

MATERIALS LICENSE

Amendment No. 02

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, 36, 39, 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

DL-032295-02

Licensee

- 1. Syncor International Corporation
1 Syncor Drive
- 2. Huntington, West Virginia 25705

In accordance with letter dated March 27, 1995

3. License Number 47-25248-01MD

is amended in its entirety to read as follows.

4. Expiration Date August 31, 1998

5. Docket or Reference No. 030-33160

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 10 CFR 32.73 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations

A. 80 curies

B. Any byproduct material identified in 10 CFR, Part 31.11(a)

B. Prepackaged *in vitro* diagnostic test kits

B. 50 millicuries total

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C PDR

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(Items 6, 7, and 8 continued)

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|--|---|---|
| <p>6. Byproduct, source, and/or special nuclear material</p> | <p>7. Chemical and/or physical form</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> |
| <p>C. Any byproduct material authorized under 10 CFR, Part 35.14(d)(4) [superseded] or 10 CFR, Part 35.57(a) [effective April 1, 1987]</p> | <p>C. Any sealed source listed in 10 CFR 35.14(d)(4) [superseded] or 10 CFR, Part 35.57(a) [effective April 1, 1987] that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations</p> | <p>C. 50 millicuries total</p> |
| <p>D. Xenon 133</p> | <p>D. 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 the FDA or an active (i.e., not withdrawn or terminated, or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA</p> | <p>D. 2 curies</p> |
| <p>E. Iodine 131</p> | <p>E. Any form listed in Groups I through V of Schedule A, 10 CFR 35.100 [superseded] or 10 CFR, Parts 35.100, 35.200, and 35.300 [effective April 1, 1987]</p> | <p>E. 900 millicuries</p> |
| <p>F. Technetium 99m</p> | <p>F. Any form listed in Groups I and II of Schedule A, 10 CFR 35.100 [superseded] or 10 CFR, Parts 35.100 and 35.200 [effective April 1, 1987]</p> | <p>F. 50 curies</p> |

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(Items 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
G.	Any byproduct material, except technetium 99m or iodine 131, listed in Group I of Schedule A, 10 CFR, Part 35.100 [superseded] or 10 CFR 35.100 [effective April 1, 1987]	G.	Any form listed in Group I of Schedule A, 10 CFR, Part 35.100 [superseded] or 10 CFR 35.100 [effective April 1, 1987]	G.	50 millicuries total
H.	Any byproduct material, except technetium 99m or iodine 131, listed in Group II of Schedule A, 10 CFR, Part 35.100 [superseded] or 10 CFR 35.200 [effective April 1, 1987]	H.	Any form listed in Group II of Schedule A, 10 CFR, Part 35.100 [superseded] or 10 CFR 35.200 [effective April 1, 1987]	H.	300 millicuries total
I.	Any byproduct material, except iodine 131, listed in Group IV of Schedule A, 10 CFR 35.100 [superseded] or 10 CFR Part 35.300 [effective April 1, 1987]	I.	Any form listed in Group IV of Schedule A, 10 CFR, Part 35.100 [superseded] or 10 CFR 35.300 [effective April 1, 1987]	I.	100 millicuries total
J.	Any byproduct material listed in Group VI of Schedule A, 10 CFR 35.100 [superseded] or 10 CFR Parts 35.400 and 35.500 [effective April 1, 1987]	J.	Any sealed source that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	J.	500 millicuries
K.	Gadolinium 153	K.	Sealed sources (Gulf Nuclear GD 1, or Amersham GDCCY 1, or E. I. du Pont (NEN) Model No. 430 or 431)	K.	4.5 curies. No single source to exceed 1.5 curies.
L.	Uranium (depleted in Uranium 235)	L.	Metal encased in stainless steel	L.	101 kilograms

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9. Authorized Use:

