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September 24, 1985

John D. Kinneman, Chief  
Nuclear Material Safety Section  
Division of Radiation Safety and Safeguards  
United States Nuclear Regulatory Commission  
Region I  
631 Park Avenue  
King of Prussia, PA 19406

RE: License #37-11438-02  
Docket #030-13111  
Control #104093

Dear Mr. Kinneman:

In response to your letter of August 28, 1985, We offer the following procedure for Dose Calibrator Linearity Testing:

I. PRELIMINARY CONSIDERATIONS

- A. The initial elution from a Technicium generator for this laboratory can be as high as 2000 Mci.
- B. To repeatedly handle 2000 Mci of Tc-99m for the linearity test is not necessary, practical, nor observing the principle of ALARA.
- C. The largest activity used in kit preparation in this laboratory is approximately 100 Mci of Tc-99m.
- D. The typical dose administered to any patient is 20 Mci of Tc-99m.
- E. The "Moly break-thru" test will be modified to use an aliquot of approximately 200 Mci of Tc-99m for each elution.
- F. The Dose Calibrator Unit used in this laboratory (Capintec -CRC-17) is preset to account for room background. Therefore, there is no need for the operator to subtract background from any reading.

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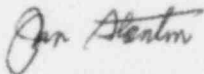
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II. TEST METHOD

- A. An aliquot of approximately 200 Mci of Tc-99m will be transferred to an elution-type vial and will be used for this test.
- B. The Dose Calibrator Unit will be set for the measurement of Tc-99M. It will be preset for background.
- C. The aliquot activity will be measured in the Dose Calibrator at approximately the following times after the initial measurement.
  - 1 hour, 2 hours, 4 hours, 6 hours,
  - 24 hours, 30 hours, and 48 hoursThe times of the measurement will be carefully noted using the same clock (watch) for each.
- D. As suggested in Licensing Guide 10.8, the 30 hour Tc-99m activity will be used as the basis for the calculation of the activities which would be expected at each of the measurement times. Since the pressure of clinical responsibilities may prevent a measurement at precisely 30 hours, it may be necessary to use an interpolated 30 activity for these calculations.
- E. The percent difference between the calculated activity (using 6.00 hours as the Tc-99m half-life) and the measured activity will be calculated for each instance.
- F. If the difference between any calculated and its corresponding measured activity exceed  $\pm 5\%$ , the test will be repeated.
- G. A persistent difference greater than  $\pm 5\%$  will indicate a need for instrument repair.

Sincerely,



John A. Stanton  
Administrator

JAS/hc