Form NRC-374

U. S. NUCLEAR REGULATORY COMMISSION
MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 31, 32, 33, 34, 35, 36, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s); and to import such byproduct and source material. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Pharmaco Nuclear, Inc. 2. 100 North Euclid Avenue, Suite 900 St. Louis, Missouri 63108	3. License number 24-19360-01MD 4. Expiration date August 31, 1985 5. Docket or Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Molybdenum 99	A. Any Molybdenum 99/ Technetium 99m generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.73 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations	A. 20 curies

Continued From Page 1

License Number 24-19360-01MD

Docket or
Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
B. Tin 113	B. Any Tin 113/Indium 113m generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.73 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations	B. 60 millicuries
C. Barium 133	C. Sealed source	C. 250 microcuries
D. Cesium 137	D. Sealed source	D. 250 microcuries
E. Xenon 133	E. Unit dose containers of gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	E. 1 curie
F. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	F. Prepackaged in vitro diagnostic test kits	F. 50 millicuries total possession limit

Form NRC-374B
(7-75)

U. S. NUCLEAR REGULATORY COMMISSION
MATERIALS LICENSE

Supplementary Sheet

Continued From Page 2

License Number 24-19360-01MD

Docket or
Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
G. Any byproduct material listed in Section 35.31(a) of 10 CFR Part 35	G. Prepackaged individual patient doses manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.70 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations	G. 3 millicuries of each byproduct material authorized in Subitem 6.G.
H. Any byproduct material listed in Group I of Schedule A, Section 35.100 of 10 CFR Part 35	H. Any form listed in Group I of Schedule A, Section 35.100 of 10 CFR 35	H. 1 curie total possession limit
I. Any byproduct material listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35	I. Any form listed in Group II of Schedule A, Section 35.100 of 10 CFR 35	I. 20 curies total possession limit
J. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35	J. Any form listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	J.. 500 millicuries total possession limit
K. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR Part 35	K. Any form listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	K. 1 curie total possession limit

9. Authorized use

A. Production of technetium 99m pertechnetate.
B. Production of Indium 113m chloride.
C. and D. Instrument calibration.

FORM NRC 374A
(5-76)

U. S. NUCLEAR REGULATORY COMMISSION
MATERIALS LICENSE
Supplementary Sheet

License Number 24-19360-01MD

Docket or
Reference No. _____

9. Authorized use

E. Distribution to authorized recipients.
F. Redistribution to general and specific licensees in accordance with statements, representations and procedures contained in application dated April 7, 1980.
G. Redistribution to general licensees in accordance with statements, representations and procedures contained in application dated April 7, 1980.
H. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.
I. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium 99m pertechnetate for processing with reagent kits in the preparation of radiopharmaceuticals.
J. and K. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

Pursuant to Section 32.72, 10 CFR 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to persons licensed pursuant to Section 35.14 and Section 35.100, 10 CFR Part 35, or under equivalent licenses of Agreement States, for the Groups indicated below.

H. Group I
I. Group II
J. Group IV
K. Group V

CONDITIONS

10. Licensed material shall be used only at 100 North Euclid Avenue, Suite 900, St. Louis, Missouri.

11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."

12. A. Licensed material shall be used by, or under the supervision of, Richard E. Reesee, David A. Hurwitz, Ph.D., Terrence O'Hara, Gary R. Redmore or William H. McHugh, Ph.D.

B. At least one individual named in Condition 12.A. shall be physically present at the authorized place of use whenever licensed material is being used.

13. Sealed sources containing licensed material shall not be opened.

CONDITIONS

14. A. (1) Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within five (5) days of the test with the U. S. Nuclear Regulatory Commission, Region III, Office of Inspection and Enforcement, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

15. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of byproduct material, location of sealed sources, and the date of the inventory.

CONDITIONS

16. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions."

17. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements and representations in application dated April 7, 1980.

18. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:

(i) Radiopharmaceuticals that are the subject of an active "New Drug Application" (NDA) approved by FDA or an active "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA, or

(ii) Radiopharmaceuticals prepared from generators and reagent kits that are the subject of an active NDA Approved by FDA or an Active IND that has been accepted by FDA.

B. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators or reagent kits for which FDA has accepted an IND shall be dispensed and/or distributed:

(i) In accordance with the directions provided by the sponsor of the IND, and

(ii) Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

The licensee shall inform in writing each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

19. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

CONDITIONS

20. Any proposed changes in packaging, shielding or labeling shall be submitted for review to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, Washington, D. C. 20555.

21. A. The licensee shall perform a test to detect and quantify the activity of molybdenum-99 contamination in each elution of technetium-99m from a molybdenum-99/technetium-99m generator and in each extraction or separation of technetium-99m from molybdenum-99 not contained in a generator.

B. The licensee shall not distribute for human use technetium-99m that, at the expiration date and time shown on the package label, contains more than one (1) microcurie of molybdenum-99 per millicurie of technetium-99m or more than five (5) microcuries of molybdenum-99 per dose of technetium-99m. The expiration date and time shown on the package label shall be such that the limits above are not exceeded for any single patient dose. The limits for molybdenum-99 contamination represent maximum values and molybdenum-99 contamination should be kept as low as reasonably achievable below these limits.

C. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99 in excess of the limits specified in Subitem B. above are detected.

D. Personnel performing tests to detect and quantify molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.

E. 1. The licensee shall maintain for inspection by the Nuclear Regulatory Commission records of the results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests.

2. Records described in Subitem E.1. above shall be maintained for two (2) years following the performance of the tests and the training of personnel.

22. The licensee's ventilation system shall be measured at quarterly intervals to assure that system performance meets the specifications submitted in letter dated July 28, 1980.

FORM NRC 374A
(5-76)

U. S. NUCLEAR REGULATORY COMMISSION
MATERIALS LICENSE
Supplementary Sheet

License Number 24-19360-01MD

Docket or
Reference No. _____

CONDITIONS

23. Except as specifically provided otherwise by this license, the licensee shall possess, use, package, label and distribute licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated April 7, 1980 and letters dated May 20, 1980, May 30, 1980 and July 28, 1980. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U. S. Nuclear Regulatory Commission

Date AUG 2 2 1980

by 8/22/80

Division of Fuel Cycle and
Material Safety
Washington, D.C. 20555