

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 dated April 21, 2005,
1. Purdue Pharma, L.P.	3. License No. 29-30698-01
	is amended in its entirety to read as follows:
2. 6 Cedarbrook Drive	4. Expiration Date: January 31, 2012
Cranbury, New Jersey 08512	5. Docket No. 030-35882

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. Hydrogen 3	A. Any	A. 100 millicuries
B. Carbon 14	B. Any	B. 50 millicuries
C. Phosphorus 32	C. Any	C. 10 millicuries
D. Phosphorus 33	D. Any	D. 10 millicuries
E. Sulfur 35	E. Any	E. 70 millicuries
F. Chromium 51	F. Any	F. 20 millicuries
G. Yttrium 90	G. Any	G. 50 millicuries
H. Iodine 125	H. Bound to non-volatile agents	H. 20 millicuries
I. Iodine 131	I. Bound to non-volatile agents	I. 50 millicuries
J. Cesium 137	J. Sealed source (Isotope Products Laboratories Model RV-137- 200U)	J. 196 microcuries
K. Cesium 137	K. Sealed source (AECL Model C-161)	K. 2,632 curies

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9. Authorized use:

- A. - I. Research and development as defined in 10 CFR 30.4; animal studies.
- J. Instrument source checks.
- K. For irradiation of materials in self-shielded irradiator devices that have been registered either with the U. S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and which 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.

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 6 Cedarbrook Drive, Cranbury, New Jersey.
- 11. A. Licensed material in Items 6.A. through 6.J. shall be used by, or under the supervision of, Dr. Kenneth Valenzano.

B. Licensed material in Item 6.K. shall be used by, or under the supervision of, individuals who have received the training described in letter dated January 16, 2002 and have been designated, in writing, by the Radiation Safety Officer.
- 12. The Radiation Safety Officer (RSO) for this license is Mathew L. Swan.
- 13. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.
- 14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
- 15. The licensee shall conduct a physical inventory every six months, or at other interval approved by the U. S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license.
- 16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
- 17. 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.

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- 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 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.
- D. 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.
- E. 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.
- F. Tests for leakage and/or contamination, limited to leak test sample collection, 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. The licensee is not authorized to perform the analysis; analysis of leak test samples must be performed by persons specifically licensed by U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- G. Records of leak test results shall be kept in units of microcuries and shall be maintained for three years.
18. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
19. 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

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- C. Maintains records of the disposal of licensed materials for three 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.
20. The procedures contained in the manufacturer's instruction manual for the irradiator authorized by this license, shall be followed, and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.
21. The licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the U. S. Nuclear Regulatory Commission or an Agreement State to perform such services.

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22. 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 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 November 19, 2001 [ML013370499]
- B. Letter dated January 2, 2002 [ML020020303]
- C. Letter dated January 16, 2002 [ML020240022]
- D. Letter dated December 2, 2002 [ML023380346]
- E. Letter dated December 21, 2004 [ML050060404]
- F. Letter dated January 11, 2005 [ML050330069]

For the U. S. Nuclear Regulatory Commission

Date October 13, 2005

By

Original signed by Elizabeth UllrichElizabeth Ullrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406