MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

May 23, 2006

MEETING SUMMARY

PURPOSE: To vote on the proposed amendment to the Advisory Committee on the Medical Uses of Isotopes ACMUI's bylaws, discussed in the closed session of the April 2006 meeting. In addition, to discuss and approve the potential changes to 10 CFR Part 35, an unfinished item from the April 2006 meeting.

AMENDMENTS TO THE ACMUI's BYLAWS (CLOSED SESSION[1])
The ACMUI voted on the proposed amendments to the bylaws that were discussed in the closed session of the April 2006 meeting. The committee also made some additional changes, to the bylaws, that will be voted on in the next meeting.

POTENTIAL CHANGES TO 10 CFR PART 35 (OPEN SESSION)
Dr. Howe, U.S. Nuclear Regulatory Commission (NRC), presented the potential changes to 10 CFR Part 35, to the ACMUI, and sought its approval of the recommendations. This presentation was a continuation of an unfinished topic from the April meeting. The committee discussed the remaining items and its recommendations are as follows:

ACMUI RECOMMENDATION: To revise 10 CFR 35.190(a)(1) to read: "...hours of training and experience as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section." and Revise 10 CFR 35.290(a)(1) to read, "...hours of training and experience as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section. "

ACMUI RECOMMENDATION: Not to revise 10 CFR 35.290 to states, "...provide two training and experience pathways for 10 CFR 35.200 physicians-- one for physicians who can only administer unit dosages and the other for physicians who are permitted to prepare radioactive drugs."

ACMUI RECOMMENDATION: Not to revise 10 CFR 35.390(b)(1)(ii), 35.392(c)(2), and 35.394(c)(2), to read: "A supervising authorized user, who meets the requirements in § 35.390 must ...."

ACMUI RECOMMENDATION: Not to revise 10 CFR 35.390(b)(1)(ii), 35.392(c)(2), and

[1]These sessions were closed pursuant to 5 U.S.C. 552b(c)(2), (6) and (9)(B) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACMUI; information the release of which would constitute a clearly unwarranted invasion of personal privacy; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and disclosure of information which would risk circumvention of an agency regulation or statute."

35.394(c)(2), to read: "A preceptor authorized user, who meets the requirements in § 35.390 must...."

ACMUI RECOMMENDATION: Not to revise 10 CFR 35.396 to read:
"(b) Is an authorized user, under §§ 35.490 or 35.690, or equivalent Agreement State requirements, and who meets the requirements in paragraphs (c)(2), (c)(3), and (c)(4), of this section; or
(c)(1) Is certified by a medical specialty board...;
(c)(2) Has successfully completed 80 hours of classroom...;
(3) Has work experience, under the supervision of...;
(4) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b), (c)(2), and (c)(3) or paragraphs (c)(1), (c)(2), and (c)(3), of this section, and has achieved a level of competency..."

Instead the committee recommends that the NRC staff clarify 10 CFR 35.396 by a guidance rather than any rulemaking.

ACMUI RECOMMENDATION: To revise 10 CFR 35.433 to expand the description of the tasks and responsibilities of the medical physicist, before, during and after use of the Strontium-90 eye applicator. The committee also recommends that NRC staff include the issue of re-examination of the medical physicist's role in manual brachytherapy, in the next ACMUI meeting's agenda.

ACMUI RECOMMENDATION: To revise 10 CFR 35.433 to permit a medical physicist with training and experience in specific tasks identified to the use of manual brachytherapy sources to perform the tasks under 10 CFR 35.433.

ACMUI RECOMMENDATION: To revise 35.3045 (a)(2), to clarify that a medical event needed to be reported when there was no written directive but a written directive should have been completed. The ACMUI, however, did not have specific language to recommend.

ACMUI RECOMMENDATION: To revise 35.3045(a)(3) to read: "(3) A dose to the skin or an organ or tissue other than the treatment site, which exceeds, by 0.5 Sv (50 rem) and 50 percent or more of the dose expected from the administration...."

ACMUI RECOMMENDATION: To revise 10 CFR 35.3045(a)(3) to read: "A dose to the skin or an organ or tissue, other than the treatment site, which exceeds by 0.5 Sv (50 rem), and exceeds 50 percent or more of the dose expected to that site, from the administration, if it had been given in accordance with the written directive ...."

ACMUI RECOMMENDATION: To revise 10 CFR 35.51(a)(2)(i) to read: "Under the supervision of a medical physicist who is certified in medical physics by a speciality board, recognized for this section by the Commission or an Agreement State."

The meeting adjourned at 5:30 p.m.