

June 06, 2014

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

FROM: Laura A. Dudes, Director **/RA/JMoses for/**
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE MAY 8-9, 2014
MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES
OF ISOTOPES

Below are the recommendations from the May 8-9, 2014 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): The Committee endorsed the Medical Policy Statement Subcommittee Report. This included a recommendation to make no changes to the current NRC Medical Policy Statement.

The recommendation passed unanimously with thirteen favorable votes. NRC staff will include the final ACMUI Medical Policy Statement Report and recommendation in a paper to the Commission.

ITEM (2): Dr. Thomadsen formed a subcommittee to review the medical event reporting criteria of the yttrium-90 microspheres (35.1000) guidance. Subcommittee members include: Dr. Guiberteau (chair), Mr. Costello, Dr. Langhorst, Dr. Palestro, Dr. Thomadsen, and Dr. Welsh. The subcommittee will present their recommendations at the fall 2014 meeting. The NRC staff resource is Dr. Howe.

No NRC action required.

ITEM (3): Dr. Thomadsen added Mr. Francis Costello to the Medical Events Subcommittee.

No NRC action required.

ITEM (4): Dr. Thomadsen formed a subcommittee to provide staff with the background information to justify the recommendation for the regulatory relief from the Decommissioning Funding Plan (DFP) of Ge-68. The subcommittee is specifically charged with evaluating the cost of a DFP for the use of Ge-68, its effect on the future clinical use of new Ga-68 radiopharmaceuticals and how appropriate regulatory relief may be gained. Subcommittee members include Mr. Mattmuller

(chair), Dr. Langhorst, Mr. Costello, Dr. Palestro and Dr. Zanzonico. The NRC staff resource is Ms. Holiday.

No NRC action required.

ITEM (5): Staff will provide the Ge-68 DFP Subcommittee with the NRC guidelines for developing a Regulatory Basis.

NRC staff distributed the documents relative to the Regulatory Basis to the ACMUI Ge-68 Subcommittee and the full Committee on June 06, 2014.

ITEM (6): The Committee recommended tabling the discussion on the revisions to the ACMUI Bylaws until summer 2014. The Committee also requested that staff provide the current and proposed bylaws with color coding for staff's proposed changes and the subcommittee's proposed changes.

The recommendation passed unanimously with thirteen favorable votes. NRC staff distributed the current and proposed bylaws to the ACMUI Bylaws Subcommittee on June 06, 2014.

ITEM (7): The Committee recommended the following: (1) To maintain the current ACMUI reporting structure and continue to review the reporting structure on an annual basis; (2) To maintain the current two face-to-face meetings at headquarters annually; and (3) To endorse the use of web-based meetings as needed, but not in place of the two annual face-to-face meetings.

The recommendation passed unanimously with thirteen favorable votes. This discussion served as the annual discussion on reporting structure for 2014. NRC staff will, when available, use applications such as Go-To-Meeting® for future teleconference meetings.

ITEM (8): The Committee planned to hold the fall 2014 ACMUI Meeting on September 29-30, 2014 at NRC Headquarters. The back-up meeting date is October 20-21, 2014.

No NRC action required.