January 18, 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 OCTOBER 13-14, 2004 MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are recommendations from the October 13-14, 2004, 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.

RADIOIMMUNOTHERAPY AND MICROSPHERE THERAPY

Remarks: During the presentation of this topic, the discussion shifted to the Seed Selectron permanent implant remote after loader device, and the ACMUI made a recommendation regarding the Seed Selectron device. No recommendation was made regarding radioimmunotherapy and microsphere therapy.

ACMUI recommendation: That NRC staff continue to regulate permanent prostate brachytherapy in 10 CFR 35.1000, but use 35.400 as the regulatory framework for creating guidance, while adding elements of 10 CFR 35.600, as necessary, to that guidance.

NRC staff response: Staff agrees with the ACMUI and was aligning the guidance for the Seed Selectron closer to the requirements in 35.400 rather than 35.600. However, Region I has withdrawn the request for this guidance because of lack of licensing requests for this device.

Attachment:
October 2004 Recommendations

CONTACT: Angela McIntosh, NMSS/IMNS
(301) 415-5030

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Distribution:
IMNS r/f

ML050030093 *see previous concurrence

OFC	MSIB	MSIB	MSIB	MSIB	IMNS
NAME	AMcIntosh*	CFlannery*	SWastler *	TEssig	CMiller
DATE	1/03/05	1/05/05	1/11/05	1/18/05	1/18/05

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RADIATION SAFETY ASPECTS OF I-125 THERAPEUTIC SEEDS USED AS MARKERS IN BREAST CANCER TUMORS

ACMUI recommendation: 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.

NRC staff response: NRC staff forwarded the research protocol to the ACMUI on December 2, 2004. Staff requests that the ACMUI review the protocol and provide a recommendation to staff at the Spring 2005 ACMUI public meeting.

DRAFT FINAL 10 CFR 35 T&E: STATUS OF RULEMAKING

ACMUI recommendation: That the number of didactic hours of training in the draft final 10 CFR 35.390 be reduced from 200 to 80, with the total number of hours of training under 35.390 remaining at 700 hours. This motion passed with one abstention.

NRC staff response: This recommendation was made in association with the draft final 10 CFR 35, during the public comment. Therefore, staff will process this recommendation with all other comments submitted by stakeholders during the formal public comment period.

ACMUI recommendation: That the draft language in 10 CFR 35.57 be modified to read as follows: That physicists who have been authorized to serve the function of authorized medical physicists for high dose rate brachytherapy, gamma stereotactic radiosurgery, and teletherapy be grandfathered to be allowed to serve as authorized medical physicists for those respective modalities.

NRC staff response: This recommendation was made in association with the draft final 10 CFR 35, during the public comment. Therefore, staff will process this recommendation with all other comments submitted by stakeholders during the formal public comment period.

ACMUI recommendation: That the staff move toward implementing the draft final 10 CFR 35, except for those items of concern raised in the above recommendations during this meeting.

NRC staff response: The draft final 10 CFR 35 will move forward in the finalization process in accordance with Agency procedure. All recommendations made in association with the draft final 10 CFR 35 will be processed in accordance with Agency procedure.

PROPOSED CHANGE TO ABNORMAL OCCURRENCE CRITERIA FOR MEDICAL EVENTS

ACMUI recommendation: That the staff move forward with the criteria as proposed, with the suggested changes that dose be expressed in “rem” rather than “rad”, and the criteria language that captures events that involve the medical administration of byproduct material (or radiations therefrom).

Staff response: Staff has given further consideration of the types of anticipated therapies that may be encountered in the future. As a result, the staff has determined it is best to leave the expression of dose, used in the context of AO medical event, criteria, in absorbed dose (rad) rather than dose equivalent (rem).

Furthermore, so that the AO criteria is aligned with the medical event criteria in 10 CFR 35, the staff believes it is best that the AO criteria keep its existing language that requires reporting of medical events, rather than "events involving the medical administration" of material.

2005 ICRP RECOMMENDATIONS

ACMUI recommendation: That the International Commission on Radiological Protection (ICRP) maintain in its recommendations the current occupational exposure limit of 500 millirem to pregnant occupational workers.

NRC staff response: Dr. Richard Vetter, ACMUI, presented this topic to the ACMUI to gain the committee's perspective on the ICRP's draft recommendations. After Dr. Vetter explained the various ICRP recommendations, the ACMUI responded by formally recommending that the ICRP maintain, in its guidance of the current occupational exposure, a limit of 500 millirem to pregnant occupational workers. Dr. Vetter presented this recommendation to representatives at the ICRP meeting sponsored by the Advisory Committee on Nuclear Waste, on October 19, 2004, at NRC Headquarters. No further action regarding this recommendation is required by NRC staff.