

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 34

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.

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| Licensee | | In accordance with the application dated July 22, 2011, | |
| 1. University of Puerto Rico Medical Sciences Campus Chancellor's Office | | 3. License number 52-01946-07 is amended in its entirety to read as follows: | |
| 2. P.O. Box 365067 San Juan, Puerto Rico 00936-5067 | | 4. Expiration date July 31, 2012 | |
| | | 5. Docket No. 030-13584 Reference No. | |
| 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 3 through 83 and half life less than 120 days, except as follows: | A. Any | A. 60 millicuries of each radionuclide, not to exceed 2 curies, except as follows: | |
| (1) Iodine 125 | (1) Any | (1) 300 millicuries | |
| (2) Phosphorous 32 | (2) Any | (2) 500 millicuries | |
| (3) Chromium 51 | (3) Any | (3) 200 millicuries | |
| (4) Sulfur 35 | (4) Any | (4) 500 millicuries | |
| (5) Rubidium 86 | (5) Any | (5) 100 millicuries | |
| (6) Selenium 75 | (6) Any | (6) 100 millicuries | |
| B. Hydrogen 3 | B. Any | B. 1,000 millicuries | |
| C. Carbon 14 | C. Any | C. 500 millicuries | |
| D. Calcium 45 | D. Any | D. 500 millicuries | |
| E. Nickel 63 | E. Sealed Sources (Isotope Products Laboratory or New England Nuclear Model NER- 004). | E. 10 millicuries per source and 20 millicuries total | |

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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 Source (AEA Technologies Model 773) | F. 159 millicuries |
| G. Any byproduct material permitted by 10 CFR 35.100 | G. Any | G. As needed |
| H. Any byproduct material permitted by 10 CFR 35.200 | H. Any | H. As needed |
| I. Any byproduct material permitted by 10 CFR 35.300 | I. Any | I. 1.2 curies |
| J. Strontium 90 | J. Sealed Source (DuPont Merck Pharmaceutical Co. Model NB-1) | J. 106.5 millicuries |
| K. Strontium 90 | K. Sealed Sources (Manufacturer unknown) | K. 15 microcuries |
| L. Radium 226 | L. Sealed Sources (Victoreen Model 540-B; Texas Nuclear Model 5901) | L. 6.5 millicuries |
| M. Radium 226 | M. Sealed Sources (Manufacturer unknown) | M. 10.71 millicuries |
| N. Americium 241 | N. Crystal liquid ampoules | N. 46 nanocuries |

9. Authorized use:

- A. through D. Medical diagnosis, therapy and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instruction; and in-vitro studies.
- E. To be used for sample analysis in compatible gas chromatography devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the devices.
- F. Calibration and checking of the licensee's instruments. Teaching and training of students.
- G. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
- H. Any imaging and localization study permitted by 10 CFR 35.200.
- I. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300, for which the patient can be released under the provisions of 10 CFR 35.75.
- J. through N. Storage only incident to disposal.

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CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at:
- A. The Central Medical Campus, University of Puerto Rico, Río Piedras, Puerto Rico.
 - B. Institute of Neurobiology Laboratory, Boulevard del Valle 201, San Juan, Puerto Rico.
 - C. University of Puerto Rico Medical Sciences Campus Nuclear Medicine Laboratory, 1st Floor, Hospital UPR, Dr. Federico Trilla, Ave. 65 de Infantería, Km. 8, Hm. 3, Carolina, Puerto Rico.
 - D. University of Puerto Rico Medical Science Campus Nuclear Medicine Laboratory, 4th Floor, Hospital Oncológico Dr. Isaac González Martínez, Puerto Rico Medical Center, Río Piedras, Puerto Rico, in accordance with the licensee's letters dated July 17 and August 13, 2007.
11. The Radiation Safety Officer for this license is Jossian J. Pagán-Lisboa, CNMT.
12. A. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.
- B. Individuals designated to work as authorized users, authorized nuclear pharmacists or authorized medical physicists, as defined in 10 CFR 35.2, shall meet the training, experience, and recentness of training criteria established in 10 CFR Part 35, and shall be designated, in writing, 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. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at 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. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. 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.

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- D. 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.
- E. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
- F. 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.
- G. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) 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.
- H. Tests for leakage and/or contamination, including leak test sample collection and analysis, 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.
- I. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
14. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
15. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, 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 radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
16. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

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- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
- C. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
17. Notwithstanding the requirements of License Condition 24 the licensee is authorized to make program changes and changes to procedures specifically identified in the condition, which were previously approved by the U.S. Nuclear Regulatory Commission and incorporated into the license without prior Commission approval as long as:
- A. The proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation.
- B. The revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program.
- C. The licensee's staff is trained in the revised procedures prior to implementation.
- D. The licensee's audit program evaluates the effectiveness of the change and its implementation.
18. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
- B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
- C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
19. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
20. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.
21. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.

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22. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
23. Pursuant to 10 CFR 20.2001 and 20.2002; and 10 CFR 20.1301 and 20.1302, and in reliance upon statements and procedures contained in letters dated April 3, 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 licensee and only in an incinerator for which an EPA permit and Commonwealth approval has been granted
 - B. Following each incineration the licensee shall monitor the ash generated, and at least monthly, monitor the incinerator and associated components that have come in contact with radioactive materials and/or its incineration byproducts. Regardless of results of ash monitoring, all ash from incineration of licensed materials shall be handled pursuant to License Condition 25.C.
 - C. Following incinerator operations the licensee shall collect all ash residue found to be equal to or more than the effluent concentrations specified for water (10% for carbon-14) in Appendix B, Table 2, 10 CFR Part 20, not accounting for any dilution that may result from incinerating no-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 Appendix B, Table 2, 10 CFR Part 20, may be construed 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 10 CFR Part 20, Appendix B, Table 2.

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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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. 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. Letter dated April 3, 1992
- C. Letter dated July 31, 1992
- D. Letter dated August 24, 1995
- E. Letter dated April 30, 1996
- F. Letter dated July 17, 1998
- G. Letter dated September 29, 1998
- H. Letter dated February 4, 1999
- I. Letter dated March 24, 1999
- J. Letter dated April 3, 2000
- K. Letter dated March 1, 2001
- L. Letter dated January 28, 2001
- M. Letter dated March 15, 2002
- N. Letter dated May 23, 2002
- O. Letter dated June 28, 2004
- P. Letter dated August 9, 2004
- Q. Letter dated July 17, 2007 (ML072130187)
- R. Letter dated August 13, 2007 (ML072390094)
- S. Application dated July 22, 2011 (ML112210325)
- T. Letter dated January 25, 2012 (ML120310043)

For the U.S. Nuclear Regulatory Commission

Date January 31, 2012

By

Original signed by Penny Lanzisera

Penny Lanzisera
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406