

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.

PL 03620

316345

Licensee	
1. Brogan Pharmaceuticals	3. License number 13-32662-01
2. 1195 Arrowhead Court Crown Point, Indiana 46307-8222	4. Expiration date August 31, 2017
	5. Docket No. 030-37503 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. Technetium-99m	A. Any	A. 600 millicuries
B. Iodine-131	B. Any non-volatile form	B. 5 millicuries
C. Cesium-137	C. Sealed sources (Isotopes Products Laboratories (IPL) Model RV-137-200u and IPL Model GF-0206)	C. 400 microcuries
D. Barium-133	D. Sealed sources (Isotopes Products Laboratories (IPL) Model RV-133-250U and IPL Model GF-0239)	D. 400 microcuries

9. Authorized Use:
- A. To perform linearity and geometry measurements on dose calibrators.
 - B. For research and development of radiopharmaceuticals.
 - C. and D. For calibration of dose calibrators and instrumentation.

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities located at 1195 Arrowhead Court, Crown Point, Indiana.
- 11. The Radiation Safety Officer for this license is Robert Reyes, R.Ph.

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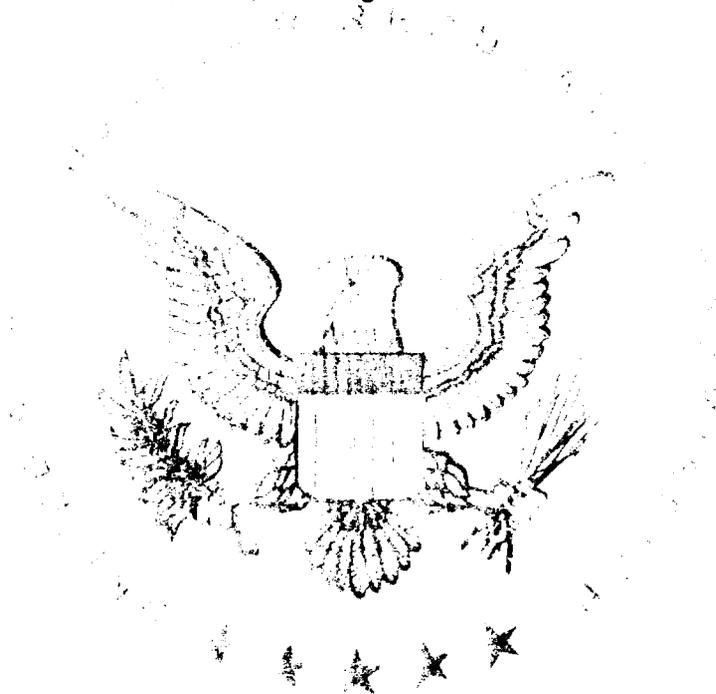
12. Licensed materials shall be used by, or under the supervision of Robert Reyes, R.Ph. or Brett Dines, R. Ph.
13. Licensed material shall not be used in or on humans except as provided otherwise by specific condition of this license.
14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
15. The licensee shall conduct a physical inventory every 6 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.
17. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
19. The licensee shall not acquire licensed material in a sealed source or device that contains a sealed source unless the source or device has been registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.
20. 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 leak 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 no 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.

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- 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.
- G. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.
21. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
22. 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.
23. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash provided:
- A. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey 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.
- B. A record of each 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 instrument 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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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. 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. Letter received April 24, 2007; and,
- B. Facsimiles dated June 27, 2007, and August 3, 2007.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date AUG 07 2007 By Colleen Carol Casey
Colleen Carol Casey
Materials Licensing Branch
Region III