

CORRECTED COPY

MATERIALS LICENSE

Amendment No. 4

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.

Licensee		In accordance with the letter dated September 28, 1996	
1.	Syncor de Puerto Rico, Inc.	3. License Number	52-16345-02MD
		is amended in its entirety to read as follows:	
2.	P.O. Box 4408 Carolina, Puerto Rico 00984	4. Expiration Date	April 30, 2005 (extended)
		5. Docket or Reference No.	030-19134
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.	Any byproduct material initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State requirements	A.	Any form initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State requirements
B.	Any byproduct material authorized under 10 CFR, 35.57(a).	B.	Any sealed source listed in paragraph 10 CFR 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 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations
C.	Any byproduct material identified in 10 CFR, Part 31.11(a)	C.	Prepackaged units for <u>in vitro</u> diagnostic tests
D.	Uranium (depleted in the isotope uranium 235)	D.	Metal enclosed in stainless steel
		A.	Molybdenum 99 - 1.85 terabecquerels (TBq) (50 curies); Technetium 99m - 1.85 TBq (50 curies); Iodine 131 - 33.3 gigabecquerels (GBq) (900 millicuries); All others combined, 18.5 GBq (500 millicuries)
		B.	555 megabecquerels (MBq) (15 millicuries) total
		C.	1.85 GBq (50 millicuries)
		D.	180 kilograms

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9. Authorized Use:

- A. Preparation and distribution of radioactive drugs (includes Mo99/Tc99m generators) to authorized recipients.
- B. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to Section 32.74 of 10 CFR Part 32, the licensee is authorized to redistribute sources to persons licensed pursuant to Section 10 CFR 35.57(a) of 10 CFR Part 35 or under equivalent licenses of Agreement States.
- C. Redistribution to specific licensees or general licensees pursuant to 31.11 of 10 CFR Part 31 provided the packaging and labelling remain unchanged.
- D. Shielding for molybdenum 99/technetium 99m generators.

Pursuant to Sections 32.72 and 32.74 of 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 A. through C. of this license to persons licensed pursuant to Sections 35.100, 35.200, and 35.300 of 10 CFR Part 35, or under equivalent Agreement State licenses.

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities located at WA 15 Los Angeles, Carolina, Puerto Rico.
- 11. A. Licensed material shall be used by, or under the supervision of:
 - (1) a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 32.72(b)(2) and 32.72(b)(3) of 10 CFR Part 32, or
 - (2) authorized on Byproduct Materials License 04-26507-01MD;
 - (3) Alicia Alpert, R.Ph.
- B. The Radiation Safety Officer for this license is Jay R. Simon, R.Ph., and in his absence, Alicia Alpert, R.Ph.
- 12. A. Sealed sources and detector cells 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 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

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CONDITIONS

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12. D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. 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.
- F. The leak 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, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), 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, Materials Licensing/Inspection Branch, 101 Marietta St. NW, Atlanta, Georgia 30323-0199. The report shall specify the source involved, the test results, and corrective action taken.
- G. 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 material shall not be opened or sources removed from source holders or detector cells by the licensee.
14. The licensee shall conduct a physical inventory every six months to account for all sources and/or devices received and possessed under this license.
15. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."
16. Radioactive waste (e.g., syringes, vials) that contains or is contaminated with radioactive materials that the licensee originally supplied to its customers may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in the application dated December 7, 1988.
17. 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.

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17. 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.
18. In addition to the possession limits in condition 8, the licensee shall further restrict the possession of licensed material so that at no time is a quantity of radioactive material possessed in excess of a quantity that requires decommissioning funding in accordance with 10 CFR 30.35(d), 10 CFR 40.36(b) or 10 CFR 70.25(d).
19. The licensee shall maintain records of information related to decommissioning at the licensee's facilities located at WA 15 Los Angeles, Carolina, Puerto Rico as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.
20. 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 December 7, 1988
 - B. Letters dated:
 1. April 20, 1989 [alternate RSO qualifications]
 2. March 2, 1994 [renewal application]
 3. April 5, 1995 [survey instruments, calibration of dose calibrator, safe use procedures]
 4. July 19, 1996 [transfer of assets to Syncor de P.R. (IAW IN 89-25 Rev. 1); changes to facility; increase I-131 authorization; I-131 handling procedures; dose container and labels; bioassay procedures]
 5. September 28, 1996 [approval of transfer by both Dr. Caamaño and Syncor de P.R., Inc.]
 6. October 24, 1996 (fax) [qualifications of Alicia Alpert]
 - C. Reference NRC Letter dated March 1, 1996, extension of expiration date per 10 CFR 30.36(a)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DAVID J. COLLINS

David J. Collins

DATE FEB 21 1997

BY

Region II, Division of Nuclear Materials Safety
101 Marietta Street, N.W., Suite 2900
Atlanta, Georgia 30323-0199

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