



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

December 2, 2019

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

FROM: Christian E. Einberg, Branch Chief */RA Lisa Dimmick for/*
Medical Safety and Events Assessment Branch
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SUBJECT: RESPONSES TO SEVERAL OPEN RECOMMENDATIONS AND
ACTION ITEMS SUBMITTED TO THE U.S. NUCLEAR
REGULATORY COMMISSION FROM THE ADVISORY
COMMITTEE ON THE MEDICAL USES OF ISOTOPES
RANGING FROM 2017 TO 2019

Below are the U.S. Nuclear Regulatory Commission (NRC) staff responses to several open recommendations and action items from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) ranging from 2017 to 2019 that have not been covered under a separate response memorandum:

- 1. ACMUI Recommendation/Action Item from 2017, #14:** The ACMUI recommended that NRC licensees with an NRC-approved patient safety program will continue to report medical events (MEs) as required with the following conditions: (1) The NRC will not include this event notification in the Event Notification Report posted on its website. If this is not possible, the ME notification posted on the website will leave the licensee information and location anonymous. (2) The NRC will not conduct a reactive inspection of the ME unless the event results or will result in death, unintended permanent harm, or unintended significant temporary harm for which medical intervention was or will be required to alleviate the harm or reduce radiation effects. (3) The medical use licensee will write a report available for the next NRC inspection describing the event cause and corrective action taken. (4) NRC will develop, with ACMUI advice, new temporary inspection procedures for NRC review of licensee patient safety event reports, and will evaluate, with ACMUI advice, the need to change enforcement manual procedures regarding MEs to support a test of this program.

Staff Response: Not Accepted. As discussed in the August 23, 2019, response memorandum to the ACMUI (Agencywide Documents Access and Management System

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(ADAMS) Accession No. ML19232A141) and during the 2019 Fall ACMUI meeting,¹ the NRC staff did not agree with the recommendation for licensees who use a patient safety organization (PSO) as a substitute or supplement to the current ME reporting process and therefore, did not accept conditions (2), (3), and (4) of ACMUI's recommendation. The NRC staff previously committed to evaluating condition (1) by exploring whether licensee information can be redacted from event notifications prior to posting them online, regardless of whether the licensee uses a PSO. With the assistance of the NRC Headquarters Operations Officer and the Office of General Counsel, NRC staff determined that existing NRC event redaction processes only apply to personally identifiable information and security-related information. In addition, the redaction of additional information would be contrary to existing Commission Policy of transparency,² the regulatory requirements for report and notification of a ME in Title 10 of the *Code of Federal Regulations* (10 CFR) 35.3045, and Section 208 of the Energy Reorganization Act of 1974 which require the wide dissemination to the public of this type of information. For this reason, the NRC recommends that this item be closed.

2. **ACMUI Recommendation/Action Item from 2017, #20:** The ACMUI endorsed the ME Reporting and Impact on Medical Licensee Patient Safety Culture Draft Report, as amended to support the concept of the pilot program with the total number of sites and duration to be determined at a later date and to include the Patient Intervention Subcommittee recommendations as an addendum.

Staff Response: Accepted. As discussed during the 2019 Fall ACMUI meeting,³ Dr. Palestro formed a subcommittee to clarify patient intervention and other general actions and circumstances that are exclusive of MEs (see ACMUI Recommendation/Action Item from 2019, #21). The subcommittee is expected to present a report at the Spring 2020 ACMUI meeting. For this reason, the NRC recommends that this item be closed.

3. **ACMUI Recommendation/Action Item from 2018, #20:** The ACMUI recommended for the NRC to draft an Information Notice (IN) on the best practices that could help prevent medical events.

Staff Response: Accepted. IN-19-07, Methods to Prevent Medical Events, was published on August 26, 2019 (ADAMS Accession No. ML19240A450). For this reason, the NRC recommends that this item be closed.

4. **ACMUI Recommendation/Action Item from 2019, #15:** Dr. Palestro amended the membership of the Training and Experience Requirements Subcommittee. Subcommittee membership now includes Dr. Schleipman as Chair and it is at the discretion of the subcommittee to allow Dr. Metter to continue to serve on the subcommittee.

Staff Response: Accepted. This subcommittee membership was amended on September 10, 2019, as shown on the ACMUI Subcommittees website.⁴ For this reason, the NRC recommends that this item be closed.

¹ Discussion begins on page 19 of the September 10, 2019 ACMUI meeting transcript (ADAMS Accession No. ML19304B440).

² <https://www.nrc.gov/public-involve/open/transparency.html>

³ Discussion begins on page 50 of the September 11, 2019 ACMUI meeting transcript (ADAMS Accession No. ML19304B462).

⁴ <https://www.nrc.gov/about-nrc/regulatory/advisory/acmui/subcommittee.html>

5. **ACMUI Recommendation/Action Item from 2019, #16:** The ACMUI endorsed the MEs Subcommittee Report as presented.

Staff Response: Accepted. The final report (ADAMS Accession No. ML19297E949) dated October 23, 2019, is available on the ACMUI Subcommittee Reports website.⁵ For this reason, the NRC recommends that this item be closed.

6. **ACMUI Recommendation/Action Item from 2019, #21:** Dr. Palestro formed a subcommittee to evaluate the definition of patient intervention and other actions and circumstances that are exclusive of MEs. Subcommittee membership includes: Dr. Dilsizian, Dr. Ennis, Mr. Sheetz (Chair), and Mr. Bloom (pending verification of clearance). NRC staff resource is Ms. Maryann Ayoade. The subcommittee is expected to present a report at the Spring 2020 meeting.

Staff Response: Accepted. This subcommittee was established on September 11, 2019, as shown on the ACMUI Subcommittees website. For this reason and because the subcommittee is expected to present a report at the Spring 2020 ACMUI meeting, the NRC recommends that this item be closed.

7. **ACMUI Recommendation/Action Item from 2019, #22:** Dr. Palestro charged the current Bylaws Subcommittee to determine: (1) Should there be term limits for the ACMUI Chair and Vice Chair? If so, how long? 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 (Chair). The NRC staff resource will now be Ms. Kellee Jamerson. The subcommittee is expected to present a report at the Spring 2020 meeting.

Staff Response: Accepted. This subcommittee membership and charge was amended on September 11, 2019, as shown on the ACMUI Subcommittees website. For this reason and because the subcommittee is expected to present a report at the Spring 2020 ACMUI meeting, the NRC recommends that this item be closed.

8. **ACMUI Recommendation/Action Item from 2019, #23:** Dr. Palestro formed a subcommittee to investigate the need for an Interventional Radiologist (IR) on the ACMUI, including whether an IR should be 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 report at the Spring 2020 meeting.

Staff Response: Accepted. This subcommittee was established on September 11, 2019, as shown on the ACMUI Subcommittees website. For this reason and because the subcommittee is expected to present an interim report at the Spring 2020 ACMUI meeting, the NRC recommends that this item be closed.

9. **ACMUI Recommendation/Action Item from 2019, #24:** The ACMUI tentatively scheduled its spring 2020 meeting for March 23-24, 2020. The alternate date is March 30-31, 2020.

⁵ <https://www.nrc.gov/reading-rm/doc-collections/acmui/reports/#2019>

Staff Response: Accepted. Given the availability of the Commission, the ACMUI Spring 2020 meeting is scheduled for March 30-31, 2020. For this reason, the NRC recommends that this item be closed.

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SUBMITTED TO THE U.S. NUCLEAR REGULATORY COMMISSION FROM THE
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES RANGING
FROM 2017 TO 2019 **DATED: DECEMBER 2, 2019**

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