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

February 26, 2019

MEETING SUMMARY

PURPOSE

To discuss the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Training and Experience Requirements for All Modalities Subcommittee's draft report on the recommendations for the training and experience (T&E) requirements for authorized users (AUs) under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.300.

OUTCOME

The ACMUI Training and Experience Requirements for All Modalities Subcommittee provided a draft report for discussion with the full Committee. Subcommittee members included: Dr. Ronald Ennis, Dr. Darlene Metter (Chair), Dr. A. Robert Schleipman, Mr. Michael Sheetz, Ms. Megan Shober, 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 evaluation of whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, how those categories should be determined (such as by risks posed by groups of radionuclides or by delivery method), what the appropriate T&E requirements would be for each category, and whether those requirements should be based on hours of T&E or focused more on competency.

A full transcript and handout for the ACMUI teleconference meeting can be found on the NRC's public web site at: http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/.

The ACMUI Subcommittee final report is also available on the NRC's public web site at: http://www.nrc.gov/reading-rm/doc-collections/acmui/reports/.

AGENDA TOPIC

Discuss the ACMUI Training and Experience (T&E) Draft Subcommittee Report regarding the requirements for authorized users under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

SUMMARY

The ACMUI Training and Experience Requirements for All Modalities Subcommittee discussed its draft report, which focused on the T&E requirements for individuals authorized for the medical use of unsealed byproduct material for which a written directive is required under 10 CFR 35.390. In its report, the Subcommittee reviewed the current pathways for AU certification; addressed the concerns of a potential AU shortage; explored the concept of a limited-scope AU pathway tailored for specific radionuclide therapies; and expressed the need for an AU competency assessment.

RECOMMENDATIONS AND ACTIONS

The Training and Experience Requirements for All Modalities Subcommittee discussed the following recommendations in the draft subcommittee report:

1. *The Subcommittee strongly supports maintaining the current and existing AU pathways (board certification and alternate pathway) as codified in the regulations, which are adequate for protecting public health and safety.*

2. *The Subcommittee concludes that there is no objective data available to confirm an AU shortage.*

3. *The Subcommittee does not recommend a limited-scope AU pathway for unsealed byproduct material for which a written directive is required under 10 CFR 35.390.*

4. *The Subcommittee unanimously agrees that if the NRC chooses to pursue the creation of a limited-scope AU pathway for unsealed byproduct material where a written directive is required, the AU candidate must acquire the basic knowledge topics in 10 CFR 35.390 and satisfactorily complete a formal competency assessment. Additionally, the individual's continued status as limited-scope AU is dependent on successfully maintaining a formal periodic reassessment of competency.*

The ACMUI unanimously approved a modification to the report to note that if and when the NRC decides to pursue a limited-scope AU pathway for radionuclide therapy, the ACMUI endeavors to work with the NRC to develop the curriculum.

The draft Training and Experience Requirements for All Modalities Subcommittee Report (ML19039A113), with the aforementioned amendment, was approved by the full ACMUI, with one dissenting vote, during its public teleconference meeting on February 26, 2019.

The final report (ML19058A598) 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
Vasken Dilsizian, M.D.	Member
Ronald Ennis, M.D.	Member
Richard Green	Member
Melissa Martin	Member
Michael D. O'Hara, M.D.	Member
Zoubir Ouhib	Member
A. Robert Schleipman, M.D.	Member
Michael Sheetz	Member
Megan Shober	Member
Lisa Weil	Member
Harvey B. Wolkov, M.D.	Non-Voting Member

