

October 29, 2014

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

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

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE
AUGUST 20, 2014, TELECONFERENCE MEETING AND
SEPTEMBER 29-30, 2014, MEETING OF THE ADVISORY
COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are recommendations and action items from the August 20, 2014, teleconference meeting and September 29-30, 2014, meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Following each recommendation or action is the U.S. Nuclear Regulatory Commission (NRC) staff response and/or position.

August 20, 2014, Meeting

ITEM (1): The Committee recommended tabling the discussion and vote for changes to the ACMUI Bylaws to the September 29-30, 2014, ACMUI Meeting.

No NRC action required. This was discussed on September 29, 2014.

September 29-30, 2014, Meeting

ITEM (1): The Committee endorsed the Yttrium-90 Microsphere Brachytherapy Medical Event Criteria Subcommittee Report. This included the following recommendations:

- 1) Specification of an "acceptable" GI tract and lung dose/activity in the written directive prior to performance of the Y-90 microsphere embolization procedure should NOT be required. Instead, the total treatment activity of

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Y-90 microspheres to be administered should be the required compliance measure for organs and tissues other than the treatment site;

- 2) The implantation of the microsphere brachytherapy sources is considered to be in accordance with the written directive if the total administered/infused activity does not vary from the activity prescribed in the written directive by 20 percent or more; except on situations in which the activity administered is limited by the termination of procedure due to stasis; and,
- 3) The above recommendations be incorporated into the NRC guidance for Y-90 microsphere brachytherapy, and that NRC staff, in consultation with ACMUI, compose and disseminate explanation of these recommended revisions in a manner best suited to both the NRC as well as to Authorized Users and other stakeholders tasked with compliance.

The recommendations passed unanimously by the Committee with 13 favorable votes. The NRC staff will review and analyze the recommendations in the report. Staff will review all of the ACMUI recommendations and make a determination about whether or not to amend the 10 CFR Part 35.1000 Y-90 microspheres guidance. If the guidance is amended, staff will share the draft changes with the ACMUI for their review and comment before implementation.

ITEM (2): The Committee endorsed the revisions to the ACMUI Bylaws presented, which includes the proposed language in section 1.3.5 and 3.1 and changes to reflect the new office structure.

The revised Bylaws passed unanimously by the Committee with 13 favorable votes. The NRC staff will finalize and publish the Bylaws by November 2014.

ITEM (3): Dr. Thomadsen tasked Dr. Langhorst and Mr. Costello with creating a proposal to present to the Committee and staff regarding the costs and logistics for an additional face-to-face meeting and/or a medical regulatory information conference. They will present this proposal at the spring 2015 meeting. The NRC staff resource is Dr. Daibes.

No NRC action required.

ITEM (4): Dr. Thomadsen tasked Dr. Suh and Dr. Welsh to work with the American Society for Radiation Oncology for their proposed changes to the language in the Draft FY15 Water and Energy Bill. Dr. Ennis will serve as a consultant to Drs. Suh and Welsh until he assumes the role of the ACMUI's Brachytherapy Radiation Oncologist in February 2015. Dr. Ennis and Dr. Suh will present the language to the Committee at the spring 2015 meeting.

No NRC action required.

ITEM (5): Dr. Thomadsen formed a subcommittee to review the advanced notice of proposed rulemaking for Title 10 *Code of Federal Regulations* Part 20, “Standards for Protection Against Radiation.” Subcommittee members include: Dr. Langhorst (chair), Mr. Costello, Dr. Dilsizian, Mr. Mattmuller, and Dr. Zanzonico. The subcommittee will present their recommendations at a future teleconference.

No NRC action required. The ACMUI will hold a public teleconference on December 10, 2014, from 2:00PM-4:00PM EDT to discuss the subcommittee’s report.

ITEM (6): The Committee planned to hold the spring 2015 ACMUI Meeting on March 19-20, 2015, at NRC Headquarters. The back-up meeting date is either March 23-24, 2015, or April 13-14, 2015.

No NRC action required.

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No NRC action required.

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