# 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: <a href="http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/">http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/</a>.

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

# **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 agentlutetium-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.

Darlene F. Metter, M.D.

Michael D. O'Hara, Ph.D.

Christopher J. Palestro, M.D.

Michael Sheetz

John H. Suh, M.D.

Laura M. Weil

Member

Member

Member

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

New York State Department of Health
Brian Erasmus

British Technology Group (BTG)

Sherrie Flaherty

Minnesota Department of Health

Karen Flanigan New Jersey Radioactive Materials Program

Sandra Gabriel unaffiliated

Munir Ghesani New York University Langone Health

Bennett Greenspan Society of Nuclear Medicine and Molecular Imaging

(SNMMI)

Michael Guastella Council on Radionuclides and Radiopharmaceuticals

Caitlin Kubler SNMMI

Ralph Lieto Saint Joseph Mercy Health System
Carol Marcus University of California, Los Angeles

Richard Martin AAPM

Michael Peters American College of Radiology

Josephine Piccone unaffiliated
Wayne Powell SNMMI

A. Robert Schleipman Partners Healthcare Eugenio Silverstrini Northwell Health

Bobby Smith Mississippi Department of Health

Glenn Sullivan Cardinal Health

Cindy Tomlinson American Society of Radiation Oncology

Tony Wang New York Presbyterian/Columbia University Medical

Center

James Yu 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