NRC Form 374
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 07
CORRECTED COPY

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 I, Parts 30, 31, 32, 33, 34, 35, 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). 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. Syncor Corporation 2. 7446 E. 42nd Place Tulsa, Oklahoma 74145	In accordance with letter dated January 13, 1987 3. License number 35-19583-01MD is amended in its entirety to read as follows: 4. Expiration date January 31, 1986 5. Docket or Reference No. 030-18918

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. 25 curies
B. Cesium-137	B. Sealed sources	B. Total activity of sources not to exceed 2 millicuries
C. Cobalt-60	C. Sealed sources	C. Total activity of sources not to exceed 2 millicuries

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6., 7., and 8. (continued)

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
D. Barium-133	D. Sealed source	D. 300 microcuries
E. Iodine-125	E. Prepackaged kits for in-vitro diagnostic testing	E. 25 millicuries
F. Xenon-133	F. 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	F. 1 curie
G. Any byproduct material identified in Section 35.100 of 10 CFR Part 35	G. Any form identified in Section 35.100 of 10 CFR 35	G. 1 curie total possession limit
H. Any byproduct material identified in Section 35.200 of 10 CFR Part 35 except Molybdenum-99/ Technetium-99m generators and unit doses containers of Xenon-133	H. Any form identified in Section 35.200 of 10 CFR 35	H. 15 curies total possession limit

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6., 7., and 8. (continued)

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
I. Any byproduct material identified in Section 35.300 of 10 CFR Part 35	I. Any form identified in Section 35.300 of 10 CFR 35	I. 3 curie total possession limit
J. Any byproduct material identified in Section 35.500 of 10 CFR Part 35	J. Any form identified in Section 35.500 of 10 CFR 35	J. 2.5 curies total possession limit
K. Any byproduct material authorized under Section 35.57(a) of 10 CFR Part 35	K. Any sealed source identified in Section 35.57(a) of 10 CFR Part 35 that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.74 or 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations.	K. 50 millicuries for all sources authorized under Subitem 6.K.
L. Uranium (Depleted in Uranium-235)	L. Metal encased in stainless steel	L. 180 kilograms

9. Authorized use:

A. Production of technetium-99m pertechnetate. Redistribution to authorized recipients.

, C., and D. Instrument calibration.

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9. (continued)

E. Redistribution to specific licensees.

F. Distribution to authorized recipients.

G. 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.

H. 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.

I. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Compounding and/or dispensing of iodine-131 theraphy capsules to authorized recipients.

J. Redistribution of sealed sources identified in Section 35.500 of 10 CFR Part 35, or to specifically authorized recipients.

K. Instrument calibration. Redistribution of sources to identified in 35.57(a) of 10 CFR Part 35, or to specifically authorized recipients.

L. As shielding of molybdenum-99/technetium-99m generators.

Pursuant to Section 32.72 and 32.73, 10 CFR Part 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 35.18, 35.100, 35.200, 35.300, and 35.500 of 10 CFR Part 35 of under equivalent licenses of Agreement States.

CONDITIONS

10. Licensed material shall be used only at 7446 E. 42nd Place, Tulsa, Oklahoma, and 7212 East 38th Street, Tulsa, Oklahoma.

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11. A. Licensed material shall be used by, or under the supervision of, Mark T. Hebner, Monty M.C. Fu, John M. Lahn, Stephen Potter, Bernard J. Mertes, J. Robert Stinchcomb, or Terry O'Hara.

B. At least one individual named in Condition 11.A. shall be physically present at the authorized place of use whenever licensed material is being used.

C. The Radiation Protection Officer for the activities authorized by this license is Robert Stinchcomb.

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

13. A. (1) The sources specified in Items 7.B., 7.C., 7.D., 7.J. and 7.K. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer 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. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011, ATTN: Chief, Nuclear Materials and Emergency Preparedness Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

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13. (continued)

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

14. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 2 years from the date of each inventory.

15. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

16. 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 October 22, 1980.

17. Reagent kits may be redistributed to persons licensed pursuant to Section 35.18, 35.100, and 35.200 of 10 CFR Part 35, or under equivalent licenses of Agreement States.

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

(1) Repackaged from prepared radiopharmaceuticals that are the subject of an FDA-approved "New Drug Application" (NDA) or for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or

(2) Prepared from generators and reagent kits that are the subject of an FDA-approved NDA or for which FDA has accepted an IND.

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:

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

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18. (continued)

(2) 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.

20. Any proposed changes in packaging, shielding, or labeling shall be submitted for review to U.S. Nuclear Regulatory Commission, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011, ATTN: Chief, Nuclear Materials Licensing Section.

21. Prepackaged in vitro diagnostic test kits that are distributed to a specific licensees shall contain labeling that conforms to the requirements of Sections 20.203(a) and 20.203(f) of 10 CFR Part 20.

22. 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 technetium-99m for human use if the technetium-99m contains more than 0.15 microcurie of molybdenum-99 per millicurie 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.

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22. (continued)

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 describing Subitem E.1. above shall be maintained for 3 years following the performance of the tests and the training of personnel.

23. The licensee may use the Calicheck device for doing linearity tests of its dose calibrator provided it follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.

24. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated October 22, 1980
B. Letter dated July 6, 1981
C. Letter dated December 10, 1982
D. Letter dated January 5, 1983
E. Letter dated May 23, 1983
F. Letter dated September 19, 1986
G. Letter dated January 13, 1987
H. Letter dated May 12, 1987

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date AUG - 1987

By Original signed by JACK E. WHITTEN

Nuclear Materials Licensing Section
Region IV
Arlington, Texas 76011

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