

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

March 1, 2018

MEETING SUMMARY

PURPOSE

To discuss the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Training and Experience Requirements for All Modalities Subcommittee's interim report on the recommendations for the total number of training and experience (T&E) hours for authorized users (AU) under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.300 that is necessary for safety.

OUTCOME

The ACMUI Training and Experience Requirements for All Modalities Subcommittee provided an interim report for discussion with the full Committee. Subcommittee members included: Dr. Darlene Metter, Dr. Christopher Palestro (Chair), 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 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 Interim 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 Interim Report of the ACMUI Training and Experience Requirements for All Modalities Subcommittee

SUMMARY

The ACMUI Training and Experience Requirements for All Modalities Subcommittee discussed two developments that indicated a need to reconsider the creation of an additional alternative pathway for AUs under 10 CFR 35.390. These developments include the U.S. Food and Drug Administration's approval of lutetium-177 dotatate for treatment of certain neuroendocrine tumors and the decrease in the number of first-time candidates sitting for the Certification Examination of the American Board of Nuclear Medicine. Due to future broad indications for use, this agent lutetium-177 is expected to have a considerable demand. Coupled with the waning number of first-time candidates of nuclear medicine physician as AUs eligible under the board certification pathway, the subcommittee believes there is reasonable concern for a near-future decline in patient access. Therefore, the subcommittee will review and evaluate T&E criteria for an additional alternate pathway.

The ACMUI Subcommittee on Training and Experience Requirements for All Modalities Interim Report (ML18051A725) is posted on the ACMUI Subcommittee Reports Webpage.

Attachments:

1. Meeting Attendees
2. Teleconference Agenda

MEETING ATTENDEES

ACMUI

Philip O. Alderson, M.D.	Chairman
Pat B. Zanzonico, Ph.D.	Vice Chairman
Vasken Dilsizian, M.D.	Member
Darlene F. Metter, M.D.	Member
Michael D. O'Hara, Ph.D.	Member
Christopher J. Palestro, M.D.	Member
Michael Sheetz	Member
John H. Suh, M.D.	Member
Laura M. Weil	Member
Richard Green	Non-Voting Member
Zoubir Ouhib	Non-Voting Member
Megan Shober	Non-Voting Member

NRC

Christian Einberg	Acting, Deputy Director, Division of Materials Safety, Security, State, and Tribal Programs (MSST)
Douglas Bollock	Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Sophie Holiday	Alternate Designated Federal Officer/ACMUI Coordinator
Maryann Ayoade	NMSS/MSST
Jennifer Bishop	RIII
Said Daibes, Ph.D.	NMSS/MSST
Robin Elliott	RI
Sara Forster	RIII
Latischa Hanson	RIV
Vincent Holahan, Ph.D.	NMSS/MSST
Esther Houseman	OGC
Donna-Beth Howe, Ph.D.	NMSS/MSST
Jan Nguyen	RI
Patricia Pelke	RIII
Gretchen Rivera-Capella	NMSS/MSST
Raeann Shane	NMSS
Zahid Sulaiman	RIII
Katherine Tapp, Ph.D.	NMSS/MSST
Lester Tripp	RI
Tara Weidner	RI
Jenny Weil	OCA
Irene Wu	NMSS/MSST

MEMBERS OF THE PUBLIC

Bette Blankenship	American Association of Physicists in Medicine (AAPM)
Mary Burkhart	Illinois Emergency Management Agency (IEMA)
David Burpee	Bayer Health Care
Whitney Cox	IEMA

Robert Dansereau
Brian Erasmus
Sherrie Flaherty
Karen Flanigan
Sandra Gabriel
Munir Ghesani
Bennett Greenspan

Michael Guastella
Caitlin Kubler
Ralph Lieto
Carol Marcus
Richard Martin
Michael Peters
Josephine Piccone
Wayne Powell
A. Robert Schleipman
Eugenio Silverstrini
Bobby Smith
Glenn Sullivan
Cindy Tomlinson
Tony Wang

James Yu

New York State Department of Health
British Technology Group (BTG)
Minnesota Department of Health
New Jersey Radioactive Materials Program
unaffiliated
New York University Langone Health
Society of Nuclear Medicine and Molecular Imaging
(SNMMI)
Council on Radionuclides and Radiopharmaceuticals
SNMMI
Saint Joseph Mercy Health System
University of California, Los Angeles
AAPM
American College of Radiology
unaffiliated
SNMMI
Partners Healthcare
Northwell Health
Mississippi Department of Health
Cardinal Health
American Society of Radiation Oncology
New York Presbyterian/Columbia University Medical
Center
Yale School of Medicine

**Advisory Committee on the Medical Uses of Isotopes
TELECONFERENCE AGENDA
Thursday, March 1, 2018
2:00 PM – 4:00 PM (ET)**

OPEN SESSION

2:00 – 4:00 pm

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