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

July 16, 2018

MEETING SUMMARY

PURPOSE

To discuss the draft report of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Subcommittee on Training and Experience Requirements for All Modalities, which includes the subcommittee's comments and recommendations on the NRC staff's evaluation of the training and experience requirements for different categories of radiopharmaceuticals in Title 10 of the *Code of Federal Regulations* (10 CFR), Part 35, "Medical Use of Byproduct Material," Subpart E, "Unsealed Byproduct Material – Written Directive Required."

OUTCOME

The ACMUI Training and Experience Requirements for All Modalities Subcommittee provided a draft report for discussion with the full ACMUI. Subcommittee members included: Dr. Philip Alderson, Dr. Darlene Metter (Chair), Ms. Megan Shober, Dr. John Suh, and Ms. Laura Weil. The NRC staff gained a better understanding of the views and opinions of the Committee. The NRC staff will consider the Committee's comments and 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 Web site at: http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/.

The ACMUI Subcommittee Draft Report is available on NRC's public Web site under "ACMUI Subcommittee Reports": http://www.nrc.gov/reading-rm/doc-collections/acmui/reports/.

AGENDA TOPIC

Discuss the Draft Report of the ACMUI Subcommittee on Training and Experience Requirements for All Modalities

SUMMARY

The ACMUI Training and Experience Requirements for All Modalities Subcommittee provided a summary of the NRC staff's draft SECY paper and provided their comments and recommendations on the paper. The subcommittee recommended: (1) reconsideration of the existing pathways to an authorized user (AU) status; (2) that for the limited AU status, the educational program must be all inclusive to cover the knowledge topics required for all AUs involved in 10 CFR 35.300; (3) having an objective method to assess AU competency that documents both initial and maintenance of competency for the limited AU status; (4) the need for greater and broader stakeholder input on this topic; and (5) having NRC staff conduct ongoing monitoring for potential AU shortage for 10 CFR 35.300, including data on the geographic distribution and practice patterns of AUs. Additional comments were provided by external stakeholders including, the American Society of Radiation Oncology (ASTRO), Society

of Nuclear Medicine and Molecular Imaging (SNMMI), American College of Nuclear Medicine (ACNM), American College of Radiology (ACR), Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR), and Bayer Health Care.

The Draft Training and Experience Requirements for All Modalities Subcommittee Report (ML18186A517), including all of its recommendations in its entirety, was unanimously approved by the full ACMUI. The Final Training and Experience Requirements for All Modalities Subcommittee Report (ML18201A417) is posted on the ACMUI Subcommittee Reports Webpage.

Enclosures:
1. Meeting Attendees
2. Teleconference Agenda

MEETING ATTENDEES

ACMUI

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

NRC

Sabrina Atack	Acting, Deputy Director, Division of Materials Safety, Security, State, and Tribal Programs (MSST)
Douglas Bollock	Chief, Medical Safety and Events Assessment Branch, and Designated Federal Officer
Lisa Dimmick	Alternate Designated Federal Officer/Medical Radiation Safety Team Leader
Maryann Ayoade	Office of Nuclear Material Safety and Safeguards (NMSS)/MSST
Jacqueline Cook	Region IV
Samantha Crane	Office of Commissioner David A. Wright
Jennifer Dalzell	Region III
Chris Einberg	NMSS/MSST
Robin Elliott	Region I
Said Daibes, Ph.D.	NMSS/MSST
Farrah Gaskins	Region I
Richard Jervey	NMSS/Fuel Cycle Safety, Safeguards, and Environmental Review
Vincent Holahan, Ph.D.	NMSS/MSST
Sophie Holiday	NMSS/MSST
Esther Houseman	Office of the General Counsel
Penny Lanzisera	Region I
Tim Mossman	Office of the Executive Director for Operations
Patty Pelke	Region III
Shawn Seeley	Region I
Daniel Strohmeyer	Region III
Katherine Tapp, Ph.D.	NMSS/MSST
Lester Tripp	Region I
Irene Wu	NMSS/MSST

MEMBERS OF THE PUBLIC

Felicity Beckfield	University of Missouri
David Burpee	Bayer Health Care
Dalton Clark	SNMMI
Whitney Cox	Illinois Emergency Management Agency
Brian Erasmus	British Technology Group
Lynne Fairobent	*unaffiliated*
Sandy Gabriel	*unaffiliated*
Wendy Galbraith	The University of Oklahoma College of Pharmacy
Munir Ghesani	New York University Langone Health
Shaemus Gleason	Bayer Health Care
Bennett Greenspan	SNMMI
Michael Guastella	CORAR
Matthew Hadden	U.S. Department of Veterans Affairs
Stanley Hampton	Eli Lilly and Company
Scott Hudek	Advanced Accelerator Applications
Brandon Juran	Minnesota Department of Health
Caitlin Kubler	SNMMI
Sue Langhorst	*unaffiliated*
Cindi Luckett-Gilbert	Shertech Pharmacy
Carol Marcus	University of California, Los Angeles
Michael Peters	ACR
Gloria Romanelli	ACR
Rachel Semon	Advanced Accelerator Applications
Cindy Tomlinson	ASTRO
Paul Wallner	ACR
Kara Weatherman	Purdue College of Pharmacy
John Witkowski	United Pharmacy Partners, LLC
Miguel de la Guardia	Cook’s Children’s Hospital

Advisory Committee on the Medical Uses of Isotopes
TELECONFERENCE AGENDA
Monday, July 16, 2018
2:00 PM – 4:00 PM (ET)

OPEN SESSION

2:00 – 4:00 pm
Discuss the Draft Report of the ACMUI Subcommittee on Training and Experience Requirements for All Modalities, which will include the subcommittee's comments on the NRC staff's evaluation of the training and experience requirements for different categories of radiopharmaceuticals in Title 10 of the *Code of Federal Regulations* (10 CFR), Part 35, "Medical Use of Byproduct Material," Subpart E, "Unsealed Byproduct Material – Written Directive Required."