



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

November 16, 2016

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

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

SUBJECT: THE U.S. NUCLEAR REGULATORY COMMISSION ACTIONS IN
RESPONSE TO THE OCTOBER 6-7, 2016, MEETING OF THE
ADVISORY COMMITTEE ON THE MEDICAL USES OF
ISOTOPES

Below are the recommendations and requests from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) meeting held on October 6-7, 2016, and the U.S. Nuclear Regulatory Commission (NRC) staff's response.

ITEM (1): Dr. Alderson requested that the ACMUI discuss the nursing mother guidelines related to cessation of breast feeding by patients receiving radioactive materials during the Spring 2017 ACMUI Meeting.

Staff will include this topic in the Spring 2017 ACMUI Meeting agenda.

ITEM (2): The Committee recommended that staff issue a generic communication (information notice) regarding tubing issues (kinking, connection, hub etc.) during the administration of Y-90 microspheres brachytherapy.

Staff will review and analyze medical events involving tubing issues during the administration of Y-90 microspheres to determine if the issuance of a generic communication document is appropriate.

ITEM (3): Dr. Pat Zanzonico stepped down from the Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy Subcommittee and Dr. Philip Alderson appointed Mr. Frank Costello to the Subcommittee. Subcommittee membership includes: Mr. Costello, Dr. Vasken Dilsizian, Dr. Ennis, Dr. Palestro, and Dr. John Suh (Chair). Mr. Zoubir Ouhib will be added to the subcommittee once he receives full voting rights.

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No action required at this time. The NRC resource is Dr. Katie Tapp.

ITEM (4): Dr. Alderson re-established the Patient Intervention Subcommittee. The subcommittee's new charge is to make a recommendation on what the definition of "patient intervention" should be. Subcommittee membership includes: Mr. Costello, Dr. Dilsizian (Chair), Dr. Ennis, Dr. Suh, and Ms. Laura Weil.

No action required at this time. Ms. Maryann Abogunde is the NRC resource.

ITEM (5): The Committee recommended that Pathway 2 remain for the Y-90 Microsphere Brachytherapy Licensing Guidance. The NRC/Organization of Agreement States (OAS) working group should determine the requirements for proctoring cases by the manufacturer(s).

This recommendation has been provided to the NRC/OAS working group for consideration.

ITEM (6): The Committee recommended support of the update to the waste disposal section and the review of the Y-90 radiation safety issues in autopsy and cremation in the draft revision of the Y-90 Microsphere Brachytherapy Licensing Guidance.

This recommendation endorses the working group's recommendation. No further action is required.

Recommendations 7-16 listed below, related to the NorthStar Medical Radioisotopes LLC (NorthStar) RadioGenix™ Molybdenum-99 (Mo-99)/Technetium-99m (Tc-99m) Generator System Licensing Guidance, were provided to the NRC/OAS working group for consideration.

ITEM (7): The Committee recommended that NorthStar provide a training module video clip showing how the system operates.

ITEM (8): Given the unique design and operation of the NorthStar system, the Committee agreed that NorthStar should have sole responsibility for the content of the training course for authorized individuals and system users and certification of individuals who will provide the training.

ITEM (9): The Committee stated that it is important to clarify that a System Administrator can be any individual assigned by the Authorized User (AU) without a specifically defined educational or training background. Given the unique role of the System Administrator, perhaps that individual should be named on the license.

ITEM (10): The Committee recommended an explicit statement regarding the System Administrator Designee, although it may not have been intended, one could infer from the description of the system administrator designee that

there can be only one designee. Presumably, there can, and should, be multiple System Administrator designees.

- ITEM (11):** The Committee recommended that the appropriate time period allotted for training on the “changes” and the responsibility of the vendor/manufacture to inform and train the applicants on changes in a timely manner be specified.
- ITEM (12):** The Committee recommended that the guidance clarify whether the generator will be “non-operational” until all individuals handling the generator are trained in the changes, including the AU, Radiation Safety Officer, system administrator, etc. or whether it requires only the AU to be trained on the “changes.” If the latter, once the AU is trained on the “changes,” is the AU then solely responsible for training all others on these changes? This should be stated.
- ITEM (13):** The Committee recommended using the term, “individual tasks” throughout the document for consistency and to clarify that there is only one protocol and software program with this system.
- ITEM (14):** The Committee recommended that the manufacturer’s procedures be reviewed and incorporated into the Licensing Guidance itself.
- ITEM (15):** The Committee recommended that the term “higher than expected” be defined in terms of a maximum specific exposure or exposure-rate limit which a survey meter should be capable of measuring.
- ITEM (16):** The Committee unanimously endorsed the NorthStar Mo-99/Tc-99m Generator (RadioGenix™) Licensing Guidance Subcommittee Report.
- ITEM (17):** The Committee tentatively scheduled the Spring 2017 Meeting for March 20-21, 2017. The back-up meeting dates are April 25-26, April 26-27, and April 27-28, subject to Commission availability.

No NRC action required.

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No NRC action required.

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DATE	10/26/2016	10/27/2016	10/31/2016	11/16/16

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