January 9, 2008

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

FROM: Sandra Wastler, Designated Federal Officer **/RA/**
Advisory Committee on the
Medical Uses of Isotopes

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE AUGUST 15-16, 2007, SEPTEMBER 20, 2007, OCTOBER 22-23, 2007, AND DECEMBER 12, 2007, MEETINGS OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are recommendations and action items from the August, September, October, and December 2007, meetings of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Following each recommendation or action is the U.S. Nuclear Regulatory Commission (NRC) staff response and/or position.

AUGUST 15, 2007, MEETING

MOTION 1: ACMUI supports grandfathering for individuals who had previously been determined to be trustworthy and reliable and granted unescorted access.

NRC staff considered the ACMUI recommendation; however, no provision for grandfathering was included in the fingerprinting orders issued to licensees on December 5, 2007.

MOTION 2: ACMUI agrees to assist the NRC, if requested, to determine those levels and types of material that could be of such significance to public health and safety to warrant fingerprinting and background checks.

ACMUI assistance was not requested. The fingerprinting orders were issued to licensees on December 5, 2007.

AUGUST 16, 2007, AND SEPTEMBER 20, 2007, MEETINGS

MOTION 1: NRC staff should revise the regulations so that board certified individuals, who were certified prior to the effective date of recognition or were certified by previously recognized boards listed in Subpart J of the previous editions of Part 35, are grandfathered.

NRC staff action on the ACMUI recommendation will be based on the outcome of the petition for rulemaking, PRM 35-20 (AAPM petition).

MOTION 2: NRC staff should revise the current regulations to include Canadian trained individuals who have passed the ABNM certification exam.

NRC staff is considering the ACMUI recommendation.

MOTION 3: NRC staff should maintain Compatibility B for training and experience requirements to ensure that authorized individuals may cross state borders and practice throughout the U.S.

The ACMUI recommendation is in alignment with current NRC regulations; therefore, NRC staff accepts the ACMUI recommendation, and no NRC staff action is required.

MOTION 4: NRC staff should accept a preceptor statement from another AU for a non-board certified individual if the AU who supervised the training and work experience is not available as a preceptor.

The ACMUI recommendation is in alignment with current NRC regulations and practice; therefore, NRC staff accepts the ACMUI recommendation, and no NRC staff action is required.

MOTION 5: NRC staff should add 'increased complexity vs. additional benefit' as an agenda item for the October ACMUI meeting, so that ACMUI may continue the discussion on this topic.

NRC staff accepted the ACMUI recommendation and added 'increased complexity vs. additional benefit' as an agenda item for the October ACMUI meeting.

OCTOBER 22-23, 2007, MEETING

MOTION 1: The AU should be required to place a signature on orders for radioactive material before the supplier can legally ship the material to an institution.

This motion did not pass. No NRC staff action is required.

MOTION 2: The Elekta Perfexion® should be regulated under 10 CFR 35.1000 until 10 CFR 35.600 is modified to be performance-based, which would allow the Perfexion® to be regulated under 10 CFR 35.600.

NRC staff accepts the ACMUI recommendation and has added the item to its User Need memorandum requesting changes to Part 35 through rulemaking.. NRC staff will consider the outcome of the ACMUI subcommittee's recommendations in future revisions to 10 CFR 35.600 (see ACTION 1 of the October 22-23, 2007 meeting below).

MOTION 3: NRC staff should require experienced RSOs and AMPs to receive additional training, if the individual is seeking authorization or responsibility for new uses.

NRC staff accepts the ACMUI recommendation and has added the item to its User Need memorandum requesting changes to Part 35 through rulemaking.

MOTION 4: NRC staff should not require experienced RSOs to obtain written attestation to become authorized or have responsibility for new uses.

NRC staff accepts the ACMUI recommendation and has added the item to its User Need memorandum requesting changes to Part 35 through rulemaking.

MOTION 5: NRC staff should revise 10 CFR 35.75 to read "5 mSv/year (0.5 rem/year)."

The initial vote on this motion was in favor of the proposed revision; however, after further review by a subcommittee (See ACTION 2) and a second discussion and vote by the full ACMUI, the motion did not pass. NRC considered both ACMUI votes and is pursuing the revision to 10 CFR 35.75 to read 5 mSv/year (0.5 rem/year), which is consistent with NRC's original intent. NRC staff added the item to its User Need memorandum requesting changes to Part 35 through rulemaking.. See related article "Dose Limit for Patient Release Under 10 CFR 35.75" in the Fall 2007 Office of Federal and State Materials and Environmental Management Programs Licensee Newsletter.

