

April 29, 2011

MEMORANDUM TO: Leon S. Malmud, M.D., Chairman
Advisory Committee on the Medical Uses of Isotopes

FROM: Michael L. Fuller, Alternate Designated Federal Officer **/RA/**
Advisory Committee on the Medical Uses of Isotopes

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE APRIL 11-12, 2011
MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES
OF ISOTOPES

Below are recommendations and action items from the April 11-12, 2011 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.

April 11-12, 2011 Meeting

ITEM (1): Dr. Malmud will serve as a reviewer to screen I-131 cases for the ACMUI Medical Events Subcommittee.

No NRC action required.

ITEM (2): ACMUI recommends the NRC reserve some time at the Fall ACMUI Meeting for public stakeholders to discuss topics that will be covered during the Part 35 Public Workshops.

The recommendation did not pass with seven opposing votes, one abstention and three favorable votes. No NRC action required.

ITEM (3): ACMUI recommends a minimum of 3 months for the NRC to provide notice for future Public Stakeholder Meetings in the medical area, in order to provide stakeholders with ample time for planning.

The recommendation passed unanimously with eleven favorable votes. NRC Staff is considering the ACMUI comments towards future planning of Part 35 Public Workshop Meetings.

ITEM (4): ACMUI recommends the NRC Staff hold the second Part 35 Public Stakeholder Workshop in August in order to better accommodate public stakeholders, with the plan that the ACMUI Permanent Implant Brachytherapy Subcommittee Report will be finalized by the Fall ACMUI meeting.

NRC staff is currently working to move the second public stakeholder workshop to August.

ITEM (5): ACMUI endorses ASTRO's statement for the Permanent Implant Brachytherapy Medical Event Definition as reflected in the meeting handout (ML111010724), as the most appropriate approach for revising the regulations. The ACMUI also recommends that the NRC require post-implant dosimetry following brachytherapy treatment. ACMUI also believes that prostate brachytherapy is a unique subset of brachytherapy and should have a separate set of rules and regulations.

The recommendation passed unanimously with eleven favorable votes. NRC staff will consider the ACMUI recommendations in developing the regulatory basis for a proposed rule.

ITEM (6): ACMUI plans to hold the Fall 2011 ACMUI Meeting on September 22-23, 2011. The back-up date is October 27-28, 2011 and the alternate back-up date is October 31-November 1, 2011.

No NRC action required.

ITEM (7): ACMUI recommends NRC eliminate the written attestation requirements for the board certification pathway, regardless of the date of certification.

The recommendation passed unanimously with eleven favorable votes. NRC staff will consider the ACMUI recommendation as it moves forward with the development of proposed rule language.

ITEM (8): ACMUI recommends NRC revise the attestation requirements to say ... "has received the requisite training and experience in order to fulfill the radiation safety duties required by the licensee," as reflected in the meeting handout (ML11089A040).

The recommendation passed unanimously with eleven favorable votes. NRC staff will consider the ACMUI recommendation as it moves forward with the development of proposed rule language.

ITEM (9): ACMUI supports the statement, as noted in the handout (ML11089A040), that residency program directors can sign attestation letters, representing consensus of residency program faculties, if at least one member of the faculty is an authorized user (AU) in the same category that is designated by the applicant seeking authorized status, and that AU did not disagree with the approval.

The recommendation passed unanimously with eleven favorable votes. NRC staff will consider the ACMUI recommendation as it moves forward with the development of proposed rule language.

ITEM (10): ACMUI continues to assert that the current regulations are based on a per release limit. ACMUI does not recommend any change to the current regulations and does not recommend the NRC consider patient release during the current rulemaking process, as there is no clinical advantage or advantage to members of the public for using an annual limit.

The recommendation passed unanimously with eleven favorable votes. NRC staff will consider the ACMUI recommendation as it moves forward with the development of proposed rule language.