TELEPHONE (505) 255-8604

nuclear pharmacy incorporated

P.O. BOX 25141
ALBUQUERQUE, NEW MEXICO 87125

0573

February 14, 1979

Mr. Joseph Del Medico
License Management Branch
Division of Fuel Cycle and
Material Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Control No. 97400

Dear Sir:

Please find enclosed two copies of our responses to your questions listed in your letter dated February 6, 1979 and received by us February 12, 1979.

Please note that the correct address of our pharmacy is 31-33 N. 2nd Street, Philadelphia, Pennsylvania. There was an error on our part in which the wrong address was submitted. A corrected floor plan is also enclosed for your review.

I trust our responses will prove satisfactory to your department, since you and I have gone over most of them over the phone. I would appreciate it very much if this application be reviewed in a timely manner since we are ready to commence operations.

Thank you for the professional and courteous manner in which you have handled our application.

Sincerely,

Robert L. Sanchez

Robert L. Sanchez
President

RLS/mn

Enclosures

cc: Nunzio De Santis
District Manager, NE

U.S. NUCLEAR REG. COMMISSION
MAIL SECTION

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INSPECTION AND ENFORCEMENT

0573

NUCLEAR PHARMACY, INC.
31-33 N. 2nd Street
Philadelphia, PA 19106
Control No. 97400

1. Information on the following individuals as users are submitted for your review (Attachment "A"):

   Mr. Art Solomon, M.S.
   Mr. Bill Guthrey, M.S.
   Mr. Steve Wilkerson, M.S.
   Mr. Nunzio De Santis, B.S.

   Please remove Mr. Larry Ruddle from this application since he will not be working at the pharmacy.

2. Dose Calibrator: Capintec Model No. CRC-5
   Well Counter: Canberra Multichannel Analyzer, Series 30, 2" crystal
   Alarm Meter: Ludlum Model 177
   Survey Meter: Ludlum Model 2
   Cutie Pie: Victoreen Model No. 051-740

3. Stan Huber Consultants will supply the pharmacy with replacement instruments when ours are in for service. N.P.I. will try to locate an NRC licensed service to provide this calibration service for convenience purposes. The NRC will be notified of such change in services.

4. Sources used for dose calibrator standard references are:

57-Co	1 mCi	±4.5%	Ref. #CR164E
137-Cs	100 uCi	±3.3%	Ref. #CR154E
60-Co	100 uCi	±3.5%	Ref. #CR168E

   Supplied by Capintec, Inc.

5. Please substitute the enclosed diagram of the facility (Attachment "B"), for the one submitted on November 8, 1978. Note the change of address. In addition, the following information is submitted for your review:

   a. Generator room: Current in-use generators will be stored behind generator shields provided by the manufacturer of that generator or behind lead bricks 2" x 4" x 8" in dimension.

   b. Radiopharmaceuticals not in use: Will be stored in their original lead container behind lead shielding of at least ½" in thickness.

c. Waste area: Will have concrete bins not less than 8" in thickness and if needed will have additional shielding of 1/8" lead around the container. These bins are approximately 4' high and have the capacity to store a 5 to 10 gallon container.

6. Whole body film badges and TLD finger badges are supplied by Fberline Instruments Company and are processed once a month.

7. Pocket dosimeters will be calibrated on a six month basis by the same firm doing our survey instruments. They will again supply us with replacements while the others are being calibrated.

8. N.P.I. will follow the guidelines set forth in the NRC guide 8.20 Applications of Bioassay for I-125 and I-131. These tests will be done at a local hospital with results kept for future reference. As stated in our application all dispensing of Iodine will be done in the fume hood and gloves will be worn while dispensing.

9. Please refer to page 8 of our radiation protection program for clarification on the question. Please note that it will be done initially and annually as a refresher course.

10. Syringe shields will be used for dispensing operations.

11. After the elution of our generators, personnel will monitor their hands and clothing for contamination prior to entering the dispensing area. Kit preparation is performed in the general dispensing area and the pharmacist will also monitor hands after the preparation of a kit.

12. Our ventilation system will be checked for its pulling capacity on a routine six month basis by an outside ventilation service. Records will be maintained on these results. If the unit is not meeting the standards set in the application, it will be fixed to conform to such standards. Please review pages 13 and 14 of our radiation protection program for further checks established by the pharmacy.

13. The pharmacy is scheduled for inspection on February 19th, and a pharmacy permit number will be telegrammed to you as soon as it is received. Please bear in mind that as soon as the pharmacy number is issued, we are ready to commence operations pending your approval.

14. Below is a sample of a completed pharmacy label and prescription form illustrating the manner in which every dose is labeled upon dispensing from the pharmacy to be received by the user.

