

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 12

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.

PCO 2500
Licensee

318276

1. PharmaLogic Michigan, L.L.C.
2. 1144 Boon Street
Traverse City, Michigan 49686

In accordance with letter dated
May 27, 2009,
3. License number 21-32190-01MD is amended in its entirety to read as follows:
4. Expiration date **September 30, 2009**
5. Docket No. **030-35125**
Reference No.

<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with atomic number 3 through 83 except molybdenum-99, technetium 99m, xenon-133, iodine-131, samarium-153, yttrium-90, Fluorine-18, Gallium-67, Indium-111, Thallium-201</p> <p>B. Molybdenum-99</p> <p>C. Technetium 99m</p> <p>D. Xenon-133</p> <p>E. Iodine-131</p> <p>F. Any byproduct material listed in 10 CFR 31.11(a)</p> <p>G. Any byproduct material listed in 10 CFR 35.400</p> <p>H. Any byproduct material listed in Section 10 CFR 35.500</p> <p>I. Any byproduct material authorized under 10 CFR 35.65</p> <p>J. Samarium-153</p> <p>K. Depleted Uranium</p>	<p>7. Chemical and/or physical form</p> <p>A. Any, except sealed sources</p> <p>B. Any, except sealed sources</p> <p>C. Any, except sealed sources</p> <p>D. Any, except sealed sources</p> <p>E. Any, except sealed sources</p> <p>F. Prepackaged units for <u>in vitro</u> diagnostic tests</p> <p>G. Sealed sources</p> <p>H. Sealed sources</p> <p>I. Sealed sources</p> <p>J. Any, except sealed sources</p> <p>K. Metal</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. Not to exceed 200 millicuries per radionuclide and 2 curies total</p> <p>B. 100 curies</p> <p>C. 100 curies</p> <p>D. 1 curie</p> <p>E. 1.5 curies</p> <p>F. 50 millicuries</p> <p>G. 500 millicuries</p> <p>H. Not to exceed 1.5 curies per source and 5.5 curies total</p> <p>I. 150 millicuries</p> <p>J. 600 millicuries</p> <p>K. 600 kilograms</p>
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SUPPLEMENTARY SHEET**

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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
L. Yttrium-90	L. Any, except sealed sources	L. 400 millicuries
M. Fluorine-18	M. Any	M. 1 Curie
N. Gallium-67	N. Any	N. 500 millicuries
O. Indium-111	O. Any	O. 300 millicuries
P. Thallium-201	P. Any	P. 1 curie

9. Authorized use:

- A. through E., J. and L. Preparation and distribution of radioactive drugs, production of technetium 99m pertechnetate, compounding of iodine-131 and distribution of unused and used molybdenum-99/technetium 99m generators to authorized recipients in accordance with 10 CFR 32.72 and to authorized recipients for non-medical use. Yttrium-90 may also be used for calibration purposes.
- F. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged.
- G. and H. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. Redistribution of sealed sources that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess, use the devices and to authorized recipients for non-medical use.
- I. For calibration of the licensee's own dose calibrator and checking of the licensee's own radiation detection instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for non-medical use.
- K. Shielding for molybdenum-99/technetium-99m generators.
- M. through P. Preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72 and to authorized recipients for non-medical use.**

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CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1144 Boon Street, Traverse City, Michigan.
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 10 CFR 32.72(b)(2)(I), or (4).
 - 2) Authorized nuclear pharmacists: William Marc Chatoff, R.Ph., BCNP; Jeff Letendre, R.Ph., BCNP; Tom Defranco, R.Ph.; Christopher Leon, R.Ph.; Dave Lamont, R.Ph.; Todd Landry, R.Ph.; Christine Wilbur, R.Ph.; Mark R. Sutor, R.Ph.; Ronald Franks, R.Ph.; Paige Eynne Smart, R.Ph., Dana L. Suttle, R.Ph. and James M. Bichler.
- B. The Radiation Safety Officer for this license is Dana L. Suttle, R.Ph.
12. A. Sealed sources 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. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months or as specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State prior to the transfer, a sealed source received from another person shall not be put into use until tested.
- C. Sealed sources need not be leak tested if:
- (i) 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
 - (ii) 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 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.
- E. The licensee is authorized to collect and analysis leak test samples. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

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13. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
14. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.
15. 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."
16. 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.
 - C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
17. The licensee is authorized to retrieve, receive and dispose of radioactive waste from its customers, limited to radiopharmacy supplied syringes and vials and their contents.
18. 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 10CFR 30.35(d) for establishing decommissioning financial assurance.
19. 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 June 10, 1999;
 - B. Letters dated July 24, 1999, February 28, 2001, May 10, 2001, November 15, 2001, December 27, 2001, December 21, 2005, **May 27, 2009**); and

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- C. Letters received August 18, 1999, February 27, 2002(with attachment) and August 15, 2002 (with enclosures).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date AUG 10 2009By 
James R. Mullauer, M.H.S.
Materials Licensing Branch
Region III