- A. For production of technetium 99m pertechnetate. Redistribution of unused generators to authorized recipients in accordance with statements, representations and procedures in application dated April 12, 1993.
- B. Redistribution to general and specific licensees in accordance with statements, representations and procedures in application dated April 12, 1993.
- C. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to 10 CFR, Part 32.74, the licensee is authorized to redistribute sources to persons licensed in accordance with 10 CFR, Parts 35.14 and 35.100 [superseded] or 10 CFR 35.57 [effective April 1, 1987] or equivalent Agreement State licenses.
- D. Distribution to authorized recipients.
- E. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Only iodide may be used in the preparation of iodine 131 therapy capsules.
- F. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium 99m pertechnetate for processing with reagent kits in preparing radiopharmaceuticals.
- G. through I. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.
- J. and K. Redistribution of sealed sources as received from the manufacturer in the manufacturer's original packaging and shielding and accompanied by the manufacturer's approved instructions to authorized recipients for use and storage.
- L. Shielding for molybdenum 99/technetium 99m generators.

Pursuant to 10 CFR, Parts 32.72, 32.73, and 32.74, and notwithstanding 10 CFR 32.72 (a)(2), the licensee is authorized to distribute the byproduct material described in Items 6 and 7 and prepared in accordance with license conditions 16, 17, 18 of this license to persons licensed in accordance with Sections 35.14 and 35.100 of 10 CFR Part [superseded] or Sections 35.100, 35.200, 35.300, 35.400, and 35.500 of 10 CFR Part 35 [effective April 1, 1987], or under equivalent Agreement State licenses, for the Groups or Sections indicated below:

- A. Unused molybdenum 99/technetium 99m generators may be redistributed to persons licensed pursuant to Group III or 10 CFR, Part 35.200.
- D. Gas or gas in saline may be distributed to persons licensed pursuant to 10 CFR 35.200 [effective April 1, 1987].
- E. through I. Any form listed in each group, Groups I, II, IV, and V of Schedule A, 10 CFR 35.100 [superseded] or authorized by 10 CFR, Parts 35.100, 35.200, and 35.300 [effective April 1, 1987], may be distributed to persons licensed pursuant to the Group or Part.
- J. and K. Sealed sources may be redistributed to persons licensed pursuant to Group VI of Schedule A, 10 CFR 35.100 [superseded] or 10 CFR, Parts 35.400 and 35.500 [effective April 1, 1987].

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CONDITIONS

10. Licensed materials shall only be used at the licensee's facilities at 1 Syncor Drive, Huntington, West Virginia.
11.
 - A. Licensed materials shall be used by, or under the supervision of, individuals who are specifically named as users in Condition 12.A of License Number 34-16654-01MD. The licensee shall verify that each individual selected as a user is specifically named in Condition 12.A of License Number 34-16654-01MD and, for this purpose, shall maintain for inspection by the Commission copies of License Number 34-16654-01MD.
 - B. At least one individual named in Condition 12.A of License Number 34-16654-01MD shall be physically present at the authorized place of use whenever licensed materials are being used.
 - C. The Radiation Safety Officer for this license is Byron A. Alfrey, R.Ph.
12.
 - A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.
 - B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
 - C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
 - D. Sealed sources need not be leak tested if:
 - (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

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(continued)

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12. E. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region II, ATTN: Chief, Nuclear Materials Licensing Section, 101 Marietta Street, N.W., Suite 2900, Atlanta, Georgia 30093. 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.
- F. 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.
13. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
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 5 years from the date of each inventory, and shall include the quantities and kinds of byproduct material, manufacturer's name and model numbers, location of the sources and/or devices, and the date of the inventory.
15. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
16. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:
- (i) 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
 - (ii) 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:
- (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.
- C. 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.

