** **M. Dapas, NRC**
Mr. Dapas will make a presentation to Dr. Alderson.
 - **Dr. Alderson's Thoughts on Leaving ACMUI** **P. Alderson, ACMUI**
Dr. Alderson will share his thoughts on leaving the ACMUI.
 - **Y-90 Microspheres Brachytherapy Licensing Guidance** **K. Tapp, NRC**
Dr. Tapp will discuss the current status of the yttrium-90 working group's revised guidance and planned actions.

10:15 – 10:45

BREAK

- 10:45 – 11:15
- **Compounding of Sterile and Non-Sterile Radiopharmaceuticals** **R. Green, ACMUI**
Mr. Green will discuss the establishment of an Expert Panel by USP to develop USP Standards of sterile and non-sterile radiopharmaceutical preparation.

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| 11:15 – 12:00 | <ul style="list-style-type: none"> • Medical Team Highlights
Ms. Dimmick will recap the work of the Medical Radiation Safety Team for fiscal year 2018. | L. Dimmick, NRC |
| | <ul style="list-style-type: none"> • Open Forum
The ACMUI will discuss medical topics of interest previous identified. | ACMUI |

12:00 – 1:00

LUNCH

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| 1:00 – 3:00 | <ul style="list-style-type: none"> • ACMUI, Subcommittees, NRC staff, NRC management: How the Team Works Under FACA
Mr. Chazell and Mr. Bollock will discuss the roles and responsibilities of each under the Federal Advisory Committee Act (FACA). | R. Chazell & D. Bollock, NRC |
| | <ul style="list-style-type: none"> • ACMUI Subcommittees, Subcommittee Membership, and the ACMUI Chair
Dr. Palestro will discuss the possible need for ACMUI bylaw changes and the need to update subcommittee membership, form new subcommittees and sunset other subcommittees. | C. Palestro, ACMUI |
| | <ul style="list-style-type: none"> • Administrative Closing
Ms. Dimmick will provide a meeting summary and propose dates for the spring 2019 meeting. | L. Dimmick, NRC |

3:00

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