NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 25

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 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 received on March 1, 2001
1. University of Puerto Rico Office of the Chancellor	3. License No. 52-01946-07 is renewed in its entirety to read as follows:
2. Attention: Radiation Safety Officer P. O. Box 365067 San Juan, Puerto Rico 00936	4. Expiration Date: August 31, 2011
	5. Docket No. 030-13584

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 with atomic numbers 1 through 83 with half-life less than 120 days, except as follows:	A. Any	A. 1.85 gigabecquerels (Gbq) (50 millicuries) of each radionuclide with a total possession limit of 74 Gbq (2 curies), except as follows:
(1) Iodine 125	(1) Any	(1) 11.1 Gbq (300 millicuries)
(2) Iodine 131	(2) Any	(2) 37 Gbq (1000 millicuries)
(3) Phosphorus 32	(3) Any	(3) 18.5 Gbq (500 millicuries)
(4) Chromium 51	(4) Any	(4) 7.4 Gbq (200 millicuries)
(5) Sulfur 35	(5) Any	(5) 18.5 Gbq (500 millicuries)
(6) Rubidium 86	(6) Any	(6) 3.7 Gbq (100 millicuries)
(7) Selenium 75	(7) Any	(7) 3.7 Gbq (100 millicuries)
B. Carbon 14	B. Any	B. 18.5 Gbq (500 millicuries)
C. Hydrogen 3	C. Any	C. 37 Gbq (1000 millicuries)
D. Calcium 45	D. Any	D. 18.5 Gbq (500 millicuries)
E. Nickel 63	E. Foil and/or plated source in a detector cell registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation	E. No single source to exceed 555 megabecquerels (15 millicuries) per detector cell

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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
F. Cesium 137	F. Sealed sources registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation	F. 6.105 Gbq (165 millicuries)
G. Any byproduct material identified in 10 CFR 35.100	G. Any radiopharmaceutical identified in 10 CFR 35.100	G. As needed
H. Any byproduct material identified in 10 CFR 35.200	H. Any radiopharmaceutical identified in 10 CFR 35.200	H. As needed
I. Any byproduct material identified in 10 CFR 35.300	I. Any radiopharmaceutical identified in 10 CFR 35.300	I. As needed
J. Any byproduct material identified in 10 CFR 35.500	J. Any diagnostic sealed source identified in 10 CFR 35.500 and registered pursuant to 10 CFR 32.210 or an equivalent Agreement State Regulation	J. Two sources not to exceed the limits for the compatible device specified in Item 9.J
K. Strontium 90	K. Sealed Source	K. 7.4 Gbq (200 millicuries)
L. Uranium metal	L. Metal Alloy	L. 999 kilograms

9. Authorized Use:

A. through D. For possession and use in research and development as defined in 10 CFR 30.4, including animal studies.

E. For possession and use of foil and/or plated source in a detector cell (registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation) for use in compatible gas chromatograph for sample analysis.

F. For possession and use for instrument calibration.

G. Medical use identified in 10 CFR 35.100.

H. Medical use identified in 10 CFR 35.200.

I. Medical use identified in 10 CFR 35.300.

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9. J. For possession and use of one source for medical use identified in 10 CFR 35.500 and contained in a compatible diagnostic device registered pursuant to 10 CFR 32.210 or an equivalent Agreement State Regulation and one source for possession incident to source exchange.

K. Storage only-eye applicator.

L. Depleted uranium shielding.

CONDITIONS

10. Location of use: The licensee's facilities located at:

A. The Central Medical Campus, Rio Piedras, Puerto Rico

B. Neurobiology Laboratory, Boulevard del Valle 201, San Juan, Puerto Rico

C. Carolina Regional Hospital, Ave. 65 de Infantería, Km. 8, Hm. 3, Carolina, Puerto Rico

11. The Radiation Safety Officer for this license is Heriberto Torres Castro, Ph.D.

12. A. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.2.

B. Physicians designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee. The licensee shall maintain records of physicians designated as users and their qualifications to use licensed materials.

C. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users and their qualifications to use licensed materials.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material as follows:

A. For unsealed sources to quantities less than 10^5 times the applicable limits in Appendix C, 10 CFR 20 as specified in 10 CFR 30.35(d)

B. For sealed sources, to quantities less than 10^{10} times the applicable limits in Appendix C, 10 CFR 20 as specified in 10 CFR 30.35(d).

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13. C. For unsealed licensed material identified in 10 CFR 30.32(I)(1) and requiring consideration for emergency plans for potential offsite releases, to levels less than specified in 10 CFR 30.72, Schedule C.

14. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

C. Sealed sources need not be tested if they 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 shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

D. The leak test shall be capable of detecting the presence of 185 becquerels (Bq) (0.005 microcurie) of radioactive material on the test sample. If the test reveals the presence of 185 Bq or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

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

15. The licensee shall conduct a physical inventory every three months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59 and 10 CFR 35.500 and every six months, or at other intervals approved by the U. S. Nuclear Regulatory Commission, to account for all other 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 radionuclides, quantities, manufacturer's name and model numbers and the date of the inventory.

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16. A. Detector cells containing titanium tritide or scandium tritide foils shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding that specified in the certificate of registration issued by NRC pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

    B. When in use, detector cells containing a titanium or scandium tritide foil shall be vented to the outside.

    C. Maintenance, repair, cleaning, replacement and disposal of foils or plated sources contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.

18. Notwithstanding the requirements of 10 CFR 35.149(a), 10 CFR 35.100, 35.200, and 35.300, the licensee may procure and use any licensed material or reagent kit for medical purposes; provided that these materials and kits shall be used in accordance with the prescriptive and performance criteria in all sections of 10 CFR 35. Furthermore, nothing stated herein shall relieve the licensee from compliance with applicable U.S. Food and Drug Administration and other Federal and State requirements.

19. The licensee is authorized to hold licensed material for non-medical use and with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash, provided:

    A. 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, the waste shall be surveyed with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity can not be distinguished from background. All radiation labels shall be removed or obliterated.

    C. The waste form shall be compatible with the storage container.

    D. Waste with a half-life longer than 65 days shall be in storage containers separate from waste with a half-life equal to or shorter than 65 days.

    E. A record of each such 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 meter 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.

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20. The licensee shall not distribute for human use or consumption experimental animals, or the products from experimental animals, that have been administered licensed material.

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

22. Pursuant to 10 CFR 20.2001 and 10 CFR 20.2002; and 10 CFR 20.1301, and 10 CFR 20.1302, and in reliance upon statements and procedures contained in letters dated April 3, 1992, July 31, 1992, December 13, 1993 and September 29, 1998, the licensee is authorized to dispose of licensed material by incineration provided that:

A. The licensee shall incinerate only waste material generated as a result of activities authorized by this license and only in an incinerator for which an EPA permit and Commonwealth approval has been granted.

B. Following each incineration the licensee shall monitor all ash generated and at least monthly, monitor the incinerator and associated components that come in contact with radioactive waste and/or its incineration byproducts. Regardless of results of ash monitoring, all ash from incineration of licensed material shall be handled pursuant to Condition No. 22. C.

C. Following incinerator operations the licensee shall collect all ash residue found to be equal or more than the effluent concentrations specified for water (10% for carbon 14) in Appendix B, Table 2, 10 CFR 20, not accounting for any dilution that may result from incinerating non-radioactive waste along with radioactive waste. These ashes will be stored until sent to a licensed low-level radioactive waste site in the U.S. mainland. All ash residue found to be less than the effluent concentration values specified for water (10% for carbon 14) in 10 CFR 20, Appendix B, Table 2, may be considered as non-radioactive waste and disposed in a sanitary landfill. If more than one radionuclide is present in the ash, then the sum of the fractions rule applies.

D. During adverse weather conditions (high winds, heavy rains, etc.) the licensee shall incinerate only if it makes a documented finding that the benefits would outweigh the potential risk.

E. The gaseous effluent from incineration shall not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20. In addition, the licensee shall either trap any fly ash generated or monitor to verify that the levels of activity in the effluent including fly ash does not exceed the limits specified for air in Appendix B, Table II, 10 CFR 20.

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23. Except as specifically provided otherwise in this licensee, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. 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: January 27, 1994

B. Letters Dated or Received:

(1) August 24, 1995 [licensee response to deficiency letter dated May 24, 1995]
(2) April 30, 1996 [data and COMPLY data for incinerator restoration]
(3) April 3, 1992 [Incinerator letter]
(4) July 31, 1992 [Incinerator letter]
(5) July 17, 1998 [revised incineration procedures]
(6) September 29, 1998 [revised incineration parameters]
(7) February 4, 1999 [add Carolina location of use]
(8) March 24, 1999 [physical location of Carolina facility]
(9) April 3, 2000 [procedural changes re: package receipt, hood face velocity and RSC]
(10) March 1, 2001 [renewal request, no brachytherapy, minor revisions]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DATE August 27, 2001

BY */RA/J. Henson for*

Héctor Bermúdez, Senior Health Physicist
Region II, Division of Nuclear Materials Safety
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