



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

April 3, 2015

MEMORANDUM TO: Bruce R. Thomadsen, Ph.D., Chairman
Advisory Committee on the Medical Uses of Isotopes

FROM: Laura A. Dudes, Director /RA/
Division of Materials Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: NRC ACTION IN RESPONSE TO THE MARCH 19-20, 2015
MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL
USES OF ISOTOPES

Below are the recommendations from the March 19-20, 2015 meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Following the recommendations are the U.S. Nuclear Regulatory Commission (NRC) staff response and/or position.

ITEM (1): Mr. Costello and Dr. Langhorst will distribute questions to the Committee regarding the proper platform, expected and necessary participants and the feasibility of conducting an additional "Medical Meeting."

No NRC action required.

ITEM (2): Dr. Thomadsen formed a subcommittee to review and evaluate the phrase "patient intervention." Subcommittee members include: Dr. Dilsizian (chair), Dr. Alderson, Mr. Costello, Dr. Ennis, Dr. Suh and Ms. Weil. The NRC staff resource contact is Dr. Gabriel. The subcommittee will present their report at the fall 2015 ACMUI Meeting.

No NRC action required.

CONTACT: Sophie Holiday, MSTR/MSEB
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ITEM (3): Dr. Thomadsen formed a subcommittee to review and make recommendations for revisions to the existing 10 CFR 35.1000 licensing guidance for radioactive seed localization. Subcommittee members include: Dr. Ennis (chair), Dr. Alderson, Mr. Costello, Dr. Mettler (pending security clearance) and Dr. Zanzonico. The NRC staff resource contact is Ms. Holiday. The subcommittee will present their report during a summer teleconference.

The ACMUI will hold a public teleconference on June 16, 2015 from 2:00PM-5:00PM EST to discuss the radioactive seed localization subcommittee report. No NRC action required.

ITEM (4): Dr. Thomadsen added Dr. Ennis, Dr. O'Hara and Dr. Zanzonico to the standing ACMUI Medical Events Subcommittee. Subcommittee members include: Dr. Ennis (chair), Dr. Langhorst, Mr. Mattmuller, Dr. O'Hara, Dr. Palestro, Dr. Suh, Dr. Thomadsen and Dr. Zanzonico.

No NRC action required.

ITEM (5): Dr. Thomadsen has tasked the existing Ge/Ga-68 subcommittee with (1) estimating the number of potential Ge/Ga-68 generator licensees and (2) making a recommendation to the Committee on which route of action it believes NRC should pursue to address the decommissioning funding plan issue. Subcommittee members include: Mr. Mattmuller (Chair), Mr. Costello, Dr. Langhorst, Dr. Palestro, and Dr. Zanzonico. The NRC staff resource contact is Ms. Holiday. The subcommittee will present their report during a summer teleconference.

The ACMUI will hold a public teleconference on August 12, 2015 from 2:00PM-4:00PM EST to discuss the Ge/Ga-68 subcommittee report. No NRC action required.

ITEM (6): Dr. Thomadsen will draft a letter to the Commission addressing the miswording of the intention of the Committee's recommendation for the ME Compatibility Category. The Committee's recommendation was to address the compatibility category for permanent implant brachytherapy only.

No NRC action required.

ITEM (7): The Committee requested that staff transmit the Committee's clarification for their recommendation for events in which radiation is administered to an embryo/fetus or a nursing child. Specifically, the Committee initially recommended that a human exposure to radiation from licensed material should be an Abnormal Occurrence if an unintended dose to an embryo/fetus or a nursing child resulted in a significant adverse health impact to the embryo/fetus or nursing child, as determined by a consultant physician(s) deemed qualified by NRC or an

Agreement State. The Committee now wants to amend the proposed Abnormal Occurrence (AO) criterion I.A.4 to state, "These criteria [in section I.A] do not apply to medical events defined in 10 CFR 35.3045 or 10 CFR 35.3047 and included in AO criteria III.C., 'Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects.'"

The recommendation passed with eleven favorable votes and one abstention. Ms. Holiday transmitted the Committee's clarification of the embryo/fetus and nursing child AO recommendation as a Commissioners' Assistants (CA) Note to the Office of Research (RES). RES will transmit the CA Note to the Commission. Ms. Holiday provided SECY-15-0040, Proposed Revisions to Policy Statement on Reporting Abnormal Occurrences Criteria, to the Committee on April 02, 2015. In addition, the Committee will have another opportunity to provide comments before the AO Criteria becomes final.

ITEM (8): The Committee planned to hold the fall 2015 ACMUI Meeting on October 08-09, 2015 at NRC Headquarters. The back-up meeting date is September 10-11, 2015.

No NRC action required.

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No NRC action required.

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DATE	4/02/2015	4/02/15	4/03/15

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