August 24, 2005

MEMORANDUM TO: Leon S. Malmud, M.D., Chairman
Advisory Committee on the
Medical Uses of Isotopes

FROM: Thomas H. Essig, Chief **/RA/**
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety, NMSS

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE APRIL 20-21, 2005 MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are recommendations from the April 20-21, 2005, 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 response and/or position.

MEDICAL EVENTS INVOLVING I-131

ACMUI recommendation: To reduce the number of medical events involving I-131, NRC staff should consider incorporating the following practices in licensees procedures:

1. Patient verification procedures similar to blood administration could be considered.
2. Verbal orders should not be permitted in any step of the therapeutic dosage administration process.
3. The dosage to be administered must be verified against the written directive prior to administration.
4. Re-verify the therapeutic dosage in a dose calibrator on site prior to administration.
5. Communication between the Authorized User (AU) and the individual administering the dosage should be strengthened.

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NRC staff response: It appears the ACMUI tailored its response to focus on reducing the incidence of medical events in general. While the staff appreciates the ACMUI's efforts, the staff's original intent was to acquire recommendations that would reduce the incidence of medical events involving I-131 administrations where diagnostic administrations were intended, but activities which require a written directive were administered.

In an August 1, 2005 teleconference, staff discussed this issue with the Chairman of the I-131 Medical Events Subcommittee, Dr. Douglas Eggli. During the discussion, Dr. Eggli stated that the subcommittee was not clear about the staff's request for recommendations. Dr. Eggli stated that he would re-engage the subcommittee to formulate recommendations for NRC staff consideration at the October 2005 ACMUI public meeting.

MEDICAL EVENTS INVOLVING PERMANENT IMPLANT BRACHYTHERAPY

Remarks: During discussion of this topic, the ACMUI recommended to NRC staff language that it believed would more accurately capture medical events resulting from permanent brachytherapy implants. This language is in the two proposed recommendations below. With respect to writing the actual rule, the ACMUI suggested that the NRC staff take the following approach: (1) Select Proposed Recommendation #1 as the new rule language, or (2) Select Proposed Recommendation #2 as the new rule language, or (3) Combine the language in Proposed Recommendations 1 and 2, and use the combined language to draft a new rule to capture medical events resulting from permanent brachytherapy implants.

ACMUI Proposed Recommendation #1: Any permanent implant in which there is no occurrence of seed migration and patient intervention, is a medical event if:

a) The total source strength implanted anywhere in the patient exceeds the written directive by more than 20 percent or;
b) The total source strength implanted in the target volume deviates from the written directive by more than 20 percent. That the ACMUI be provided with a copy of the research protocol for review, before making recommendations on guidance regarding the use of I-125 seeds as markers in breast tumors.

ACMUI Proposed Recommendation #2: Any permanent brachytherapy is a medical event, excluding seed migration and patient intervention, if a total source strength implanted in the treatment site in the patient varies from the written directive by more than 20 percent.

NRC staff response: Subsequent to the ACMUI's submission of these recommendations to the NRC staff, the ACMUI developed a different approach to defining medical events resulting from permanent brachytherapy procedures. Rather than recommending that the staff choose between Proposed Recommendations 1 and 2 above, the ACMUI's Medical Events Subcommittee (MESC) decided that it would develop a set of principles that it would recommend that the staff use to create a definition of medical events resulting from permanent brachytherapy procedures.

Toward this end, the ACMUI and the staff conducted a June 28, 2005, public teleconference meeting. During the teleconference, the MESC forwarded to the ACMUI the set of principles.

The ACMUI discussed and refined the principles with the MESC, then voted to approve the principles. The ACMUI will formally present these principles to the staff in a memorandum.

Once the staff has received the principles, the staff will use these principles as the basis for part of a Commission paper on medical event definition and conveying risk information to the public. The paper will recommend to the Commission whether the staff should use these principles as a guide for writing rule language that will define permanent implant brachytherapy medical events.

MAINTAINING THE 20% THRESHOLD FOR REPORTING MEDICAL EVENTS NOT INVOLVING PERMANENT IMPLANT THERAPY (BRACHYTHERAPY)

ACMUI recommendation: That as long as medical event reporting is not automatically treated as an indicator of potential patient harm, ± 20 percent remains a reasonable action level for reporting events of Quality Assurance significance to NRC for the following modalities: temporary implants, external beam treatments and unsealed radiopharmaceutical administrations.

NRC staff response: During previous rulemaking efforts, NRC staff has communicated the concept that the purpose of medical event reporting is to keep the NRC informed of the occurrence of these events, but that their occurrence is not necessarily indicative of actual patient harm.

In the Statements of Consideration contained within the *Federal Register* notification published May 14, 1980, (i.e., 45 FR 31701), the Commission published a final rule in 10 CFR Part 35, which stated, in part, that the NRC amended its medical regulations to require prompt reporting of medical events (then referred to as medical "misadministrations"). In that publication, the Commission acknowledged that misadministrations could occur without actual harm done to the patient.

In the Statements of Consideration contained within the *Federal Register* published July 25, 1991, (i.e., 56 FR 34104), the Commission published a final rule to 10 CFR Part 35, which stated that the NRC amended its regulations to include the requirement for a quality management program[1] that was intended to ensure that byproduct material was administered as directed by the authorized user (AU). In the publication of 56 FR 34104, the NRC noted that there exists the possibility that medical events may cause patient harm, but also acknowledged that the "overall significance" of medical events is that they "indicate a breakdown in the licensee's program for ensuring that byproduct material or radiation is administered as directed by the AU."

Thus, the NRC has historically acknowledged that the presence of medical events is not

[1]The requirement for a Quality Management Program was rescinded with the publication of the rule in 10 CFR Part 35, that became effective October 24, 2002.

necessarily indicative of patient harm, and continues to adopt this stance.

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ML051940084 *See previous concurrence

OFC	MSIB	MSIB	MSIB	MSIB	IMNS
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DATE	7/13/05	7/14/05	7/20/05	7/27/05	8/19/05

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[2]The requirement for a Quality Management Program was rescinded with the publication of the rule in 10 CFR Part 35, that became effective October 24, 2002.