

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

March 11, 2020

MEETING SUMMARY

PURPOSE

To discuss the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Regulatory Guide 8.39 Subcommittee's draft report on the final recommendations for the draft final Phase 1 revision to Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material."

OUTCOME

The ACMUI Regulatory Guide 8.39 Subcommittee provided a draft report for discussion with the full Committee. Subcommittee members include: Mr. Gary Bloom, Dr. Vasken Dilsizian, Ms. Melissa Martin, Dr. A. Robert Schleipman, Mr. Michael Sheetz (Chair), and Ms. Megan Shober. The NRC staff gained a better understanding of the views and opinions of the Committee. The NRC staff will consider the ACMUI's comments while finalizing Phase 1 of the draft proposed Regulatory Guide 8.39, which will be issued in April 2020. A full transcript and handout for the ACMUI teleconference meeting can be found on the NRC's public web site at: <https://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/2020.html>.

The ACMUI Regulatory Guide 8.39 Subcommittee report is available on the NRC's public web site under ACMUI Subcommittee Reports: <https://www.nrc.gov/reading-rm/doc-collections/acmui/reports/>.

AGENDA TOPIC

Draft Final Phase 1 revisions to Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material."

SUMMARY

The ACMUI Regulatory Guide 8.39 Subcommittee presented its draft report (Agencywide Documents and Access Management System (ADAMS) Accession No. ML20056D823), which focused on final recommendations that only pertained to the final draft Phase 1 revision to Regulatory Guide 8.39. In its report, the Subcommittee provided for consideration, several specific comments and recommendations which directed changes pertaining to wording, items of emphasis, and formatting. The draft subcommittee report was endorsed by the full Committee.

RECOMMENDATIONS AND ACTIONS

The Regulatory Guide 8.39 Subcommittee discussed the following recommendations from the Subcommittee report.

1. In the Patient Precautions and Instructions Sections, it should be emphasized that the major source of radiation dose to other individuals will be from external exposure from

the patient. Therefore, the most important precautions to take are measures to reduce or avoid the external radiation exposure from the patient, especially in the early time period after administration of the radionuclide therapy.

2. The patient instructions should be simple, clear, and concise.
3. Discussions on the radionuclide therapy procedure and release instructions should also include a caregiver or family member, if possible.
4. Instructions should also be provided on how long the precautions should be followed. As a guideline, the licensee may consider using several (3-5) effective half-lives of the radionuclide therapy.
5. The Regulatory Guide should not include instructions that are excessive, likely to cause patient anxiety, and not likely to reduce public exposures.
6. Table 1, 2, and A1 should be updated to include the new and potential radionuclides used in medicine.
7. In Table 3, "Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child," the subcommittee supports the guidance for a standardized interruption time period of 24 hours for all Tc-99m radionuclides, and the recommended interruption period to limit the dose to the nursing infant to 1 millisievert (mSv), and not the regulatory limit of 5 mSv.

The ACMUI unanimously approved the draft Regulatory Guide 8.39 Subcommittee Report, as presented, during its public teleconference meeting on March 11, 2020. The recommendations above can be viewed, in their entirety, in the final Regulatory Guide 8.39 Subcommittee Report (ADAMS Accession No. ML20085H267) on the NRC's ACMUI Subcommittee Reports webpage.

Enclosures:

1. Meeting Attendees
2. Teleconference Agenda

MEETING PARTICIPANTS

ACMUI

Darlene F. Metter, M.D.	Chairman
A. Robert Schleipman, PhD	Vice Chairman
Gary Bloom	Member
Vasken Dilsizian, M.D.	Member
Richard Green	Member
Melissa Martin	Member
Michael D. O'Hara, M.D.	Member
Zoubir Ouhib	Member
Michael Sheetz	Member
Megan Shober	Member
Harvey B. Wolkov, M.D.	Member

NRC STAFF

Christian Einberg	Chief, Medical Safety and Events Assessment Branch (MSEB)/Designated Federal Officer
Lisa Dimmick	Medical Radiation Safety Team Leader, NMSS/MSST/MSEB
Kellee Jamerson	Designated Federal Officer/ACMUI Coordinator
Said Daibes Figueroa, Ph.D.	NMSS/MSST/MSEB
Daniel Dimarco	NMSS/MSST/MSEB
Jennifer Fisher	NMSS/MSST/MSEB
Anita Gray, Ph.D.	NMSS/MSST/SMPB
Vincent Holahan, Ph.D.	NMSS/MSST
Esther Houseman	OGC/GCLR/RMR
Donna-Beth Howe, Ph.D.	NMSS/MSST/MSEB
Penny Lanzisera	R-I/DNMS/MLAB
Sarah Lopas	NMSS/MSST/MSEB
Jeffery Lynch	NMSS/MSST/SLPB
Minh-Thuy Nguyen	RES/DSA/RPB
Vered Shaffer	RES/DSA/RPB
Katherine Tapp, Ph.D.	NMSS/MSST/MSEB
John Tomon	RES/DSA/RPB
Irene Wu	NMSS/MSST/MSEB

MEMBERS OF THE PUBLIC

Jaime Barnes	Cook Children's Medical Center
Roland Benke	Renaissance Code Development, LLC
Lisa Bruedigan	Texas Department of State Health Services
Tina Buehner	Unaffiliated
David Crowley	North Carolina Department of Health and Human Services, Radiation Protection Section
Elizabeth Franklin	Atrium Health
Noelle Geier	Froedtert & The Medical College of Wisconsin
Jennifer Gersman	Northwestern Medicine

Phil Goble	Utah Division of Waste Management and Radiation Control
Miguel de la Guardia	Cook Children's Medical Center
Stanley Hampton	Eli Lilly
Curtis Hicks, Jr.	Scripps Health
Bill Hinchcliffe	Yale New Haven Health
Mary Ellen Jafari	Gundersen Health
Tyler Kruse	Minnesota Radioactive Materials Unit
Ralph Lieto	St. Joseph Mercy Health System
Carol Marcus, Ph.D., M.D.	University of California at Los Angeles
Steven Marsh	Baystate Health
Richard Martin	American Association of Physicists in Medicine
Jeffrey Mason	Department of Veterans Affairs
Candi McDowell	University of Pennsylvania
Mary Moore	CMC Veterans Affairs Medical Center
Lora Moyle	North Carolina State University
Michael Peters	American College of Radiology
Carmine Plott	Novant Health
Daniel Samson	New York State Department of Health
Jeffry Siegel, Ph.D.	Nuclear Physics Enterprises
Eric Skotak	Texas Department of State Health Services
Cindy Tomlinson	American Society for Radiation Oncology
Brian Vamvakias	Texas Department of State Health Services
Karen Wheeler	Bio-Med Associates
William White	Rush University
Matthew Williamson	Memorial Sloan Kettering Cancer Center
Melonie Wissing	Department of Veterans Affairs

**Advisory Committee on the Medical Uses of Isotopes
TELECONFERENCE AGENDA
Wednesday, March 11, 2020
2:00 PM – 4:00 PM (ET)**

OPEN SESSION

2:00 pm – 4:00 pm

Discuss the Draft ACMUI Subcommittee Report for the Final Draft of Regulatory Guide 8.39,
“Release of Patients Administered Radioactive Material” Phase 1 Revisions