

June 8, 2010

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

FROM: Christian E. Einberg, Designated Federal Officer **/RA/**  
Advisory Committee on the Medical Uses of Isotopes

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE MAY 24-25,  
2010 MEETING OF THE ADVISORY COMMITTEE ON THE  
MEDICAL USES OF ISOTOPES

Below are recommendations and action items from the May 2010 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.

**ITEM (1):** Dr. Thomadsen created a subcommittee to evaluate patient release issues; to objectively review and analyze data, which may include state regulations and guidance and international recommendations; to provide a statement on the issue; and to provide recommendations for improvements to existing NRC rules and guidance, if necessary, which should include the issue of patient release to hotels. Subcommittee members include: Dr. Susan Langhorst (chair), Dr. Darrell Fisher, Ms. Debbie Gilley, Mr. Steven Mattmuller, Dr. Orhan Suleiman, Dr. Bruce Thomadsen, Dr. James Welsh and Dr. Pat Zanzonico. The subcommittee should report to the full ACMUI at the fall meeting.

No NRC action required.

**ITEM (2):** The Permanent Implant Brachytherapy subcommittee will revise the draft subcommittee report and resubmit it to the full ACMUI for an e-mail vote. The ACMUI will submit a final subcommittee report to the NRC.

The recommendation passed with eight favorable votes.

No NRC action required.

**ITEM (3):** NRC staff should provide information that describes safety culture problems as contributing factors to violations.

NRC staff requested information from the Regions and will provide a summary to the ACMUI.

**ITEM (4):** NRC staff should review the Y-90 microsphere brachytherapy guidance to delete "but before the patient or human research subject leaves the post-procedural recovery area" under item 2 of the written directive section.

The recommendation passed with eight favorable votes.

NRC staff accepts the ACMUI recommendation and will revise the Microsphere Brachytherapy Sources and Devices licensing guidance.

**ITEM (5):** NRC staff should revise the Y-90 microsphere brachytherapy guidance to read (under 1 for written directives) “and, if the procedure was not performed in accordance with the pre-administration written directive”, then 2) “after administration and within 48 hours of the procedure, the signature of an AU.”

The recommendation passed with eight favorable votes.

NRC staff accepts the ACMUI recommendation and will revise the Microsphere Brachytherapy Sources and Devices licensing guidance.

**ITEM (6):** NRC staff should consider the necessity and evaluate options to collect or obtain data for the denominator for medical events to improve the overall value of the medical events subcommittee report.

NRC staff will investigate the adequacy of the IMV data and will make a decision whether to purchase the report titled “2007 Radiation Oncology Benchmark Report.”

**ITEM (7):** The ACMUI fully supports Dr. Darrell Fisher as Patients’ Rights Advocate. The Committee expressed their appreciation and honor to serve with him.

The recommendation passed with seven favorable votes and one abstention from the Patients’ Rights Advocate.

No NRC action required.

**ITEM (8):** NRC staff should provide optimal staff and support to facilitate the licensing process for new domestic producers of the medical isotope, molybdenum 99.

The recommendation passed with eight favorable votes.

NRC staff will transmit the ACMUI recommendation to the Commissioners.

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<b>OFFICE</b>	MSSA/RMSB	MSSA/RMSB	MSSA/RMSB
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