Medical Center North Chicago IL 60064

Veterans Administration

MAR 20 1985

In Reply Refer To: 556/114

Material Licensing Branch
Division of Fuel Cycle
Material Safety and Safeguards
United States Nuclear Regulatory Commission
Washington, DC 20555

Gentlemen:

Please amend our by-product material license number 12-10057-04, control number 17771 to include normal saline solution containing Xenon-133 for research use on human volunteers.

Xenon-133 in saline will be prepared by the method of DiPiazza and Herbert. Sterile saline is added aseptically in 1 ml aliquots to 20 mCi vials of gaseous Xenon-133 (New England Nuclear, Boston, MA). Following a 15-minute equilibration time, the activity of a 0.2 cc aliquot is determined and recorded using a dose calibrator (CRC-5, Capintec, Montvale, NJ). Pyrogens will be tested for using a Limulus kit (Limulus Lysate Assay, Mallinckrodt, St. Louis, MO). The sterility of each vial will be determined by incubating 0.3 cc of the solution in thioglycolate broth for three days at 40° C. Plating of the cultures will be done in the Nuclear Medicine Department. A stock solution previously tested for pyrogens and sterility will be stored at 4° C.

The patient dose is 50 microcuries of Xenon-133 and will require a possession limit of 20 millicuries of Xenon-133 (10 millicuries is the smallest amount one can purchase).

One to five-tenths milliliter of normal saline containing 50 microcuries of Xenon-133 will be injected one centimeter into the thickest part of the brachioradialis muscle. The needle will be withdrawn 30 seconds after the injection to reduce possible backflow of the injected material along the needle tract. After injection, the clearance of the isotope is determined over a 10-minute period from the decline in radioactivity over one intramuscular depot as imaged by a gamma scintillation camera (Sigma 420 Mobile Camera, Ohio Nuclear).

The patient dose will be assayed prior to administration, on a Capintec CRC-5 dose calibrator.

CONTROL NO. 78667

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All the above described procedures will be done under the supervision of Gregory A. Gergans, M.D., Chief of the Nuclear Medicine Service with the technical assistance of the Nuclear Medicine Service staff. (For Dr. Gergan's training and experience, please see our previously submitted application for renewal of our NRC License Number 12-10057-04, Control Number 17771). Personnel preparing assaying and administering this radiopharmaceutical are monitored with film badges obtained on a monthly basis.

The excess material will be disposed of in accordance with the established procedures for disposal of radioactive waste.

This research proposal has the approval of the Research and Development Committee and the Subcommittee on Human Studies of our medical center. It was submitted for approval to the Food and Drug Administration and received an IND Number 24,978.

Sincerely yours,

LAWRENCE C. STEWART
Medical Center Director

Enclosures:
Research Proposal: Mechanisms of Septic Shock
Approval of Research and Development Committee
Approval of Subcommittee on Human Studies
Letter from Food and Drug Administration

APR 01 1985