

October 5, 2006

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

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

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE MAY 23,
2006 MEETING OF THE ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

In the May 23, 2006 teleconference meeting, the staff presented eleven potential changes to 10 CFR Part 35. Below are recommendations from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) for each of these potential changes. Following each ACMUI recommendation is the U.S. Nuclear Regulatory Commission (NRC) staff's response and/or position.

POTENTIAL CHANGES TO 10 CFR PART 35 (OPEN SESSION)

1. 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." In addition, to 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. "

NRC staff response:

NRC staff accepts the ACMUI recommendation to propose revising 10 CFR 35.190(a)(1).

2. ACMUI RECOMMENDATION: Not to revise 10 CFR 35.290 to 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.

NRC staff response:

NRC staff accepts the ACMUI recommendation and will not propose revising 10 CFR 35.290.

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3. 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"

NRC staff response:

NRC staff accepts the ACMUI recommendation and will not propose revising 10 CFR 35.390(b)(1)(ii), 35.392(c)(2).

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

NRC staff response:

NRC staff accepts the ACMUI recommendation and will not propose revising 10 CFR 35.390(b)(1)(ii), 35.392(c)(2).

5. 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 the correct reading of 10 CFR 35.396 in a publicly available guidance.

NRC staff response:

NRC staff accepts the ACMUI recommendation and instead of making the above change will clarify the correct reading of 10 CFR 35.396 by a newsletter article.

6. 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.

NRC staff response:

NRC staff accepts the ACMUI recommendation and will propose revising 10 CFR 35.433.

7. 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.

NRC staff response:

NRC staff accepts the ACMUI recommendation to propose revising 10 CFR 35.433.

8. ACMUI RECOMMENDATION: To pursue revision of 35.3045 (a)(2), to clarify that a medical event needed to be reported where there was no written directive but a written directive should have been completed. The ACMUI, however, did not have specific changes to recommend.

NRC staff response:

NRC staff accepts the ACMUI recommendation and will propose revising 10 CFR 35.3045(a)(2).

9. 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...."

NRC staff response:

NRC staff accepts the ACMUI recommendation to propose revising 10 CFR 35.3045(a)(3).

10. 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"

NRC staff response:

NRC staff accepts the ACMUI recommendation to propose revising 10 CFR 35.3045(a)(3).

11. 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."

NRC staff response:

NRC staff accepts the ACMUI recommendation to propose revising 10 CFR 35.51(a)(2)(i).

NRC staff response:

NRC staff accepts the ACMUI recommendation to propose revising 10 CFR 35.433.

8. ACMUI RECOMMENDATION: To pursue revision of 35.3045 (a)(2), to clarify that a medical event needed to be reported where there was no written directive but a written directive should have been completed. The ACMUI, however, did not have specific changes to recommend.

NRC staff response:

NRC staff accepts the ACMUI recommendation and will propose revising 10 CFR 35.3045(a)(2).

9. 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...."

NRC staff response:

NRC staff accepts the ACMUI recommendation to propose revising 10 CFR 35.3045(a)(3).

10. 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"

NRC staff response:

NRC staff accepts the ACMUI recommendation to propose revising 10 CFR 35.3045(a)(3).

11. 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."

NRC staff response:

NRC staff accepts the ACMUI recommendation to propose revising 10 CFR 35.51(a)(2)(i).

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