AUG 2 8 1985

License No. 37-11438-02
Docket No. 030-13111
Control No. 104093

Franklin Regional Medical Center
ATTN: John A. Stanton
Administrator
One Spruce Street
Franklin, Pennsylvania 16323

Gentlemen:

This is in reference to your request in a letter dated July 11, 1985 to amend License No. 37-11438-02. In order to continue our review, we need the following additional information:

1. With regard to your proposed procedure to test dose calibrator linearity, we do not find your procedure equivalent to that in Appendix D, Section 2 (enclosed).

   a. The initial activity you propose to use, 25 mCi is not adequate. If you wish to use an aliquot from the first elution of the generator, it should at least be comparable to the maximum activity used in kit preparation which is approximately 200 millicuries.

      Readings taken to 48 hours (as suggested by Regulatory Guide 10.8) would then yield data to approximately 0.8 millicurie per your proposal.

      If you elect to use an aliquot of activity, the routine Mo-99 test, required by 10 CFR 35.14(b)(4) (enclosed) on each elution from the generator, should be performed on an aliquot of Tc-99m having an activity within the range tested by the dose calibrator linearity test.

   b. Your method of plotting the observed data is acceptable, i.e., activity versus time on semi-log graph paper but should also include a plot of the calculated values on the same paper with ± 5% error lines or a computation of the % difference between the observed and calculated values for all data points. The 24 or 30 hour activity should be used to calculate the predicted activities.

Please submit a revised procedure for dose calibrator linearity testing.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 104093.

Sincerely,

Original Signed By:
John D. Kinneman

John D. Kinneman, Chief
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

Enclosures:
1. 10 CFR Part 35
2. Regulatory Guide 10.8

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