

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

October 17, 2019

**MEETING SUMMARY**

**PURPOSE**

Discuss the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Training and Experience (T&E) Draft Subcommittee Report regarding the U.S. Nuclear Regulatory Commission (NRC) staff's evaluation of the T&E requirements for radiopharmaceuticals under Title 10 *Code of Federal Regulations* (10 CFR) 35.300, "Use of unsealed byproduct material for which a written directive is required."

**OUTCOME**

The ACMUI T&E Subcommittee provided a draft report on their review of the NRC staff's evaluation of the T&E requirements for radiopharmaceuticals requiring a written directive for discussion with the full ACMUI. Subcommittee members included: Mr. Gary Bloom, Dr. Ronald Ennis, Dr. Darlene Metter, Dr. A. Robert Schleipman (chair), Mr. Michael Sheetz, and Ms. Megan Shoher. 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 the development of its Commission notation vote paper.

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 TOPICS**

Discuss the ACMUI T&E Subcommittee's report on the staff's evaluation of training and experience requirements for radiopharmaceuticals requiring a written directive.

**SUMMARY**

The ACMUI T&E Subcommittee discussed its review of the staff's preliminary draft Commission paper entitled, "Evaluation of Training and Experience Requirements for Administration of Radiopharmaceuticals Requiring a Written Directive." As provided in the draft subcommittee report, the subcommittee shared their comments on each of the staff's draft approaches.

**RECOMMENDATIONS AND ACTIONS**

**The ACMUI T&E Subcommittee provided the following recommendations in its draft subcommittee report:**

1. *The Subcommittee recommends maintaining the status quo under 10 CFR 35.390. While strongly affirming the structural superiority of the status quo over the other options proposed in the draft paper, we acknowledge there is room for a comprehensive review of the specific requirements in 35.390 such as the seemingly arbitrary requirement of 700 hours. The subcommittee (and likely, ACMUI) would welcome the opportunity to critically assess these details.*
2. *If the NRC proceeds to grant AU status by NRC-recognized specialty boards, the T&E should be equivalent to 35.390.*
3. *The Subcommittee recognizes the value of an alternate pathway and is willing to review and evaluate the requisite knowledge, preceptor-reviewed experience, and competency assessments.*

The draft T&E Subcommittee Report (ML19143A367), and all its recommendations provided therein, was unanimously approved by the ACMUI during its public teleconference meeting on October 17, 2019. The final report (ML19296D256) will be posted on the ACMUI Subcommittee Reports webpage.

Enclosures:

1. Meeting Attendees
2. Teleconference Agenda

## MEETING ATTENDEES

### ACMUJ

Darlene F. Metter, M.D.	Chairman
A. Robert Schleipman, Ph.D.	Vice Chairman
Vasken Dilsizian, M.D.	Member
Ronald Ennis, M.D.	Member
Richard Green	Member
Michael D. O'Hara, M.D.	Member
Zoubir Ouhib	Member
Michael Sheetz	Member
Megan Shober	Member

### NRC

Lisa Dimmick	Designated Federal Officer, Medical Radiation Safety Team Leader, NMSS/MSST/MSEB
Maryann Ayoade	NMSS/MSST/MSEB
Ian Irvin	OGC/GCLR/RMR
Sarah Lopas	NMSS/MSST/MSEB

### MEMBERS OF THE PUBLIC\*

Bette Blankenship	American Association of Physicists in Medicine
Roger Estafanos	Novartis
Michael Guastella	Council on Radionuclides and Radiopharmaceuticals, Inc.
Caitlin Kubler	Society of Nuclear Medicine and Molecular Imaging
James Logan	Bayer Healthcare
Carol Marcus, Ph.D, M.D.	University of California at Los Angeles (UCLA)
Richard Martin	AAPM
Aria Razmaria, M.D.	UCLA Medical Center
Gloria Romanelli	American College of Radiology
Bruce Thomadsen, M.D.	<i>Unaffiliated</i>
Cindy Tomlinson	American Society of Radiation Oncology

*\*This list is inconclusive of all teleconference participants.*

**Advisory Committee on the Medical Uses of Isotopes  
TELECONFERENCE AGENDA  
October 17, 2019  
2:00 PM – 4:00 PM (ET)**

**OPEN SESSION**

**2:00 PM – 4:00 PM**

Discuss the ACMUI Training and Experience (T&E) Draft Subcommittee Report regarding the NRC staff's evaluation of the T&E requirements for radiopharmaceuticals under Title 10 *Code of Federal Regulations* (10 CFR) 35.300, "Use of unsealed byproduct material for which a written directive is required."