



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, D.C. 20555-0001

October 18, 2019

MEMORANDUM TO: Darlene F. Metter, M.D., Chairman
Advisory Committee on the Medical Uses of Isotopes

FROM: Christian Einberg, Chief **/RA/**
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION ACTIONS IN
RESPONSE TO THE SEPTEMBER 10-11, 2019, MEETING OF
THE ADVISORY COMMITTEE ON THE MEDICAL USES OF
ISOTOPES

Below are the U.S. Nuclear Regulatory Commission (NRC) staff's actions in response to the recommendations and action items from the September 10-11, 2019, meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI or Committee).

ITEM (1): Effective September 23, 2019, Dr. Darlene Metter and Dr. A. Robert Schleipman will serve as ACMUI Chair and Vice Chair, respectively.

The NRC staff will update the ACMUI Membership webpage to reflect this change.

ITEM (2): Dr. Palestro amended the membership of the Training and Experience Requirements for All Modalities Subcommittee to remove Dr. Metter as Subcommittee Chair. The subcommittee membership now includes Mr. Bloom, Dr. Ennis, Dr. Schleipman (chair), Mr. Sheetz, and Ms. Shober. It is at the discretion of the subcommittee to allow Dr. Metter to continue to serve on the subcommittee. Ms. Maryann Ayoade remains the NRC staff resource.

The NRC staff will update the ACMUI Subcommittees webpage to reflect this change.

ITEM (3): The ACMUI endorsed the Medical Events Subcommittee report as presented.

CONTACT: Kellee Jamerson, NMSS/MSST
(301) 415-7408

The recommendation passed unanimously with 10 votes. No NRC action is required at this time. The subcommittee will perform a full trend analysis of medical events over a several year period in 2020.

ITEM (4): The ACMUI endorsed the Appropriateness of Medical Event Reporting Subcommittee report and the recommendations provided therein.

The recommendation passed unanimously with 11 votes. The NRC staff is currently assessing the recommendations to enhance the Nuclear Materials Events Database.

ITEM (5): The ACMUI endorsed the Evaluation of Extravasations Subcommittee report, as amended, to note that under future revisions to Part 35 rulemaking, extravasations be captured as a type of passive patient intervention with the definition of patient intervention.

The recommendation passed unanimously with 11 votes. The NRC staff is continuing to evaluate the subcommittee's recommendations related to extravasations and medical event reporting.

ITEM (6): The ACMUI endorsed the Xcision® GammaPod™ Licensing Guidance Subcommittee report, as amended, to include the rationale that (1) the written directive should include both dose and frequency and (2) replacing the chemical/physical form line to describe the sealed source rather than the device.

The recommendation passed unanimously with 11 votes. The NRC staff is considering the subcommittee's recommended changes for inclusion in the draft Xcision® GammaPod™ Licensing Guidance.

ITEM (7): The ACMUI endorsed the Institutional Memory Subcommittee report, as amended, to include the recommendation that a complete list of ACMUI members be updated and added to the ACMUI webpage. The subcommittee membership was amended to add Dr. Wolkov. The updated membership includes Dr. Ennis, Dr. O'Hara, Dr. Shleipman (chair), Ms. Shober, and Dr. Wolkov. Ms. Kellee Jamerson remains the NRC staff resource.

The recommendation passed unanimously with eleven votes. The NRC staff is working to address this recommendation and will update the comprehensive membership list on the ACMUI webpage as information becomes available.

ITEM (8): Dr. Palestro formed a subcommittee to evaluate the definition of patient intervention and other actions and circumstances that are exclusive of medical events. Subcommittee membership includes Mr. Bloom, Dr. Dilsizian, Dr. Ennis, and Mr. Sheetz (chair). The NRC staff resource is Ms. Maryann Ayoade.

The subcommittee is expected to present its report at the spring 2020 meeting. No NRC action is required at this time.

ITEM (9): Dr. Palestro charged the existing Bylaws Subcommittee with determining the following: (1) Should there be term limits for the ACMUI Chair and Vice Chair? If so, how long should those terms be? and (2) Should the ACMUI Vice Chair automatically become the ACMUI Chair? The subcommittee membership was amended to remove Dr. Schleipman and add Dr. Wolkov. The updated subcommittee membership includes Mr. Sheetz, Ms. Shober, and Dr. Wolkov (chair). Ms. Kellee Jamerson will replace Ms. Sophie Holiday as the NRC staff resource.

The subcommittee is expected to present its report at the spring 2020 meeting. No NRC action is required at this time.

ITEM (10): Dr. Palestro formed a subcommittee to investigate the need for an Interventional Radiologist on the ACMUI and determine whether this position should serve as a non-voting consultant or a full Committee member. Subcommittee membership includes Dr. Dilsizian, Dr. Ennis, Dr. Jadvar (pending security clearance), and Ms. Shober (chair). It is at the discretion of the subcommittee to allow Dr. Metter to serve on the subcommittee. The NRC staff resource is Dr. Katie Tapp.

The subcommittee is expected to present an interim draft report at the spring 2020 meeting. No NRC action is required at this time.

ITEM (11): The ACMUI tentatively scheduled the spring 2020 meeting for March 23-24, 2020. The alternative meeting date is March 30-31, 2020.

Subject to Commission availability, the NRC staff will work to confirm a date for the annual ACMUI meeting with the Commission.

SUBJECT: NRC ACTIONS IN RESPONSE TO THE SEPTEMBER 10-11, 2019 MEETING OF
THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
DATED: OCTOBER 18, 2019

DISTRIBUTION:

Public
ACMUI

ADAMS Accession No.: ML19274C622***via email**

OFFICE	MSST/MSEB	MSST/MSEB	MSST/MSEB
NAME	KJamerson	LDimmick*	CEinberg
DATE	10/01/2019	10/01/2019	10/11/2019

OFFICIAL RECORD COPY