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

### June 10, 2019

### **MEETING SUMMARY**

### PURPOSE

To discuss the Advisory Committee on the Medical Uses of Isotopes (ACMUI) proposed amended Bylaws and the Regulatory Guide 8.39 Subcommittee's draft report on the recommendations for Phase 1 of the draft proposed revision to Regulatory Guide 8.39, Revision 1, "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 included: Dr. Vasken Dilsizian, Ms. Melissa Martin, Dr. A. Robert Schleipman, Mr. Michael Sheetz (Chair), 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 development of Phase 1 of the draft proposed Regulatory Guide 8.39, which will be published for public comment in the near future.

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

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

## AGENDA TOPICS

Discuss the proposed amendments to the ACMUI Bylaws, as discussed and approved at the April 3-4, 2019, ACMUI meeting.

Discuss the ACMUI Regulatory Guide 8.39 Draft Subcommittee Report on the recommendations for Phase 1 of the preliminary draft proposed Regulatory Guide 8.39, Revision 1.

### SUMMARY

The ACMUI discussed the proposed amendments to the 2019 Bylaws, with specific changes to Sections 1.3.6 and 4.1, regarding the ACMUI Chair's involvement in subcommittees and conflicts of interest, respectively.

The ACMUI Regulatory Guide 8.39 Subcommittee discussed its draft report, which focused on recommendations on Phase 1 of the draft proposed revision to Regulatory Guide 8.39. In its report, the Subcommittee provided several directed changes pertaining to wording, items of emphasis, and formatting. Other recommendations presented by the Subcommittee include the addition of a Table of Contents; updates to Table 1 and Table 2 to include the new and potential radionuclides used in medicine; update to Table 3 to reflect the radionuclides, activities, and recommended duration of interruption of breastfeeding as contained in the ACMUI

Subcommittee report on "Nursing Mother Guidelines for the Medical Administration of Radioactive Materials, Final Report, January 31, 2019"; and the addition of instructions for evaluation of holding trash to allow for radioactive decay at the landfill.

# **RECOMMENDATIONS AND ACTIONS**

# The Regulatory Guide 8.39 Subcommittee provided the following recommendations in its draft subcommittee report:

- 1. The Subcommittee recommends emphasizing in the Patient Precautions and Instructions Sections that the major source of radiation dose to other individuals will be from external exposure from the patient.
- 2. While there is adequate guidance on the precautions to take to minimize radiation exposure for post mortem activities of a patient who dies after being administered a therapeutic quantity of radioactive material, there is little or no consistent guidance on what retained activity or time period when the precautions should be followed. The Subcommittee recommends that a dose-based model be developed to provide guidance on when precautions or restrictions would be appropriate following the death of a patient administered a therapeutic quantity of radioactive d a therapeutic quantity of radioactive material.

The draft Regulatory Guide 8.39 Subcommittee Report (ML19143A367), and all its recommendations provided therein, was unanimously approved by the ACMUI during its public teleconference meeting on June 10, 2019. The final report (ML19171A222) will be posted on the ACMUI Subcommittee Reports webpage.

Additionally, the proposed amendments to the ACMUI Bylaws were approved by the ACMUI, with one abstention, during its public teleconference meeting on June 10, 2019. The revised ACMUI Bylaws (ML19184A622) will be posted on the ACMUI webpage.

## Enclosures:

- 1. Meeting Attendees
- 2. Teleconference Agenda

### **MEETING ATTENDEES**

Chairman

Member

Vice Chairman

### ACMUI

Christopher J. Palestro, M.D. Darlene F. Metter, M.D. Vasken Dilsizian, M.D. Richard Green Melissa Martin Michael D. O'Hara, M.D. Zoubir Ouhib A. Robert Schleipman, PhD Michael Sheetz Megan Shober Laura Weil Harvey B. Wolkov, M.D.

