Medical Center

3200 Vine Street
Cincinnati, OH 45220

Veterans Administration

July 31, 1984

U.S. Nuclear Regulatory Commission
Material Licensing Department
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Gentlemen:

We request the following amendment to our NRC license, number 34-00799-03 to allow use of the following radiopharmaceuticals obtained from the Eugene L. Saenger Radioisotope Laboratory of the University of Cincinnati Medical Center (NRC license #34-06903-05).

A. 1. ^{99m}Tc-Antimony Sulfide Colloid (IND 20997) for injection to study lymph flow and node imaging.

2. ^{133}Xe in saline (IND pending) for injection for cerebral, muscle, and skin flow studies.

3. ^{111}In-labeled blood cells (IND No. 16,759) for injection to study inflammation, g.i. bleeding, or as a blood pool agent to subtract in monoclonal antibody imaging.

The above will be obtained from the University of Cincinnati due to their lack of availability or difficulty in obtaining them from sources as required by 10CFR 35.14(b) through 6.

Further, we wish to obtain, on a very infrequent basis, any other NDA or IND radiopharmaceutical from the University of Cincinnati whose use is already permitted by our VA license but is out of stock at the VA due to weather, lost shipments, emergency add-on patients, etc.

B. We also request permission to conduct xenon ventilation studies and cerebral blood flow studies using a NOVO system in new Nuclear Medicine Department facilities, rooms C213 and C204 respectively.

In regard to the lung perfusion (ventilation studies), typically 2 patients per week (10 mCi each patient) and a maximum of 15 patients will be studied each week. The NOVO system will be used for approximately 20 patients per week (10-20 mCi per patient). A maximum of 800 mCi Xe-133 will be used per week for the NOVO studies.

In Reply Refer To:

Each room will be kept under negative pressure through the use of specially installed exhaust ducts. Measurements of air flow confirm these rooms are in the negative pressure. Xenon will be collected through the use of charcoal traps. Calculations based on a 20% loss of xenon from the traps and air flow measurements show the MPC value of 1×10^{-5} uCi/ml for a restricted area (roof top) will not be exceeded. The closest air intake is at least 150 feet from the exhaust.

^{133}Xe will be used in lung ventilation studies and cerebral blood flow studies (NOVO) as a gas or dissolved in saline. When administered in activities greater than 1 mCi, the patient will be connected to a disposable ^{133}Xe breathing system or commercial ^{133}Xe ventilator using a face mask or mouth and nose pieces. After use, the ^{133}Xe will be collected in an activated charcoal xenon trap. In areas used continuously for Xe studies, air flow measurement are made yearly (rooms C213, C204). Instructions supplied by the manufacturer for devices such as xenon bags and traps and the NOVO system will be followed unless data show an alternate procedure is better. ^{133}Xe will be stored in an exhaust hood until used.

In the event of an accidental release of xenon, the exhaust will be left on and the room will be evacuated if the patients condition will permit. Prior to re-entry the room will be monitored with a GM counter. If the reading does not exceed background, the room will be reoccupied and the exhaust will be left on the remainder of the day.

C. We also would like our license amended to allow use of Atomic Products Lineator 086-507 or other equivalent linearity check devices according to the manufacturer's recommended procedure.

Sincerely,

Edward B. Silberstein

Edward B. Silberstein, M.D.
Professor of Radiology and Medicine

EBS:snm

Helen Maloskiewicz for

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9/7/84