

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.	NMSS
Torre Taylor	NMSS
Frank Tran	RIII
Lester Tripp	RI
Jason VonEhr	RIII
Jenny Weil	OCA
Shirley Xu	NMSS

MEMBERS OF THE PUBLIC

Kathi Benson	Cardinal Health
Nathaniel Boesch	Spectrum Pharmaceuticals, Inc.; Foley Haag LLP
Sue Bunning	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Jennifer Cultrera	Spectrum Pharmaceuticals, Inc.; Florida Cancer Specialists & Research Institute
Al Dejesus	Spectrum Pharmaceuticals, Inc.
Gary Dillehay	Northwestern University
Bryan Edwards	Fox Chase Cancer Center
Deirdre Elder	University of Colorado Health
Hugh Evans	Eckert & Ziegler Radiopharma, Inc.
Miguel de la Guardia	Cook Children's Health Care System
Sandra Gabriel	<i>unaffiliated</i>
Munir Ghesani	New York University School of Medicine
Bennett Greenspan	Medical College of Georgia
Michael Guastella	Council on Radionuclides and Radiopharmaceuticals
Sherrie Flaherty	Organization of Agreement States Board (OAS Board)
Gregg Franklin	American Society for Radiation Oncology (ASTRO)
Stan Hampton	Eli Lilly and Company
Nicki Hilliard	University of Arkansas for Medical Sciences
Kendall Horvath	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Steve Howard	University of Kansas Medical Center
Clare Jennings	Bayer
Clint Joffrion	<i>unaffiliated</i>
Yungmi Kim	Spectrum Pharmaceuticals, Inc.
Caitlin Kubler	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Ralph Lieto	St. Joseph Mercy Health System
Craig Little	Health Physics Society (HPS)
Steve Mack	Arkansas Department of Health
Richard Martin	American Association of Physicists in Medicine (AAPM)
Gene Menendez	Spectrum Pharmaceuticals, Inc.
Michael Miller	Spectrum Pharmaceuticals, Inc.; Foley Hoag
Clarine Nardi Riddle	Spectrum Pharmaceuticals, Inc.; Kasowitz, Benson, Torres & Friedman LLP
Jeffrey Norenberg	University of New Mexico College of Pharmacy
Avi Oler	Spectrum Pharmaceuticals, Inc.
Virginia Pappas	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Michael Peters	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.