May 19, 1975

Amend. 23

United States Nuclear Regulatory Commission
Washington, D. C.

Gentlemen:

Subject: Application for the Use of Technetium 99m-Labeled Osteoscan for Bone Imaging

We hereby request amendment of our license, No. 34-01197-01, to permit our use of technetium 99m labeled Osteoscan (5.9 mg. disodium etidronate, 0.16 mg. stannous chloride) Skeletal Imaging Agent, supplied by Procter and Gamble.

In support of this application, we provide the following information.

1. The planned dosage range. The adult dose recommended for this procedure is 10-15 millicuries.
2. Procter and Gamble's Osteoscan kit will be used to prepare the materials.
3. The manufacturer's direction for use will be followed.
4. The source of Tc-99m to be used is Sodium Pertechnetate Tc99m Sterile Solution purchased from Isotope Industries Inc., Cleveland, Ohio
5. The following is a description of the radio assay procedures to be followed to assure 90% accuracy. The activity of the final preparation and each patient dose will be checked in a Radex Mark V Isotope Dosecalibrator to insure that it does not exceed the recommended dose and to further insure at least 90% accuracy of dose.
6. The following methods will be used to control and evaluate radiation exposure to personnel during preparation, assay and administration of the radiopharmaceutical. The Tc99m and the Tc99m labeled Osteoscan will be contained in lead shields during preparation and subsequent use. Syringe shields will be used when patient doses are administered.. Film badges and ring badges obtained from R. S. Landauer and Co., monitored monthly, will be worn by all personnel working with this material to determine radiation dose to arms, hands and body. Areas used in conjunction with radioactivity will be monitored for radiation levels with a suitable survey meter to assure compliance with regulations (Title 10, Chap. 1, Part 20).

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7. If the vial is removed from the shield for the three minute shaking period, we confirm use of an ultrasonic agitator with auxiliary shielding.

8. We confirm that excess material will be disposed of in accordance with established procedures for disposal of radioactive waste.

9. The areas used for preparation of radiopharmaceuticals will be assayed for contamination after each procedure and/or at the end of each working day.

10. The personel who elute generators or prepare radiopharmaceuticals from reagent kits will monitor their hands and clothing for contamination after each procedure and all personnel who prepare patient doses or work in areas used for elution of generators, preparation of radiopharmaceuticals, or preparation of individual patient doses will monitor their hands and clothing for contamination before leaving those areas.

Truly yours,

William J. Fayen, M.D.
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WJF:mlf
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