July 5, 2001

Alan H. Schoenfeld, MS, DABR
Senior Physicist
Montefiore Medical Center
The University Hospital for the Albert Einstein
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Henry and Lucy Moses Division
111 East 210th Street
Bronx, New York 10467-2490

Dear Mr. Schoenfeld:

I am responding to your letter of May 31, 2001, concerning Regulatory Guide 10.8, "Guide for the Preparation and Applications for Medical Use Programs." In that letter, you stated that Table 1 in Appendix G of Regulatory Guide 10.8 needed to be revised. Table 1 provides guidance on investigational levels, for occupational external doses, that will initiate a review or investigation by a Radiation Safety Officer. We agree with your concern about the information in the Regulatory Guide. We have addressed the concern as described below.

The U.S. Nuclear Regulatory Commission (NRC) has developed a guidance document titled NUREG-1556, Vol. 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses," in parallel with the proposed revision of 10 CFR Part 35, "Medical Use of Byproduct Material." Volume 9 will supersede the guidance previously found in Regulatory Guide 10.8. The investigational levels on Table 1 in Appendix G of Regulatory Guide 10.8 were updated to make them consistent with current dose limits, and moved to Appendix L of NUREG-1556, Vol. 9. NRC expects that the revised Part 35, and final report on NUREG-1556, Vol. 9, will be published concurrently some time this year. Please note that the draft version of Vol. 9 did not include the corrected information, but that the final version does.

I trust that this information responds to your concern. If you have any further questions or concerns, you may contact John Hickey, of my staff, at (301) 415-7231, or through e-mail, at jwh1@nrc.gov.

Sincerely,

/RA/

William D. Travers
Executive Director
for Operations

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