Nuclear Pharmacy, Inc.
31-33 N. 2nd Street
Philadelphia, PA 922-2226

DATE 01 Jan 19 79 Rx No. 0001

HOSPITAL Name and address Pal-01

Procedure Cerebral Imaging and Flow

Radiopharmaceutical 99m Tc-Sodium Pertechnetate

Lot No. RP# 003 Assay 20.00 ~~uCi~~ mCi/ml

Dose Req. 20.00 uCi / mCi At 1200

Volume Dispensed 1.00 ml Activity Dispensed 20.0 mCi

Doctor Name and license Price $ 0.00

Filled By: Initials Delivery Charge $ 0.00

CAUTION: To be used under the direct supervision of a physician P.O. No. 1234

PATIENT John Doe

SPEC. INSTRUCTIONS:

(SAMPLE COPY) "D"

Warning: This radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission distribution to persons licensed pursuant to 34.14 and 35.100 Group I, Group II, Group IV or Group V of 10 CFR part 35. Syringe containing drug should be kept in this container or within heavier shield.

99m Tc-Sodium Pertechnetate

DATE 01 Jan 79
CAL TIME 1200
EXP TIME 24 hrs post
DR. Name
HOSP. Name
PATIENT John Doe

Rx 0001
VOL. 1.00 ml
ACTIVITY 20.0 mCi

"A"

Nuclear Pharmacy, Inc.
31-33 N. 2nd Street
Philadelphia, PA 922-2226

CAUTION RADIOACTIVE MATERIAL

99m Tc-Sodium Pertechnetate

DATE 01 Jan 79
CAL TIME 1200
EXP TIME 24 hrs post
DR. Name
HOSP. Name
PATIENT John Doe

Rx 0001
VOL. 1.00 ml
ACTIVITY 20.0 mCi

"C"

Nuclear Pharmacy, Inc.
31-33 N. 2nd Street
Philadelphia, PA 922-2226

CAUTION RADIOACTIVE MATERIAL

Rx No: 0001 "B"
Drug: TC04

Explanation: *One pharmacy label ("A") is affixed to the shielding container and the small label ("3") with the Rx number and drug name is affixed to the syringe. The second label ("C") and prescription form ("D") are wrapped around the container so the hospital can use them for their records.*

15. Our pharmacy will dispense its drugs with only the applicable group classification for the drugs listed on the prescription form by scratching any in the inappropriate groups. An error was made by our printer on the form, and Section 34.14 will be corrected to read Section 35.14.

16. See samples on previous page.

17. The anticipated maximum levels of drugs shipped out in our containers are:

99m Technetium and/or its labeled products: 200 mCi
-The container is approximately 3/8" thick and no, or very little, external readings.

131 Iodine and its labeled products (excluding oral solution): Not more than 1 mCi
-The container is approximately 3/8" thick with readings less than those given off in the original manufacturer shipping container.

131 Iodine Oral Solution or therapy caps:
-Therapy caps, regardless of dosage, will be dispensed in their original containers as shipped by the manufacturer.

-Oral solution will usually be sent out in its original shipping container as supplied by the manufacturer. When the pharmacy dispenses a dose out of an original container (i.e., a 10 mCi therapy dose is removed from a 50 mCi source), the dispensed dose will be sent out in a container similar to and in most cases exactly like the original container. Under no circumstances will a dose be sent out in a shielded container that is less in thickness and shielding capacity than the original container.

Other Isotopes (including Xenon): Other drugs are dispenses on a unit dose basis in our shielded containers or redistributed in the original containers supplied by the manufacturer (i.e., 201-Thallium).

Under no circumstances will a user be dispensed a drug for which he is not licensed, and the final packaging will meet all DOT requirements.

18. Radiopharmaceuticals districuted for human use shall be:

a. Repackaged from radiopharmaceuticals obtained from manufacturers licensed to distribute them in accordance with 10 CFR 32.72 under equivalent Agreement State regulations; or

b. Prepared from generators and reagent kits obtained from manufacturer licensed or approved to distribute them in accordance with 10 CFR 32.73 or under equivalent Agreement State regulations.

c. Xenon will be purchased from a supplier who distributes the product marked for human use.

19. Please include the following in our application:

a. All radiopharmaceuticals are assayed prior to transfer to customers.

b. Consumption of beverages and the application of cosmetics are prohibited in areas where radioisotopes are handled or stored.

20. Please confirm that our pharmacy will only be able to redistribute in vitro kits obtained from manufacturers licensed to distribute them in accordance with 10 CFR 32.71 or under equivalent regulations of an Agreement State; and that we will redistribute the kits as received from the manufacturer in the original manufacturer's packaging and accompanied by the manufacturer's approved package insert.