

U.S. NUCLEAR REGULATORY COMMISSION

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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<p style="text-align: center;">Licensee</p> <p>1. PharmaLogic Michigan, L.L.C.</p> <p>2. 1501 Cass Street Traverse City, Michigan 49686</p>	<p>In accordance with letter dated June 22, 2012,</p> <p>3. License No. 21-32190-01MD is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration Date: February 29, 2020</p> <hr/> <p>5. Docket No. 030-35125 Reference No.</p>
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<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 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. 1.5 curies</p> <p>E. 2.5 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. 750 millicuries</p> <p>K. 600 kilograms</p>
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SUPPLEMENTARY SHEET**

License No.
21-32190-01MD

Docket or Reference No.
030-35125

Amendment No. 15

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. 500 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. For performing leak test sample analysis as a commercial service for customers.
- 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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030-35125**Amendment No. 15**CONDITIONS

- 10 Licensed material shall be used only at the licensee's facilities located at 1144 Boon Street, Traverse City, Michigan and **1501 Cass 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; Tom Defranco, R.Ph.; Dana L. Suttle, R.Ph.; James M. Bichler, R.Ph.; Shawn Lorrain, R.Ph.; Gerard Strugala, R.Ph., BCNP; Glen Palmer, R.Ph., BCNP; Selina Mirjavadi, R.Ph.; William Espie Gillette, R.Ph.; Joseph Lofaro, R.Ph.; Tamiko Ushio, R.Ph.; Matthew Witt Hinton, R.Ph.; Garth Kistner, R.Ph.; Richard Sucece, R.Ph.; and Laurie Stallings, R.Ph.
- B. The Radiation Safety Officer (RSO) 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 the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by 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 NRC under 10 CFR 32.210 or by an Agreement State prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- 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 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. The report shall be filed within five days of the date the leak test result is known with the appropriate NRC Regional Office referenced in Appendix D of 10 CFR Part 20. The report shall specify the source involved, the test results, and corrective action taken.
- E. Tests for leakage and/or contamination shall be performed by the licensee or other persons specifically licensed by the Commission or an Agreement State to perform such services. In addition, the licensee is authorized to collect leak test samples for analysis by persons specifically licensed by the Commission or an Agreement State to perform such services.

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- F. Records of leak test results shall be kept in units of microcuries and shall be maintained for three years.
13. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
14. The licensee shall conduct a physical inventory every six months, or at other intervals approved by NRC, to account for all sealed 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 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;
 - 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;
 - C. Maintains records of the disposal of licensed materials for three years. The record must include the date of the 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.
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. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from NRC before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 31.210 or by an Agreement State.
19. This license does not authorize distribution to persons exempt from licensing.

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20. 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 January 19, 2010;
- B. Letters dated June 22, 2012; August 27, 2012; and August 30, 2012; and,
- C. Facsimile dated February 16, 2010.

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Date SEP 07 2012By  _____Bryan A. Parker
Materials Licensing Branch
Region III