February 12, 2001

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

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

SUBJECT: RECOMMENDATIONS FROM NOVEMBER 8-9, 2000, MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

To facilitate the conversation between the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the Division of Industrial and Medical Nuclear Safety, I am providing you with a response and status for each of the recommendations made by ACMUI at the November 8-9, 2000, meeting.

Using 10 CFR 7, "Advisory Committees," and 41 CFR 101, "Federal Advisory Committee Management," we are considering whether a more effective process for interaction between NRC and the ACMUI can be developed. Proposals for the revised process will be discussed with ACMUI at the next meeting scheduled for April 18-19, 2001.

Listed below are the recommendations with the staff's response.

New Medical Technologies:

The ACMUI recommended that a license amendment be required under § 35.400, "Use of sources for brachytherapy," for the TheraSphere®.

Staff response: The staff plans to implement this recommendation when issuing TheraSphere® license amendments under the existing 10 CFR Part 35, "Medical Use of Byproduct Material."

NRC/Agreement State Event Reporting:

The ACMUI recommended that the NRC develop an NRC web site to include a search engine that would enable one to find relevant sections for reporting requirements and that guidance on reporting be organized by type of licensee, e.g., materials, medical, industrial, etc.

Staff response: An extensive effort is underway to improve the NRC web site. This recommendation is consistent with previous input to that effort, and will be considered as part of the agency's ongoing web redesign.

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Update on Other Rulemaking Activities:

1) The ACMUI recommended that the new risk-informed reporting limit of 5 rem in 10 CFR 35 be limited to reporting of errors made in the release procedure or delivery of instructions to the patient that results in exposures to individuals, other than the patient, in excess of 5 rem.

Staff response: The staff is following the Commission's direction proposing a revision to 10 CFR 35 to require a licensee to notify NRC when it becomes aware that an individual has received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under § 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material." The staff will include the ACMUI recommendations in the paper transmitting the proposed rule.

2) The ACMUI recommended that no further rulemaking be required for exposure to embryo/fetus because 10 CFR 20, "Standards for Protection against Radiation," already contains reporting requirements for all exposures to the general public.

Staff response: The staff provided the ACMUI recommendations, along with the staff's recommendations, as part of the paper sent to the Commission addressing the issue of embryo/fetus exposure. The staff received Commission approval to terminate any further action on the proposed embryo/fetus rulemaking.

Training Requirements:

Regarding the training requirement in § 35.961, "Training for teletherapy physicist," the ACMUI recommended that exemptions be based on a case-by-case review by the ACMUI Chairman with input from the members.

Staff response: The staff plans to implement the recommendation and review requests, on a case-by-case basis, for exemptions to the training requirement with input from the ACMUI chairman.

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***See previous concurrence**

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