

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

March 10, 2016

MEETING SUMMARY

PURPOSE

To discuss the draft Advisory Committee on the Medical Uses of Isotopes (ACMUI) subcommittee report on the training and experience (T&E) requirements of authorized users (AUs) of alpha, beta and gamma emitters under 10 CFR 35.390.

OUTCOME

The subcommittee provided a draft report for discussion with the full Committee. Subcommittee members included: Dr. Vasken Dilsizian, Dr. Ronald Ennis, Dr. Susan Langhorst, Dr. Christopher Palestro (Chair), Ms. Laura Weil and Dr. Pat Zanzonico. During the meeting, the Committee unanimously approved the draft report. The U.S. Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the ACMUI. The final report will be submitted to the NRC staff, and the staff will consider the ACMUI's 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 website at <http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/>.

The draft and final ACMUI Subcommittee report on the T&E requirements of AUs of alpha, beta and gamma emitters under 10 CFR 35.390 is available on NRC's public website under "ACMUI Subcommittee Reports": <http://www.nrc.gov/reading-rm/doc-collections/acmui/reports/>.

AGENDA TOPIC

Discuss the Draft ACMUI Subcommittee Report on the Training and Experience Requirements of Authorized Users of Alpha, Beta and Gamma Emitters under 10 CFR 35.390.

SUMMARY

The ACMUI T&E for AUs of Alpha and Beta Emitters Subcommittee evaluated (1) if the current requirement of 700 T&E hours for AUs under 10 CFR 35.390 places hardship on the patient community; and (2) the total number of hours of T&E for AUs of such emitters that appropriately balances safety with reasonable patient access to these agents.

Ms. Weil presented her differing opinion described in the report, in which she did not agree that the current requirements do not effectively create some barriers to access to care.

RECOMMENDATIONS AND ACTIONS

The subcommittee discussed the following recommendations in the draft subcommittee report:

1. Page 6: The Subcommittee recommends against the reduction in the number of hours of T&E required for 10 CFR 35.390 use. *[Maintain the current 700 hours for T&E]*

The recommendation was unanimously approved by the ACMUI.

2. Page 7: The Subcommittee recommends that the ACMUI establish a standing subcommittee with the specific charge of periodically reviewing the T&E requirements currently in effect and make recommendations for changes as warranted.

The recommendation was unanimously approved by the ACMUI.

The Draft ACMUI Subcommittee Report on the Training and Experience Requirements of Authorized Users of Alpha, Beta and Gamma Emitters under 10 CFR 35.390 (ML16055A420) was unanimously approved by the full ACMUI. The Final ACMUI Report on the Training and Experience Requirements of Authorized Users of Alpha, Beta and Gamma Emitters under 10 CFR 35.390 (ML16089A271) is posted on the ACMUI Subcommittee Report Webpage.

Attachments:

List of Attendees

MEETING ATTENDEES

ACMUI

Philip O. Alderson, M.D.	Chairman
Pat B. Zanzonico, Ph.D.	Vice Chairman
Francis M. Costello	Member
Vasken Dilsizian, M.D.	Member
Ronald D. Ennis, M.D.	Member
Susan M. Langhorst, Ph.D.	Member
Steven R. Mattmuller	Member
Darlene F. Metter	Member
Michael D. O'Hara, Ph.D.	Member
Christopher J. Palestro, M.D.	Member
John H. Suh, M.D.	Member
Laura M. Weil	Member
Zoubir Ouhib	Non-Voting Member

NRC

Pamela Henderson	Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs (MSTR)
Douglas Bollock	Branch Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Sophie Holiday	Alternate Designated Federal Officer/ACMUI Coordinator
Michael Fuller	Medical Radiation Safety Team Leader
Luis Benevides, Ph.D.	RES
Hector Bermudez	RI
Jennifer Bishop	RIII
Tammy Bloomer	COMM/OCMWO
Colleen Casey	RIII
Jackie Cook	RIV
Sara Forster	RIII
Alan Frazier	COMM/OCMKS
Cassandra Frazier	RIII
Gina Davis	NMSS
Robert Gallagher	RI
Vincent Holahan, Ph.D.	NMSS
Esther Houseman	OGC
Donna-Beth Howe, Ph.D.	NMSS
Penny Lanzisera	RI
Johari Moore	COMM/OCM
Angel Moreno	OCA
Jan Nguyen	RI
Dennis O'Dowd	RIII
Patty Pelke	RIII
Gretchen Rivera-Capella	NMSS
Cinthya Roman	NMSS
Vered Schaffer	RIII
Toye Simmons	RIII

Katherine Tapp, Ph.D.
Torre Taylor
Frank Tran
Lester Tripp
Jason VonEhr
Jenny Weil
Shirley Xu

NMSS
NMSS
RIII
RI
RIII
OCA
NMSS

MEMBERS OF THE PUBLIC

Kathi Benson
Nathaniel Boesch
Sue Bunning

Jennifer Cultrera

Al Dejesus
Gary Dillehay
Bryan Edwards
Deirdre Elder
Hugh Evans
Miguel de la Guardia
Sandra Gabriel
Munir Ghesani
Bennett Greenspan
Michael Guastella
Sherrie Flaherty
Gregg Franklin
Stan Hampton
Nicki Hilliard
Kendall Horvath

Steve Howard
Clare Jennings
Clint Joffrion
Yungmi Kim
Caitlin Kubler

Ralph Lieto
Craig Little
Steve Mack
Richard Martin
Gene Menendez
Michael Miller
Clarine Nardi Riddle

Jeffrey Norenberg
Avi Oler
Virginia Pappas

Michael Peters

Cardinal Health
Spectrum Pharmaceuticals, Inc.; Foley Haag LLP
Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Spectrum Pharmaceuticals, Inc.; Florida Cancer Specialists & Research Institute
Spectrum Pharmaceuticals, Inc.
Northwestern University
Fox Chase Cancer Center
University of Colorado Health
Eckert & Ziegler Radiopharma, Inc.
Cook Children's Health Care System
unaffiliated
New York University School of Medicine
Medical College of Georgia
Council on Radionuclides and Radiopharmaceuticals
Organization of Agreement States Board (OAS Board)
American Society for Radiation Oncology (ASTRO)
Eli Lilly and Company
University of Arkansas for Medical Sciences
Society of Nuclear Medicine and Molecular Imaging (SNMMI)
University of Kansas Medical Center
Bayer
unaffiliated
Spectrum Pharmaceuticals, Inc.
Society of Nuclear Medicine and Molecular Imaging (SNMMI)
St. Joseph Mercy Health System
Health Physics Society (HPS)
Arkansas Department of Health
American Association of Physicists in Medicine (AAPM)
Spectrum Pharmaceuticals, Inc.
Spectrum Pharmaceuticals, Inc.; Foley Hoag
Spectrum Pharmaceuticals, Inc.; Kasowitz, Benson, Torres & Friedman LLP
University of New Mexico College of Pharmacy
Spectrum Pharmaceuticals, Inc.
Society of Nuclear Medicine and Molecular Imaging (SNMMI)
American College of Radiology (ACR)

Justin Quinn
Gloria Romanelli
Karl Schwartz
Karen Sheehan
Michael Sheetz
Phillip Stevens
Michael Tomblyn
Cindy Tomlinson
Allen Yang

University of Michigan Health System
American College of Radiology
Patients Against Lymphoma (P.A.L.)
Fox Chase Cancer Center
University of Pittsburgh
Spectrum Pharmaceuticals, Inc.
unaffiliated
American Society of Radiation Oncology (ASTRO)
Spectrum Pharmaceuticals, Inc.