

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

April 30, 2020

MEETING SUMMARY

PURPOSE

To discuss the Advisory Committee on the Medical Uses of Isotopes (ACMUI) COVID-19 Subcommittee's draft recommendations for regulatory relief measures for medical licensees during the COVID-19 public health emergency.

OUTCOME

The ACMUI COVID-19 Subcommittee provided a draft report for discussion with the full Committee. Subcommittee members include: Dr. Vasken Dilsizian, Mr. Richard Green, Dr. Hossein Jadvar (chair), Ms. Melissa Martin, Ms. Megan Shober, and Dr. Harvey Wolkov. The NRC staff gained a better understanding of the views and opinions of the Committee. The NRC staff will consider the ACMUI's recommendations when developing guidance for medical licensees that request temporary exemptions during the COVID-19 pandemic.

Full transcripts and handouts from the ACMUI meeting can be found on the NRC's ACMUI Meetings and Related Documents webpage, located at: <https://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/2020.html>.

The ACMUI COVID-19 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

Discuss the draft ACMUI COVID-19 Subcommittee recommendations for potential regulatory relief measures for medical use licensees during the COVID-19 pandemic.

SUMMARY

The ACMUI COVID-19 Subcommittee presented its draft report (Agencywide Documents and Access Management System (ADAMS) Accession No. ML20125A145), which focused on recommendations for potential regulatory relief options during the COVID-19 pandemic. In its report, the Subcommittee provided for the NRC's consideration, several recommendations in specific areas where licensees may be unable to meet specific regulatory requirements in a timely manner due to the public health emergency. The draft subcommittee report was endorsed by the full Committee.

RECOMMENDATIONS AND ACTIONS

The COVID-19 Subcommittee discussed regulatory relief options for medical licensees during the COVID-19 pandemic in the following specific areas: 1) training and education; 2) regulatory reporting; 3) medical event reporting; 4) radiation protection activities; 5) physical presence; 6) inspections; and 7) regulatory fees.

Regarding regulatory relief options for physical presence, the ACMUI discussed some hypothetical scenarios in which a facility's authorized user (AU) or authorized medical physicist (AMP) could not be physically present for treatment due to suspected or confirmed COVID-19 infection. The ACMUI concluded that there should be no change to the physical presence requirements for high dose rate brachytherapy or gamma knife stereotactic radiosurgery, as these are high-risk procedures that require the physical presence of the AU and AMP.

Additionally, the ACMUI discussed and considered concerns about the possibility of regulatory relief for patient release criteria for patients who receive radionuclide therapy during the COVID-19 pandemic. The ACMUI agreed that for exceptional situations related to patient release during COVID-19, medical licensees should contact the NRC or their regional regulatory office to seek a temporary exemption request on a case-by-case basis.

The ACMUI unanimously approved the draft COVID-19 Subcommittee Report and its recommendations, as presented, during its public teleconference meeting on April 30, 2020. The final report (ADAMS Accession No. ML20125A148) can be viewed, in its entirety, 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
Ronald Ennis, M.D.	Member
Richard Green	Member
Hosseini Jadvar, M.D.	Member
Melissa Martin	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
Darrell Adams	OCA
Maryann Ayoade	NMSS/MSST/MSEB
David Brown	COMM/OCM
Colleen Casey	R-III/DNMS/MLB
Laura Cender	R-III/DNMS/MLB
Said Daibes Figueroa, Ph.D.	NMSS/MSST/MSEB
Sara Forster	R-III/DNMS/MLB
Cassandra Frazier	R-III/DNMS/MLB
Vincent Holahan, Ph.D.	NMSS/MSST
Sophie Holiday	NSIR/DPR
Esther Houseman	OGC/GCLR/RMR
Donna-Beth Howe, Ph.D.	NMSS/MSST/MSEB
Ian Irvin	OGC/GCLR/RMR
Janelle Jessie	COMM/OCMJB
Cynthia Jones	COMM/OCMAC
Erin Kennedy	R-III/DNMS/MLB
Michael LaFranzo	R-III/DNMS/MCID
Penny Lanzisera	R-I/DNMS/MLAB
Olivier Lareynie	NRR
Samantha Lav	COMM/OCMDW
Christine Lipa	R-III/DNMS
Sarah Lopas	NMSS/MSST/MSEB
Kathy Modes	NMSS/MSST/SLPB
Dennis O'Dowd	R-III/DNMS/MIB
Robert Orlikowski	R-III/DNMS/MLB
Bryan Parker	R-III/DNMS/MLB

Darren Piccirillo
Vered Shaffer
Katherine Tapp, Ph.D.
Geoff Warren
Duncan White
Irene Wu

R-III/DNMS
RES/DSA/RPB
NMSS/MSST/MSEB
R-III/DNMS/MIB
NMSS/MSST/SLPB
NMSS/MSST/MSEB

MEMBERS OF THE PUBLIC

Christina Arenas
Rex Ayers
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Gloria Romanelli
Katie Scott
Tracy Scherer
Tim Showalter
Diana Thompson
Christopher Tighe
Cindy Tomlinson
Jeff Wagner

Society of Nuclear Medicine and Molecular Imaging
American Association of Physicists in Medicine
Society of Nuclear Medicine and Molecular Imaging
Morgan Lewis
Cook Children's Medical Center
Boston Scientific
Illinois Emergency Management Agency
Illinois Emergency Management Agency
Pennsylvania Department of Environmental Protection
North Carolina Department of Health and Human Services,
Radiation Protection Section
Morgan Lewis
Virtua Health
Nuclear Diagnostic Products
Boston Scientific
Unaffiliated
Lantheus Medical Imaging
Emory University School of Medicine
Cook Children's Medical Center
Eli Lilly
NorthStar Medical Technologies
Pennsylvania Department of Environmental Protection
Minnesota Radioactive Materials Unit
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American College of Radiology
American College of Radiology
Pennsylvania Department of Environmental Protection
Pennsylvania Department of Environmental Protection
University of Virginia
Sirtex
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American Society for Radiation Oncology
University of California at San Diego

Bradley Williams
John Witkowski
Pat Zanzonico, Ph.D.

U.S. Senate Committee on Environment and Public Works
United Pharmacy Partners
Memorial Sloan Kettering

**Advisory Committee on the Medical Uses of Isotopes
TELECONFERENCE AGENDA
Thursday, April 30, 2020
2:00 PM – 4:00 PM (ET)**

OPEN SESSION

2:00 pm – 4:00 pm

Discuss the Draft ACMUI COVID-19 Subcommittee recommendations for potential regulatory relief measures for medical use licensees during the COVID-19 pandemic.