### NRC

Robert Lewis

Christian Einberg

Kellee Jamerson Maryann Ayoade Stephanie Bush-Goddard Colleen Casey Samantha Crane Said Daibes, Ph.D. Lisa Dimmick Julie Ezell Cassandra Frazier Robert Gallaghar Sophie Holiday Esther Houseman Donna-Beth Howe, Ph.D. Cynthia Jones Harriet Karagiannis Sarah Lopas Minh-Thuy Nguyen Patty Pelke Halfon Schlom Vered Shaffer Daniel Strohmeyer Katherine Tapp, Ph.D. Alexus Willis Irene Wu

Deputy Director, Office of Nuclear Material Safety and Safeguards (NMSS) Chief, Medical Safety and Events Assessment Branch (MSEB)/Designated Federal Officer Designated Federal Officer/ACMUI Coordinator/MSEB NMSS/MSST/MSEB **RES/DSA/RPB** R-III/DNMS/MLB OCM/DAW NMSS/MSST/MSEB Medical Radiation Safety Team Leader, NMSS/MSST/MSEB OGC/GCHA/AGCNRP R-III/DNMS/MLB R-I/DNMS/MLAB NMSS/MSST/MSEB OGC/GCLR/RMR NMSS/MSST/MSEB OCM/AXC **RES/DE/RGGIB** NMSS/MSST/MSEB **RES/DSA/RPB** R-III/DNMS/MLB RES **RES/DSA/RPB** R-III/DNMS/MLB NMSS/MSST/MSEB **RES/DE/CMB** NMSS/MSST/MSEB

### MEMBERS OF THE PUBLIC

Jaime Barnes

Roland Benke Kendall Berry Janice Campbell Peter Crane David Crowley Brian Erasmus Sandy Gabriel Bennett Greenspan, M.D. Miguel de la Guardia David Hamby Alan Jackson Brandon Juran Linda Kroger **Tvler Kruse** Alexis LaViolette Ralph Lieto Terry Lindley Cindi Luckett-Gilbert Carol Marcus, Ph.D, M.D. Richard Martin Candi McDowell Chris Mitchell Jose Morales, M.D. Michael Peters Carmine Plott Aria Razmaria, M.D. Samuel Rhoades, IV Gloria Romanelli Jeffry Siegel, Ph.D Eugene Silvestrini Andres Sinisterra Joe Steiner Cindy Tomlinson Joseph Wissing Miyuki Yoshida-Hay Andrew Zimnoch

Cook Children's Medical Center Renaissance Code Development, LLC Fox Chase Cancer Center **Beaumont Health** Unaffiliated North Carolina Department of Health and Human Services, **Radiation Protection Section** British Technology Group Unaffiliated Society of Nuclear Medicine and Molecular Imaging (SNMMI) Cook Children's Medical Center Renaissance Code Development, LLC Henry Ford Health System Minnesota Radioactive Materials Unit University of California at Davis Minnesota Radioactive Materials Unit Boston Children's Hospital, Harvard Medical School St. Joseph Mercy Health System University of Cincinnati Unaffiliated University of California at Los Angeles (UCLA) American Association of Physicists in Medicine (AAPM) University of Pennsylvania Kettering Health Unaffiliated American College of Radiology (ACR) Novant Health **UCLA Medical Center** Mercy Health ACR **Nuclear Physics Enterprises** Northwell Health UConn Health Henry Ford Health System American Society of Radiation Oncology (ASTRO) St. Joseph Mercy Health System Northwell Health Environmental Health and Radiation Safety, University of Pennsylvania

### Advisory Committee on the Medical Uses of Isotopes TELECONFERENCE AGENDA Monday, June 10, 2019 2:00 PM – 4:00 PM (ET)

# **OPEN SESSION**

2:00 pm – 4:00 pm

Discuss the proposed amendments to the Advisory Committee on the Medical Uses of Isotopes Bylaws

Discuss the ACMUI Regulatory Guide 8.39 Draft Subcommittee Report regarding the review and comments on Phase 1 of the preliminary draft proposed Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material."