



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

May 30, 2017

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 APRIL 26-27, 2017, 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 April 26-27, 2017, and the U.S. Nuclear Regulatory Commission (NRC) staff's response.

ITEM (1): The Committee requested that the recommendations and actions pertaining to the Part 35 rulemaking be reviewed during the Fall 2017 ACMUI meeting and that additional time be provided to review each item.

Staff will include additional time for this topic during the Old Business portion of the Fall 2017 ACMUI meeting agenda.

ITEM (2): Dr. Alderson formed a subcommittee to review the recommendations from Elekta to consider amending the licensing guidance physical presence requirements for the Elekta Gamma Knife® Icon. Subcommittee membership includes Dr. Suh (Chair), Dr. Ennis, and Ms. Laura Weil.

Ms. Sophie Holiday is the NRC resource. No action required at this time.

ITEM (3): The Committee requested an update, from NRC staff, on source security initiatives involving Category 3 sources at the Fall 2017 ACMUI meeting.

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Staff will coordinate with the Source Management and Protection Branch to provide a status update on source security initiatives involving Category 3 sources for the Fall 2017 ACMUI meeting.

ITEM (4): Dr. Alderson formed a subcommittee to review the SECY Paper on Patient Release. The subcommittee will be comprised of Dr. Zanzonico (Chair), Dr. Langhorst, Dr. Palestro, and Ms. Weil.

Dr. Donna-Beth Howe is the NRC resource. No action required at this time.

ITEM (5): Dr. Alderson formed a subcommittee to review the nursing mother guidelines. The subcommittee charge is to review the radiation exposure from diagnostic and therapeutic radiopharmaceuticals including brachytherapy to the nursing mother and child. The subcommittee will be comprised of Dr. Metter (Chair), Dr. Dilsizian, Dr. Palestro, and Dr. Zanzonico.

Dr. Said Daibes is the NRC resource. No action required at this time.

ITEM (6): The Committee endorsed the Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy Subcommittee Report.

The report has been marked as final and included on the ACMUI Web site. The Commission is currently reviewing the proposed definition of permanent implant brachytherapy previously submitted by the ACMUI. ACMUI will continue discussion on patient intervention and will encourage major societies to issue white papers to develop consensus on what should be incorporated into a written directive for various diagnostic and therapeutic modalities. The report did not include any new actionable recommendations for NRC staff.

ITEM (7): The Committee endorsed the Training and Experience for all Modalities Subcommittee Status Report.

The report has been included on the ACMUI Web site. This report provided a template for the ACMUI subcommittee's review of the training and experience requirements for all modalities. There are no actions for NRC staff at this time. If further recommendations come from the subcommittee as they continue their analysis of each modality, the NRC will review and assess the recommendations as appropriate.

ITEM (8): The Patient Intervention Subcommittee will amend its Subcommittee Report and will discuss the amended report at the ACMUI Fall 2017 meeting or by teleconference prior to the Fall meeting.

Staff will coordinate with ACMUI leadership to determine whether a teleconference should be held before the Fall 2017 ACMUI meeting to further discuss this topic.

ITEM (9): The Committee recommended to (1) amend the title of Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture report from draft report to interim report, (2) to continue discussions on this topic, and (3) to endorse the interim report.

The report has been updated accordingly and included on the ACMUI Web site. The Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture Subcommittee will report at the Fall 2017 ACMUI meeting. No further action required at this time.

ITEM (10): The Committee tentatively scheduled the fall 2017 ACMUI meeting for September 11-12, 2017. The back-up dates are October 18-19, 2017.

Staff has confirmed that travel funds are available for the September date.

ITEM (11): The NRC staff will provide the Committee with information related to the escalated enforcement actions to medical licensees over a 5-year span.

Ms. Sophie Holiday is the NRC resource.

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