

OFFICIAL RECORD COPY MATERIALS LICENSE

Amendment No. 18

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-013096-07

<p style="text-align: center;">Licensee</p> <p>1. Syncor Corporation</p> <p>2. 230 Clearfield Avenue, Suite 125 Virginia Beach, Virginia 23462</p>	<p>In accordance with letter dated December 12, 1995</p> <p>3. License Number 45-18778-01MD</p> <p>is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration Date January 31, 1997 (extended)</p> <hr/> <p>5. Docket or Reference No. 030-14964</p>
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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. 40 curies
B. Any byproduct material identified in 10 CFR, Part 31.11(a)	B. Prepackaged <u>in vitro</u> diagnostic test kits	B. 50 millicuries total

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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. 75 millicuries</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. 1.0 curie</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. 990 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. 40 curies</p> |

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| 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. | Uranium (depleted in the isotope uranium 235) | K. | Metal encased in stainless steel | K. | 101 kilograms |
| L. | Gadolinium 153 | L. | Sealed sources (Gulf Nuclear GD-1, or Amersham GDC.CY-1, or E. I. du Pont (NEN) Model No. 430 or 431) | L. | 4.5 curies. No single source to exceed 1.5 curies. |

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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
M. Iodine 125	M. Sealed sources (AECL Model No. C-324 or C-325 or Amersham Model IMC-P2)	M. 1.0 curie. Not to exceed 800 millicuries per source.
N. Iodine 131	N. Iodinated human monoclonal antibodies with an FDA accepted IND and/or sodium iodide for iodination of human monoclonal antibodies with an FDA accepted IND	N. 600 millicuries

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 December 23, 1987.
- B. Redistribution to general and specific licensees in accordance with statements, representations and procedures in application dated December 23, 1987.
- 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.
- K. Shielding for molybdenum 99/technetium 99m generators.

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9. Authorized Use (continued)

J., L., and M. 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.

N. For iodination of human monoclonal antibodies in accordance with FDA accepted IND's and distribution to principal investigators accepted by appropriate FDA accepted IND's.

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, and 18 of this license to persons licensed in accordance with Sections 10 CFR, Parts 35.14 and 35.100 of 10 CFR Part 35 [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. Sealed sources may be redistributed to persons licensed pursuant to Group VI or 10 CFR, Parts 35.400 and 35.500.

CONDITIONS

10. Licensed materials shall only be used at the licensee's facilities at 230 Clearfield Avenue, Suite 125, Virginia Beach, 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 11.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 Clifford D. McClendon, R.Ph.

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CONDITIONS

12. A. (1) The sealed source(s) or detector cell(s) specified in Items 7.C, 7.J, 7.L, and 7.M. shall be tested for leakage and/or contamination at intervals not to exceed six (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 II, Division of Radiation Safety and Safeguards, Nuclear Material Safety Section, 101 Marietta Street, N.W., Suite 2900 Atlanta, Georgia 30323. 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.
- 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.
13. Sealed sources or detector cells containing licensed materials shall not be opened by the licensee. Sources shall not be removed from source holders or detector cells by the licensee.
14. The licensee shall conduct a physical inventory every six (6) months to account for all sources and/or devices received and possessed under the license. Records of all inventories shall be maintained for two (2) years from the date of each inventory.
15. The licensee may transport licensed materials in accordance with the provisions of 10 CFR 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.

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CONDITIONS

16. 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.
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 32.72 (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 normal waste, radioactive waste shall be surveyed 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.
20. 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 2900, Atlanta, Georgia 30323.
21. 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.

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- 22. 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 March 25, 1989.
- 23. The licensee may use the Calicheck® device for performing linearity tests of its dose calibrator provided it follows the procedures in the Calcorp, Inc., manual dated March 2, 1982.
- 24. 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.
- 25. The licensee shall maintain records of information important to safe and effective decommissioning at the licensee's facilities located at 230 Clearfield Avenue, Suite 125, Virginia Beach, Virginia in accordance with the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.
- 26. 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 March 25, 1989
 - B. Letter dated November 30, 1989
 - C. Letter dated January 9, 1990
 - D. Letters dated July 30, 1991 and August 13, 1991
 - E. Letter dated August 29, 1991
 - F. Letter dated August 24, 1992 (new authorized use location)
 - G. Letter dated October 22, 1992 (new authorized use location)
 - H. Letter dated November 15, 1992 (new authorized use location)
 - I. Letter dated January 7, 1993 (close-out and release of former authorized use location)
 - J. Letter dated February 25, 1994 (new unit dose shield)
 - K. Letters dated September 28, 1994 and November 18, 1994 (revised product labels, revised unit dose activity limits, modified iodination hood air sampling system, change of RSO, revised dosimetry procedures)
 - L. Letters dated December 12, 1995 & January 17, 1996 (Extend expiration date)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

JOHN M. PELCHAT

Date JAN 30 1996

By



Region II, Division of Nuclear Materials Safety
101 Marietta Street, N.W., Suite 2000
Atlanta, GA 30323

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