MOTION 6: NRC staff should modify 10 CFR 35.491(b)(2) to specify "superficial' ophthalmic treatments. Additionally, NRC staff should change the title of 10 CFR 35.491 to specify 'superficial' ophthalmic treatments.

NRC staff accepts the ACMUI recommendation and has added the item to its User Need memorandum requesting changes to Part 35 through rulemaking.

MOTION 7: NRC staff should not revise 10 CFR 35.491 (intended for ophthalmologists) to include training and experience for the new intraocular device. Instead, NRC staff should regulate the new intraocular device under 10 CFR 35.490.

NRC staff considered the ACMUI recommendation and has added an item for the intraocular device to its User Need memorandum requesting changes to Part 35 through rulemaking.. NRC staff is pursuing the addition of the intraocular device in 10 CFR 35 Subpart F but not specifically in 10 CFR 35.490. Placing the use of this device in 10 CFR 35.490 would restrict the use by ophthalmologists.

MOTION 8: NRC staff should not require medical licensees regulated under 10 CFR 35.400, 500, or 600, as applicable, to only use the sealed sources and devices for the principle use as approved in the SSDR.

NRC staff accepts the ACMUI recommendation and has added the item to its User Need memorandum requesting changes to Part 35 through rulemaking..

MOTION 9: NRC staff should revise 10 CFR 35.290 to allow physicians to receive training and experience in the elution of generators and preparation of kits under the supervision of an ANP.

NRC staff accepts the ACMUI recommendation and has added the to its User Need memorandum requesting changes to Part 35 through rulemaking...

MOTION 10: NRC staff should revise the microsphere guidance to allow the written directive to include either "dose to target tissue (Gy or rad)" or "activity administered (mCi or GBq)."

NRC staff accepts the ACMUI recommendation and will revise the microsphere guidance accordingly.

MOTION 11: NRC staff should revise the microsphere guidance to include a paragraph referencing medical event reporting for microsphere use. (10 CFR 35.3045 Medical Event Reporting)

NRC staff accepts the ACMUI recommendation and will revise the microsphere guidance accordingly.

MOTION 12: NRC staff should revise the microsphere guidance to reinsert the proposed paragraph with modification. The paragraph should state, "Procedures for administrations requiring a written directive should, for yttrium-90 microsphere administration, be performed in accordance with the written directive."

NRC staff accepts the ACMUI recommendation and will revise the microsphere guidance accordingly.

MOTION 13: NRC staff should revise the microsphere guidance to allow an experienced AU for a certain type of microsphere to become an AU for the same type of microsphere use on a different license, similar to the notification provision in 10 CFR 35.14.

NRC staff accepted the ACMUI recommendation and revised the microsphere guidance accordingly in December 2007.

MOTION 14: NRC staff should revise the microsphere guidance to add a paragraph which states, "Training in manufacturer's procedures, commensurate with the individual's duties to be performed, must be provided to individual preparing, measuring, performing dosimetry calculations, or implanting microspheres."

NRC staff accepts the ACMUI recommendation and will revise the microsphere guidance accordingly.

MOTION 15: NRC staff should revise the microsphere guidance to read, "The written directive should include after implantation but before release of the patient from licensee control: the radionuclide (including the chemical/physical form [Y-90 microspheres]), the manufacturer, treatment site, and the total dose or administered activity.

NRC staff accepts the ACMUI recommendation and will revise the microsphere guidance accordingly.

MOTION 16: (a) ACMUI recommended for each training program, including radiology, radiation oncology, radiation physics, and nuclear pharmacy, that the curricular requirements be established by those boards, which recognize the importance of the NRC standards for radiation safety and radiation physics.

(b) ACMUI also recommended the deletion of the word "competence" and suggested replacing it with a statement regarding the successful completion of a residency training program.
(c) Additionally, ACMUI recommended that the word 'minimum' be removed from Motion (2) from the June 12-13, 2007 ACMUI meeting. Motion (2) should read, "NRC staff should remove the attestation requirement for board certified individuals and rewrite the attestation requirement for individuals seeking authorization under the alternate pathway. The rewritten attestation should not include the word "competency" but should instead read "has met the training and experience requirements."

