



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

October 20, 2015

MEMORANDUM TO: Philip O. Alderson, M.D., Chairman  
Advisory Committee on the Medical Uses of Isotopes

FROM: Josephine M. Piccone, Ph.D., Director */RA/ CEinberg for JPiccone*  
Division of Materials Safety, State, Tribal,  
and Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION ACTION IN RESPONSE  
TO THE OCTOBER 8-9, 2015 MEETING OF THE ADVISORY  
COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are the recommendations from the October 8-9, 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. The NRC staff will provide additional communication(s) for items pending completion of staff review and evaluation.

**ITEM (1):** The Committee recommended to make the following change to the Patient Intervention Subcommittee Recommendation Issue II:

*Unintentional Treatment outcome due to anatomic or physiologic anomaly ~~and/or imaging uncertainty~~ falls into the category "the Art of Medical Practice" provided that the standards of medical practice are met.*

The recommendation passed with ten approvals and one abstention. No NRC action required.

**ITEM (2):** The Committee endorsed the Patient Intervention Subcommittee Report with the caveat that the revision be made to issue II (referenced immediately above).

The recommendation passed with ten approvals and one dissention. The NRC staff, including legal counsel, will review and analyze the recommendations in the report.

**ITEM (3):** The Committee recommended that staff issue a Generic Communication (i.e. Information Notice or Regulatory Issue Summary) to licensees to inform them of the interpretation of "patient intervention."

The recommendation was unanimously approved. Staff will determine the most effective and appropriate method to communicate the interpretation of "patient intervention."

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**ITEM (4):** Dr. Thomadsen, ACMUI Chairman, charged the Training and Experience (T&E) for Alpha and Beta Emitters Subcommittee with establishing a recommendation for the total number of hours of T&E for authorized users of such emitters that is necessary for safety. This subcommittee will present its recommendation(s) at the spring 2016 meeting. The NRC resource is Sophie Holiday.

No NRC action required.

**ITEM (5):** Dr. Ennis recommended that the individual who implants the source for radioactive seed localization be the authorized user only - and not an individual under the supervision of an authorized user.

The recommendation did not pass with two approvals, eight dissensions and one abstention.

**ITEM (6):** The Committee recommended that the individual who implants the source for radioactive seed localization procedures can do so under the supervision of an authorized user.

The recommendation passed with ten approvals and one dissension. No NRC action required.

**ITEM (7):** The Committee endorsed the Radioactive Seed Localization Subcommittee Report.

The recommendation was unanimously approved. The final report was provided to the Radioactive Seed Localization Working Group for consideration during its review and evaluation of revisions to the licensing guidance.

**ITEM (8):** The Committee endorsed the Yttrium-90 (Y-90) Microspheres Subcommittee Report. This report supported the proposed revisions to the (Y-90) licensing guidance.

The recommendation was unanimously approved. The final report was provided to the Y-90 Microspheres Working Group for incorporation in its revisions to the licensing guidance.

**ITEM (9):** The Committee planned to hold the spring 2016 ACMUI Meeting on March 17-18, 2016 at NRC Headquarters. The back-up meeting date is March 3-4, 2016.

No NRC action required.

**ITEM (10):** The Committee endorsed the 2015 Abnormal Occurrence (AO) Criteria Subcommittee Report with the caveat that the report be amended to include an introductory paragraph that provides the rationale for the recommendations, as well as a summary paragraph to state that the Committee desires that the recommendations be incorporated into this revision of the NRC's Abnormal Occurrence Criteria Policy Statement.

The recommendation was passed with ten approvals and one dissension. Once the final report is received, staff will review and evaluate the Committee's recommendations for the revisions to the NRC's AO Criteria Policy Statement. The Commission Paper for the draft final AO Criteria Policy Statement will include the Committee's unfettered comments (the report) as an enclosure.

**ITEM (11):** The Committee endorsed the NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses," Subcommittee Report.

The recommendation was unanimously approved. The final report was provided to the NUREG-1556, Volume 9 Working Group for consideration during its development of revisions to the licensing guidance.

**ITEM (12):** Dr. Thomadsen formed a subcommittee to propose the appropriate criteria for Medical Event Reporting for events other than permanent implant brachytherapy. Subcommittee members include: Dr. Dilsizian, Dr. Ennis, Mr. Ouhib, Dr. Palestro, Dr. Suh (Chair), and Dr. Zanzonico. The subcommittee will present its recommendations at the spring 2016 meeting.

No NRC action required.

**ITEM (11):** The Committee endorsed the NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses," Subcommittee Report.

The recommendation was unanimously approved. The final report was provided to the NUREG-1556, Volume 9 Working Group for consideration during its development of revisions to the licensing guidance.

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No NRC action required.

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<b>DATE</b>	10/15/2015	10/19/15	10/20/15

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