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September 20, 1974

United States Atomic Energy Commission Materials Branch Division of Materials Licensing Washington, D. C.

Subject: Application for the Use of Technetated (Tc99m) Aggregated Albumin(Human) for Lung Imaging.

Gentlemen:

We hereby request amendment of our license number 34-01197-01 to permit the use of Technetated (Tc99m) Aggregated Albumin (human) for lung imaging.

- The usual adult dosage for this procedure will be 2-4 millicuries intravenously.
- We will prepare the product from products supplied under the trade name of Macrotec by E. R. Squibb and Sons, Inc. and under the trade name of TechneScan MAA by Mallinckrodt, Inc.
- 3. The manufacturers' directions for use of the kit will be followed.
- 4. The following is a description of the radioassay 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.
- 5. The source of the technetium 99m used with the kit will be prepackaged, preassayed "Instant" Technetium 99m Pertechnetate supplied by Isotope Industries, Inc., Cleveland, Ohio.

(OCT) 2 1 1974

- 6. All radioactive material will be labeled and kept in 1/8" lead shields during manufacture, use and storage. Personnel will use film badges and ring badges obtained from R. S. Landauer & Co., monitored monthly, during manufacture and use of the radioactive materials.
- 7. We confirm that excess material will be disposed of in accordance with established procedures for disposal of radioactive waste.

Truly yours,

Mfayen
William J. Fayen, M.D.

Director

Nuclear Medicine

WJF:mlf Encl.

Lakewood Hospital Lakewood, Ohio 9/20/7h License No. 34-01197-01