October 2, 2006

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

FROM: Thomas H. Essig **/RA/**
Designated Federal Official
Advisory Committee on the
Medical Uses of Isotopes

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE APRIL 25-26, 2006 MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are recommendations from the April 25-26, 2006, 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.

## Regulatory Information Summary (RIS) ON VISITOR DOSE LIMITS

ACMUI MOTION: To allow an exemption for exceeding the public limit dose limit to the family members who are care givers to hospitalized patients criteria or aspects considered in allowing exemption. The elements of exemption should include:

- It is the responsibility of the licensee;
- The licensee will give the regional office contemporaneous notification of this exception;
- Informed consent will be required;
- There will be a discouragement of pregnant woman and minors from excessive exposure;
- Standard safety precautions will be in place; and
- A dosimeter will be used to measure the exposure of the parties.

NRC staff response:
The staff accepted the motion for incorporation in the RIS.

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## PART 35 TRAINING AND EXPERIENCE

ACMUI RECOMMENDATION: The Committee suggested that NRC staff send two letters to the American Board of Radiology (ABR), one related to the Radiation Oncology Specialty, and the other to the Diagnostic Radiology Specialty, requesting the Board determine whether earlier effective dates can be used for recognition of their certification processes. The staff will provide the draft of these letters to Dr. Malmud, Dr. Diamond, and Dr. Eggli for review before they are submitted to the board.

NRC staff response:
The NRC staff made telephone contact with ABR and followed up with letters, dated May 8, 2006, and September 8, 2006. The letters were reviewed by named ACMUI members before they were sent to the ABR, Radiation Oncology, and ABR, Diagnostic Radiology, respectively.

## TRAINING AND EXPERIENCE RULE CHANGE FOR AN AUTHORIZED USER SEEKING RSO STATUS

ACMUI RECOMMENDATION: The ACMUI recommended the NRC staff to send the information on the rule change, correcting 10 CFR Part 35.50(d) to the Agreement States, either by an article or Information Notice.

NRC staff response:
The staff agreed with the decision of the committee. The Office of State and Tribal Programs (OSTP) sent out a letter to all Agreement State on July 12, 2006. The letter explains that NRC recently made a correction in 10 CFR Part 35.50(d) by adding, "( c )(2)," to the list of training and experience pathways.

## TRAINING AND EXPERIENCE FOR USE OF MICROSPHERES THERAPY

ACMUI MOTION: The ACMUI recommended that the NRC staff revise current guidance to permit 10 CFR Part 35.390 physicians as authorized users for Y-90 microspheres. The elements of recommendation are: 1) a multi-speciality team approach, and 2) qualification for Y-90 micisphers is a minimum of three cases.

The ACMUI defined the technical experience making up the team should include:

- Catheter placement;
- Particle therapy;
- Dosimetry calculations;
- Training in 35.300 or 35.400;
- Expertise in oncology;
- Safe handling of unsealed sources; and,
- Pharmacology (resin leaks).

NRC staff response:
NRC staff is in the process of revising the guidance posted on NRC's website. The estimated completion date for this task is November 15, 2006.

**PROPOSED BREAST BRACHYTHERAPY USING I-125 SEEDS**

ACMUI RECOMMENDATION: The committee recommends that these patients, undergoing treatment with devices used for temporary implants of 1-125, be released with the shields in place and follow instructions and requirements of 10 CFR Part 35.75.

NRC staff response:
Staff agreed with this recommendation, however, no action by NRC staff will be taken until requests are received.

**ACMUI REVIEW OF MEDICAL EVENTS INVOLVING I-131**

ACMUI RECOMMENDATION: To remind the licensees that they have an obligation under current regulations to verify any dose of greater than 30 microcuries against a written directive, and strongly recommend an effective positive approach to identify patients. The committee recommends encouraging free communication between the authorized user and administering technologist. Also the possibility of communication by Information Notice (IN) was discussed in the meeting and subsequent dissemination to professional organizations to more effectively reach the affected parties.

NRC staff response:
NRC staff agrees with the ACMUI and is in the process of developing an IN. Estimated completion date is Oct. 15, 2006. The IN will be distributed to the appropriate professional organizations.

## POTENTIAL CHANGES TO 10 CFR 35

ACMUI RECOMMENDATION: Revise 10 CFR Part 32.72(b)(5) to read:
"(5) Shall provide to the Commission a copy of each individual's certification by the Board of Pharmaceutical Specialties and the written attestation(s), signed by a preceptor . . ."

NRC staff response:
The staff agreed with the ACMUI to propose revising 10 CFR Part 32.75(b)(5) to reflect the above changes.

ACMUI RECOMMENDATION: Revise 10 CFR Part 35.2 to read:
"Medium dose-rate remote after loader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads)per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed."

NRC staff response:
The staff agreed with the ACMUI and will propose revising this 10 CFR Part 32.2 to reflect the above changes.

ACMUI RECOMMENDATION: Revise 10 CFR Part 35.12(d) to clarify either a license application or amendment requires submission of the information required in 10 CFR 35.12(b), regardless of the format used to submit it.

NRC staff response:
The staff agreed with ACMUI to propose revising 10 CFR Part 35.12 (d) to reflect the above changes.

ACMUI RECOMMENDATION: Revise 10 CFR Part 35.50(c)(2) to read:
"(2) Will be identified as an authorized user, authorized medical physicist, or authorized nuclear pharmacist on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities."

NRC staff response:
The staff agreed with ACMUI to propose revising 10 CFR Part 35.50(c)(2) to reflect the above changes.

ACMUI RECOMMENDATION: Revise 10 CFR Part 35.65 by replacing the phrase, ". . . not exceeding 1.11 GBq (30 mCi) each . . ." with, "not exceeding either 1.11 GBq (30 mCi) each or a total activity of 1.11 GBq (30 mCi) when used as a simultaneous aggregate . . ."

NRC staff response:
The staff agreed with the ACMUI to propose revising 10 CFR Part 35.65.

ACMUI RECOMMENDATION: Revise 10 CFR Part 35.92 to read:
"A licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage without regard to its radioactivity . . ."

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