



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

May 3, 2019

MEMORANDUM TO: Christopher J. Palestro, M.D., Chairman
Advisory Committee on the Medical Uses of Isotopes

FROM: Andrea L. Kock, Director
Division of Materials Safety, Security, State */RA/*
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION ACTIONS IN
RESPONSE TO THE APRIL 3-4, 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 requests from the April 3-4, 2019 meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI or Committee).

ITEM (1): The Committee recommended adding an additional column to the Recommendations and Action Items Chart to include the anticipated date of completion for NRC staff actions.

The recommendation passed unanimously with twelve votes. The NRC staff will include an additional column on the Recommendations and Action Items Chart, which will incorporate the target date of completion for NRC staff actions.

ITEM (2): The Committee recommended that the NRC staff request a presentation from the National Nuclear Security Administration (NNSA) to provide a review of its plans for isotope utilization in the United States.

The recommendation passed unanimously with twelve votes. The NRC staff will coordinate with the NNSA to request such a presentation be given at the fall 2019 ACMUI meeting.

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ITEM (3): Dr. Palestro formed a subcommittee to review the NRC's 1980 [45 FR 31703] determination related to infiltrations and medical event reporting. The subcommittee is expected to report to the Committee at the fall 2019 meeting with any recommendations. Subcommittee membership includes Dr. Dilsizian, Mr. Green, Ms. Martin (chair), Mr. Sheetz, Ms. Shober, and Ms. Weil. The NRC staff resource is Ms. Maryann Ayoade.

No action required at this time. This subcommittee will present any recommendations at the fall 2019 meeting.

ITEM (4): Dr. Palestro formed a subcommittee to improve the ACMUI's institutional memory and provide possible recommendations for methods of tracking and/or retrieving ACMUI documents. Subcommittee membership includes Dr. Ennis, Dr. O'Hara, Dr. Schleipman (chair), Ms. Shober, and Ms. Weil. The NRC staff resource is Ms. Kellee Jamerson.

No action required at this time.

ITEM (5): The NRC staff will amend its Opening Remarks such that a statement regarding conflict of interest be included at every ACMUI meeting.

The NRC staff intends to update its Opening Remarks in preparation for an upcoming public teleconference in June 2019.

ITEM (6): The Committee endorsed the ACMUI Bylaws Subcommittee report, with the following amendments: (1) amend the subcommittee's recommendation regarding the ACMUI Chairman's role on subcommittees in Section 1.3.6 to remove the phrase "in these instances"; (2) add language in Section 1.3.6 regarding the ACMUI Chairman serving on a subcommittee at the subcommittee's discretion; and (3) amend the subcommittee's recommendation regarding the explicit language defining conflict of interest in Section 4.1 to instead reference the appropriate Office of Government Ethics citation.

The ACMUI Bylaws Subcommittee will incorporate the revisions and provide the revised Bylaws to the Office of General Counsel for review. The Committee will vote on the changes to the ACMUI Bylaws at an upcoming public teleconference in June 2019.

ITEM (7): The Committee endorsed the Yttrium-90 Microspheres Brachytherapy Sources and Devices TheraSphere® and SIR_Spheres® Licensing Guidance, Revision 10, Subcommittee report, and the recommendations therein, with the caveat to replace the term "drug" with the term "device."

The recommendation to replace the term "drug" with "device" passed unanimously with twelve votes.

ITEM (8): The Committee endorsed the Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance, Revision 1, Subcommittee report and the recommendations therein.

The recommendation passed unanimously with twelve votes.

ITEM (9): The Committee tentatively scheduled the fall 2019 meeting for September 11-12, 2019. The alternative meeting date is September 10-11, 2019.

SUBJECT: NRC ACTIONS IN RESPONSE TO THE APRIL 3-4, 2019 MEETING OF THE
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

DATE: May 2, 2019

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***via email**

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