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CONDITIONS

17. 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; or not withstanding 10 CFR 35.72(a)(2), the licensee may prepare radiopharmaceuticals in accordance with the specific departures authorized in License Condition 17 of License Number 34-16654-01MD, provided that the licensee has all current specific departure directions and equipment required by License Condition 17 of License Number 34-16654-01MD and they are available for inspection by the Nuclear Regulatory Commission.
18. Notwithstanding 10 CFR 32.72(a)(2), the licensee may make departures to prepared iodine 131 (as sodium iodide) therapy dose radiopharmaceuticals, provided that the departures are made in accordance with License Condition 24 of License Number 34-16654-01MD and that the licensee has all current specific departure directions and required equipment and they are available for inspection by the Nuclear Regulatory Commission.
19. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
- A. **Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.**
 - B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
 - D. A record of each disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
20. The licensee shall not store licensed material contained in waste for more than two years from the date the waste is put into storage. The licensee shall maintain records which indicate the date that licensed material contained in waste is put into storage.
21. Any proposed changes in packaging, shielding, or labelling shall be submitted for review to the U. S. Nuclear Regulatory Commission, Region II, Division of Radiation Safety and Safeguards, Nuclear Material Safety Section, 101 Marietta Street, N.W., Suite 2000, Atlanta, Georgia 30323.
22. Reagent kits may be redistributed to persons licensed pursuant to 10 CFR, Parts 35.14 and 35.100 [superseded] for Group III or pursuant to 10 CFR, Part 35.200 [effective April 1, 1987] or under equivalent Agreement State licenses.
23. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the statements, representations, and procedures in the application dated April 12, 1975.

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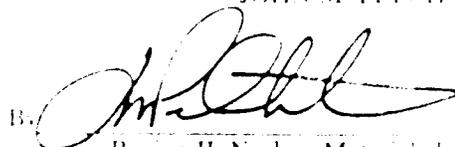
(continued)

CONDITIONS

- 24. This license does not authorize the use of licensed materials in or on human beings.
- 25. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
- 26. The licensee shall maintain records of information important to safe and effective decommissioning at the licensee's facilities located at 1 Syncor Drive, Huntington, West Virginia in accordance with the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.
- 27. A. The licensee may not possess and use materials authorized in Items 6, 7, and 8, until: 1) the licensee has constructed facilities and obtained the equipment described in the application and supporting documentation; and 2) the U.S. Nuclear Regulatory Commission, Region II, ATTN: Chief, Nuclear Materials Inspection Section, 101 Marietta Street, N.W., Suite 2900, Atlanta, Georgia 30093, has been notified in writing that activities authorized by the license will be initiated.
 B. In accordance with the requirements set forth in 10 CFR 30.36(b), the licensee shall promptly notify the Nuclear Regulatory Commission, in writing of a decision not to complete the facility, acquire equipment, or possess and use authorized material.
- 28. 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 April 12, 1993 [new license]
 - B. Letter dated August 20, 1993 [supplemental information]
 - C. Letter dated February 18, 1994 [modified labeling, new unit dose shield, modified floor plan, modified personnel dosimetry exchange frequency]
 - D. Letter dated March 27, 1995 [new RSO, new higher dose rate Product Shielding table]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

JOHN M. PECHTAL



Region II, Nuclear Materials Licensing Section
101 Marietta Street, N.W., Suite 2900
Atlanta, Georgia 30323

Date

APR 18 1995

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02500
Status Code: 0
Fee Category: 3C 28
Exp. Date: 19980831
Fee Comments:
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION IT

1. APPLICATION ATTACHED

Applicant/Licensee: SYNCOR INTERNATIONAL CORPORATION
Received Date: 950403
Docket No.: 3033160
Control No.: 256378
License No.: 47-25248-01MD
Action Type: Amendment

2. FEE ATTACHED

Amount: 196
Check No.: 41157

3. COMMENTS

Signed Cecilia B. Kern
Date 4/4/95

8. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered)

1. Fee Category and Amount: 3C 28 196

2. Correct fee paid. Application may be processed for:

Amendment
Renewal
License

3. OTHER

Signed _____
Date _____