NRC staff is considering part (a) the ACMUI recommendation. Part (b) of the ACMUI recommendation is encompassed in MOTION 2 from the June 12-13, 2007, meeting. As stated in a memo dated October 11, 2007, NRC staff is considering part (b) of the ACMUI recommendation. NRC staff accepts the ACMUI recommendation in part (c) to modify MOTION 2 from the June 12-13, 2007, meeting. NRC staff is considering the revised MOTION 2.

ACTION 1: ACMUI will form a subcommittee to address issues with 10 CFR 35.600 as they relate to the Elekta Perfexion®. The subcommittee includes: Dr. Nag (chair), Dr. Thomadsen, Dr. Welsh, and Mr. Lieto. The subcommittee should consult with: Ms. Gilley on behalf of the Agreement States; the vendor; the American Society for Therapeutic Radiology and Oncology (ASTRO); and the AAPM.

NRC staff will consider the subcommittee's recommendations when received. See MOTION 2 from the October 22-23, 2007 meeting above for related information.

ACTION 2: ACMUI should form a subcommittee to further discuss the proposed change (MOTION 5) to 10 CFR 35.75 to release patients, if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv/year. The subcommittee includes: Dr. Vetter (chair), Dr. Eggli, and Dr. Fisher.

On October 22, 2007, ACMUI took an initial vote on MOTION 5 for the proposed change to 10 CFR 35.75. After the initial vote, the above mentioned subcommittee was formed. The subcommittee researched the issue further and engaged the full Committee in a second discussion on October 23, 2007. ACMUI took a second vote on MOTION 5. The motion did not pass, and ACTION 2 is closed.

ACTION 3: NRC staff should set-up NMED accounts for new members and reset passwords for other members, as needed, following the October meeting.

NRC staff set-up NMED accounts for new members and reset passwords for other members, as needed. ACTION 3 is closed.

ACTION 4: NRC staff should add an item to the spring 2008 agenda for Dr. Thomadsen to provide a presentation to ACMUI members and NRC staff on the causes of medical events. Dr. Thomadsen's presentation will also provide suggestions for questions NRC should ask to receive more accurate information on the causes of events.

NRC staff will add the item to the spring 2008 meeting.

ACTION 5: ACMUI should form a subcommittee to annually review byproduct material events, perform analysis, and report to the full Committee. NMED data should continue to be presented to ACMUI at the fall meetings, and the subcommittee should analyze the data presented at the fall meeting in order to provide a full report at the spring meeting. The subcommittee includes: Mr. Lieto (chair), Dr. Nag, Dr. Thomadsen, and Dr. Suleiman. The subcommittee will consult with an Agreement State representative, Ms. Gilley, and designated NRC staff, as appropriate.

NRC staff will continue to support ACMUI, as appropriate, to annually review byproduct material events. NRC staff will add an item for the subcommittee's presentation to the spring agenda.

ACTION 6: ACMUI byproduct material events subcommittee should publish reports, as necessary, to ensure end-users receive the message.

NRC staff will support ACMUI, as necessary, to publish subcommittee reports via NRC's normal distribution channels, e.g. NRC website, medical listserver, licensee newsletter. No action is required for NRC staff at this time.

DECEMBER 12, 2007, MEETING

MOTION 1: ACMUI recommends a subcommittee comprised of Dr. Vetter and Dr. Nag to make comments and recommendations on behalf of the entire ACMUI in terms of the medical implications of the upcoming National Academies of Science study, which is in response to the 2005 Energy Policy Act.

NRC staff accepts the ACMUI recommendation. NRC staff will coordinate, as necessary, with the subcommittee members and will notify the full ACMUI when a report becomes available.

NRC staff will add the item to the spring 2008 meeting.

ACTION 5: ACMUI should form a subcommittee to annually review byproduct material events, perform analysis, and report to the full Committee. NMED data should continue to be presented to ACMUI at the fall meetings, and the subcommittee should analyze the data presented at the fall meeting in order to provide a full report at the spring meeting. The subcommittee includes: Mr. Lieto (chair), Dr. Nag, Dr. Thomadsen, and Dr. Suleiman. The subcommittee will consult with an Agreement State representative, Ms. Gilley, and designated NRC staff, as appropriate.

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