

December 23, 2002

MEMORANDUM TO: Manuel D. Cerqueira, M.D., Chairman
Advisory Committee on the
Medical Uses of Isotopes

THRU: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

FROM: Thomas H. Essig, Chief **/RA/**
Materials Safety and Inspection Branch
Division of Industrial and Medical
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SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE OCTOBER
28, 2002 MEETING OF THE ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

Below are the recommendations from the October 28, 2002 meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Following each recommendation is the U.S. Nuclear Regulatory Commission (NRC) staff's position.

Status: ACMUI-formulated Training and Experience Recommendations to Amend the Revised 10 CFR Part 35, Medical Use of Byproduct Material

ACMUI recommendation: The ACMUI recommends that the Chairman, ACMUI, contact the NRC Chairman to inquire about the status of the training and experience (T&E) recommendations the ACMUI subcommittee formulated to amend the T&E in the revised 10 CFR Part 35, Medical Use of Byproduct Material.

Staff response: This recommendation does not require action by NRC staff. However, staff will monitor the resolution of the T&E issue and keep the ACMUI informed.

Contact: Angela Williamson, NMSS/IMNS
(301) 415-5030

Review Licensing Guidance for Emerging Technologies

ACMUI recommendation: The ACMUI recommends that the Chairman, ACMUI, form a standing subcommittee to review 10 CFR 35.1000 licensing guidance as it is developed by NRC staff.

Staff response: Staff supports this proposal and plans to utilize the ACMUI subcommittee when it is formed.

Sealed Source Model Numbers as License Conditions on NRC Licenses

ACMUI recommendation: The ACMUI recommends that NRC initiate a rulemaking process to modify 10 CFR Part 35 to override 10 CFR Part 30.32(g)(1), to allow more generic listing of interstitial seeds and sources on NRC licenses.

Staff response: Staff believes that a rulemaking initiative to modify 10 CFR Part 35 to override 10 CFR Part 30.32(g)(1), for the purpose stated, may ultimately reduce radioactive source accountability.

Title 10 CFR Part 30.32 (g)(1), which requires the listing of all sources or devices by manufacturer and model number, was implemented to ensure that licensees maintain full accountability of the sources/devices under their care. Staff believes that identification of all sources/devices by manufacturer and model number is a reasonable measure to ensure that accountability is maintained. Such accountability aids licensees in keeping an accurate inventory of sources, which helps prevent loss of radioactive material, thereby protecting public health and safety.

Furthermore, staff does not believe it to be prudent to reduce accountability of radioactive material in an environment of heightened public awareness and sensitivity, brought on by the terrorist events of September 11, 2001.

For these reasons, staff is unable to support the stated rulemaking initiative.

Approaching ACMUI Vacancies

ACMUI recommendation: The ACMUI recommends that NRC initiate replacement of the approaching Nuclear Cardiologist, Patient Advocate, and State Representative vacancies. Inherent in this recommendation is the replacement of a Chair, since the current Nuclear Cardiologist is also the Chair of the ACMUI.

Staff response: Staff agrees with this recommendation. Furthermore, staff discussed these approaching vacancies before bringing this issue to the October 28, 2002, ACMUI meeting as an agenda topic, and had already made the decision to pursue this matter expeditiously, to minimize disruption of ACMUI's service to the staff.

Moreover, the Commission formally approved - via issuance of a staff requirements memorandum dated December 17, 2002 - the staff's request to launch the replacement process. Although the process includes the routine step of soliciting resumes in the Federal Register, staff will also contact several professional societies (per Commission instruction) so that the solicitation of resumes is broadly announced.

*See previous concurrence

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