



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

July 25, 2016

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

FROM: Daniel M. Collins, Director */RA/*
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: NRC ACTION IN RESPONSE TO THE JUNE 24, 2016
TELECONFERENCE MEETING OF THE ADVISORY
COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are the recommendations from the June 24, 2016 teleconference meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). These recommendations reflect the ACMUI's comments on the draft "Low Activity Radioactive Seeds Used for Localization of Non-palpable Lesions and Lymph Nodes Guidance." Following each recommendation is the U.S. Nuclear Regulatory Commission (NRC) staff response and/or position.

ITEM (1): The Committee agreed with the elimination of the written directive with the understanding that there will be documentation in the medical record pre-procedure and post-procedure that would allow regulators to determine whether a medical event occurred.

The recommendation passed unanimously with nine favorable votes.

ITEM (2): The Committee agreed with the third pathway in which a radiologist could become an authorized user with the listed 80-hours of training and experience. However, the subcommittee did not support surgeons or others without a significant background in radiation (from a residency or other similarly intense education and practical experience) becoming Authorized Users for RSL with only 80 hours of training.

The recommendation passed unanimously with nine favorable votes.

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ITEM (3): The Committee supports the modified definition of medical events (MEs) with the caveat that such an outcome would not be an ME if “the physician makes the determination not to explant the seed for various patient conditions (e.g. doing so would jeopardize the patient’s well-being).” The subcommittee accepts this change and supports exclusion from an ME under circumstances in which the physician deems removal would not be in the best interest of the patient. Additionally, the subcommittee supports the position that an ME has not occurred if the patient fails to return for the surgical removal procedure, considering this to be an instance of “patient intervention,” provided the patient has been properly counseled about the importance of returning for the procedure and the risk of radiation exposure if the sources are not removed. Documentation of this counseling should be made in the patient’s medical record.

The recommendation passed unanimously with nine favorable votes.

ITEM (4): The subcommittee recommended inclusion of the following in the Draft Guidance:

“Patient should be advised not to breast feed from a breast into which one or more radioactive seeds been implanted and not yet removed. Breast feeding is, of course, permissible once the seed(s) has(ve) been removed. In the event of seed rupture within the breast, the subcommittee recommends the patient be advised to never breast feed from the effected breast for this child.”

During the discussion, this recommendation was modified as follows:

“Patient should be advised not to breast feed from a breast into which one or more radioactive seeds been implanted and not yet removed. Breast feeding is, of course, permissible once the seed(s) has(ve) been removed. In the event of seed rupture within the breast, the subcommittee recommends the patient be advised to never breast feed from **either** breast for this child.”

The recommendation passed unanimously with nine favorable votes.

The ACMUI submitted their final report to the NRC staff on June 24, 2016. NRC staff will consider the ACMUI’s recommendations for possible changes to the “Low Activity Radioactive Seeds Used for Localization of Non-palpable Lesions and Lymph Nodes Guidance.”

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OFC	MSTR/MSEB	MSTR/MSEB	MSTR/MSEB	MSTR
NAME	MSmethers	MFuller	DBollock	DCollins
DATE	7/14/2016	7/18/2016	7/18/2016	7/25/2016

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