



14519 DETROIT AVENUE

LAKEWOOD, OHIO 44107

PHONE (216) 521-4200

August 14, 1970

U. S. Atomic Energy Commission
Isotopes Branch
Division of Materials Licensing
Washington, D. C.

Amendment 14

Re: Byproduct Material License No. 34-01197-01

Gentlemen:

We are hereby requesting an amendment to our Byproduct Material License No. 34-01197-01 to include the use of:

1. The Squibb Technetope II Technetium 99m Sterile Generator, Catalogue No. 08871, with a maximum possession limit of 1000 mCi of Mo-99 and 1000 mCi Tc-99m and with a maximum dose not to exceed 10 mCi per patient.
2. Technetium-99m Labeled Sulfur Colloid with a maximum dose not to exceed 3 mCi per patient.
3. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

Attached specifications include the supplemental information required for licensing.

Truly yours,

W. J. Fayen
William J. Fayen, M.D.
Director
Nuclear Medicine

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1. Squibb Technetope II Technetium 99m Sterile Generator
Catalogue No. 08871

Maximum possession limit -1000 mCi of Mo-99 and 1000 mCi Tc-99m. Maximum dose not to exceed 10 mCi per patient.

Expired generators will be decayed in storage for a period of fifteen Mo-99 half lives and/or until surface radiation from the generator indicates no more than normal background radiation, or generator will be returned to supplier in original shipping container.

Radiation exposure will be monitored with Gardray film badges, R. S. Landauer Jr. & Co., on a monthly basis. Radiation field surrounding the generator will be monitored with a Radector III Model 2035 survey meter manufactured by Victoreen Instrument Co. and capable of measuring at least one roentgen per hour.

Unused Tc-99m sources or residues will be decayed in storage for a period of no less than fifteen Tc-99m half-lives.

Tc-99m calibration and Mo-99 assay of the eluted material will be performed with the Nuclear-Chicago Mediac Dose Calibrator, Model 6372. Eluted sources containing more than one uCi of Mo-99 per mCi of Tc-99m or patient doses containing more than five uCi of Mo-99 will not be used.

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2. Technetium 99m Labeled Sulfur Colloid for the purpose of liver and spleen scanning. Maximum dose will not exceed 3 mCi per patient.

The 99m Tc Sulfur Colloid requested will be obtained through the mixture of 99m Tc eluate and Tesuloid (E. R. Squibb list #08856). We shall follow the manufacturer's directions with regard to elution and assay of the 99m Tc eluate. In addition we shall also check each elution for the presence of 99Mo contamination. If the 99Mo is found to exceed 1.0 uCi per 1.0 mCi of 99m Tc or a total of 5.0 uCi per dose, the material will not be used.

We shall follow the manufacturer's (E. R. Squibb) direction rigidly as it is spelled out on the Tesuloid package under Directions for Use so that a consistent particle size and proper binding can be expected.

A lung count will be performed to determine if there is a high lung deposition of the 99m Tc Sulfur Colloid. If such a condition is found to exist then the remainder of the batch manufactured shall not be used for any further liver and spleen scans.

In addition a thyroid and heart check will be done to check for the presence of free pertechnetate. The 10% or less limit will be strictly adhered to. If an increase of greater than 10% of 99m Tc activity is found in the thyroid or heart then the remainder of the batch shall not be used for any further liver and spleen scans.

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