NRC

Andrea Kock	Director, Division of Materials Safety, Security, State, and Tribal Programs (MSST)
Christian Einberg	Chief, Medical Safety and Events Assessment Branch (MSEB)/Designated Federal Officer
Sophie Holiday	Designated Federal Officer
Kellee Jamerson	Designated Federal Officer/ACMUI Coordinator
Maryann Ayoade	NMSS/MSST/MSEB
Said Daibes, Ph.D.	NMSS/MSST/MSEB
Lisa Dimmick	Medical Radiation Safety Team Leader, NMSS/MSST/MSEB
Sara Forster	R-III/DNMS/MLB
Robert Gallaghar	R-I/DNMS/MLAB
Edward Harvey	R-III/DNMS/MIB
Esther Houseman	OGC/GCLR/RMR
Donna-Beth Howe, Ph.D.	NMSS/MSST/MSEB
Ian Irvin	OGC/GCLR/RMR
Donna Janda	R-I/DNMS/MLAB
Sarah Lopas	NMSS/MSST/MSEB
Kathy Modes	NMSS/MSST/ASPB
Janice Nguyen	R-I/DNMS/MLAB
Patty Pelke	R-III/DNMS/MLB
Zahid Sulaiman	R-III/DNMS/MIB
Katherine Tapp, Ph.D.	NMSS/MSST/MSEB

MEMBERS OF THE PUBLIC

Michael Baxter	American Pharmacists Association
Kendall Berry	Fox Chase Cancer Center
Janet Bukovcan	British Technology Group (BTG)
Mary Burkhart	Illinois Emergency Management Agency (IEMA)

William Chen	Unaffiliated
John Chippo	Pennsylvania Department of Environmental Protection (PDEP)
Thomas Conley	University of Kansas Medical Center
Whitney Cox	IEMA
David Crowley	North Carolina Department of Health and Human Services, Radiation Protection Section
Ariel Doucet	Virtua Health
Brian Erasmus	BTG
Lynne A. Fairobent	Unaffiliated
Sherrie Flaherty	Minnesota Radioactive Materials Unit
Mike Fuller	Virginia Department of Health (VDH)
Sandy Gabriel	Unaffiliated
Wendy Galbraith	University of Oklahoma Health Sciences Center
Bennett Greenspan, M.D.	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Miguel de la Guardia	Cook Children's Medical Center
Michael Guastella	Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR)
Stanley Hampton	Eli Lilly
Dan Hill	Cardinal Health
Daniel Januseski	Virtua Health
Tracy Jue	California Department of Public Health
Sue Langhorst, Ph.D.	Unaffiliated
Ralph Lieto	St. Joseph Mercy Health System
Cindi Luckett-Gilbert	Shertech Pharmacy
Carol Marcus, Ph.D, M.D.	University of California at Los Angeles (UCLA)
Richard Martin	American Association of Physicists in Medicine (AAPM)
Samuel Mehr, M.D.	Nebraska Cancer Specialists
Ashley Mishoe	University of California, San Francisco
Mary Moore	VDH
Joshua Myers	PDEP
Christopher Ott	PDEP
Brandon Paterson	Unaffiliated
Richard Peros	New Jersey Department of Environmental Protection (NJDEP)
Michael Peters	American College of Radiology (ACR)
Carmine Plott	Novant Health
Aria Razmaria, M.D.	UCLA Medical Center
Gloria Romanelli	ACR
George Segall, M.D.	American Board of Nuclear Medicine (ABNM)
Ben Seiber	PDEP
Beth Shelton	Tennessee Department of Environment and Conservation
Jeffry Siegel, Ph.D.	Nuclear Physics Enterprises
Daniel Strohmeyer	Unaffiliated
Cindy Tomlinson	American Society of Radiation Oncology (ASTRO)
Michael Ujhelyi	BTG
Paul Wallner, M.D.	21st Century Oncology, Inc.
Matthew Williamson	Memorial Sloan Kettering Cancer Center
Melonie Wissing	VDH
John Witkowski	United Pharmacy Partners (UPPI)

Advisory Committee on the Medical Uses of Isotopes
TELECONFERENCE AGENDA
Tuesday, February 26, 2019
10:00 AM – 12:00 PM (ET)

OPEN SESSION

10:00 am – 12:00 pm
Discuss the ACMUI Training and Experience (T&E) Draft Subcommittee Report regarding the requirements for authorized users under Title 10 Code of Federal Regulations (10 CFR) 35.300, "Use of unsealed byproduct material for which a written directive is required."