U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 36

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, 37, 39, 40, 70 and 71, 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 letter dated September 25, 2018.	4. Expiration Date: November 30, 2024
1. PharmaLogic Ltd. 2. 1191 S. Brownell Road, Suite 40 Williston, VT 05495	3. License number: 44-30124-01MD is amended in its entirety to read as follows:	5. Docket No.: 030-33449 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	9. Authorized use
A. Any byproduct material between Atomic Numbers 3 and 83 with Exceptions	A. Any Except Sealed Sources	A. 200 millicuries per source and 2 curies total	A. For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
B. Fluorine-18	B. Any	B. 1 curie total	B. For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
C. Gallium-67	C. Any	C. 500 millicuries total	C. For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.

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D. Strontium-89	D. Any	D. 40 millicuries total	D. For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
E. Yttrium-90	E. Any	E. 500 millicuries total	E. For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
F. Molybdenum-99	F. Any	F. 100 curies total	F. For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients. For redistribution of used and unused Molybdenum-99/Technetium-99m generators to authorized recipients in accordance with 10 CFR 32.72.
G. Technetium-99m	G. Any	G. 100 curies total	G. For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients. For redistribution of used and unused Molybdenum-99/Technetium-99m generators to authorized recipients in accordance with 10 CFR 32.72.

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H. Indium-111	H. Any	H. 300 millicuries total	H. For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
I. Iodine-123	I. Any	I. 50 millicuries total	I. For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
J. Iodine-131	J. Any	J. 2.5 curies total	J. For preparation and distribution of radioactive drugs, including compounding of iodine-131, and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
K. Xenon-133	K. Any	K. 1.5 curies total	K. For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
L. Samarium-153	L. Any	L. 750 millicuries total	L. For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.

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M. Thallium-201	M. Any	M. 1 curie total	M. For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
N. Any byproduct material permitted by 10 CFR 31.11	N. Prepackaged Kits	N. 50 millicuries total	N. For redistribution to specific licensees or to general licensees in accordance with 10 CFR 31.11, provided the packaging and labeling remain unchanged.
O. Any byproduct material authorized under 10 CFR 35.65	O. Sealed Sources (Eckert & Ziegler Isotope Products dba Isotope Products Laboratories, Model MED3503, GF Type R Series, RV-XXX Series, and EGLVM Series; International Isotopes Idaho, Inc. , Model BM06-37, BM06E Series, and BM06S Series; International Isotopes, Inc. , Model BM03-57L and BM03-57A; North American Scientific, Inc., Model MED3550, MED3400, and MED3402; Squibb Medical Imaging formerly E.I. Dupont, Model NES-356)	O. 500 millicuries total	O. For use in calibration and checking of the licensee's instruments. For redistribution of sealed sources initially distributed by a manufacturer licensed in accordance to 10 CFR 32.74 to authorized recipients for medical and non-medical use.

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P. Any byproduct material permitted in 10 CFR 35.400	P. Sealed Sources (Bard Brachytherapy, Model STM 1251; IsoAid, LLC, Model IAI-125A; North American Scientific, Inc., Model MED 3631 or MED 3633; Theragenics, Model Theraseed 200)	P. 2 curies total	P. For redistribution of sealed sources initially distributed by a manufacturer licensed in accordance to 10 CFR 32.74 to authorized recipients for medical use. For 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 and use the authorized device.
Q. Any byproduct material between atomic numbers 2 & 83 with exceptions	Q. Analytical Samples	Q. 50 millicuries total	Q. For possession incident to the performance of tests for leakage on customers sealed sources.
R. Uranium- depleted in Uranium-235	R. Metal	R. 400 kilograms total	R. For shielding of molybdenum-99/technetium-99m generators .
S. Germanium-68	S. Any	S. 100 millicuries total	S. For use of the Eckert and Ziegler GalliaPharm™ generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies.
T. Gallium-68	T. Any	T. 100 millicuries total	T. For preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72 and radiochemicals for non-medical use to authorized recipients.

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CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at 1191 S. Brownell Road, Suite 40, Williston, Vermont.

11. Licensed material shall only be used by, or under the supervision of:

    A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) or (4).

    B. Authorized Nuclear Pharmacists:

Steven C. Green, R.Ph.	Robert S. Hickman, Pharm.D.	Bynum L. Kimmons, R.Ph.
Joseph Olinzock, Pharm.D.	Glen Palmer, R.Ph.	Ruth Mary Wetzel, R.Ph.
Zonker White, R.Ph.	Anna K. Wierzbicki, R.Ph.	

    C. Authorized Users working under the supervision of an authorized nuclear pharmacist:

James Cordonier, II, R.Ph.	David Ellis, R.Ph.	Kevin Hart, R.Ph.
Garth Kistner, R.Ph.	Peteris Kruze, R.Ph.	Laurie Stallings, R.Ph., BCNP
Timothy Summers, R.Ph.	Dana Suttle, R.Ph.	Tamiko Ushio, R.Ph.

12. The Radiation Safety Officer (RSO) for this license is Robert S. Hickman, Pharm.D.

13. 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.

14. This license does not authorize distribution to persons exempt from licensing.

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15. 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 by an Agreement State. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.

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 by 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 185 becquerels (0.005 microcuries) of radioactive material on the test sample. If the test reveals the presence of 185 becquerels (0.005 microcuries) 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, including leak test sample collection and analysis, shall be performed by the licensee or 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 becquerels (microcuries) and shall be maintained for 3 years.

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16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.

17. 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 sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 3 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.

18. 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, the waste shall be surveyed at the container surface with the appropriate survey instrument 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, 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.

    B. A record of each such disposal permitted under this license condition shall be retained for 3 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.

19. 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.

20. Notwithstanding the requirements of 10 CFR 30.35(a)(1), the licensee is exempt from the requirement to have a decommissioning funding plan needed for the possession and use of Ge-68/Ga-68 medical use generators (Eckert and Ziegler GalliaPharm™ generators), based on the commitments between the licensee and manufacturer (Eckert and Ziegler). The licensee shall return the generators to the manufacturer/distributor in accordance with the generator return agreement described in the letter dated July 10, 2018.

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21. 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. 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 16, 2012 [ML12342A318]
B. Letter dated January 18, 2013 [ML13024A274]
C. Letter dated October 30, 2014 [ML14321A541]
D. Letter dated November 7, 2014 [ML14323A351]
E. Letter dated January 20, 2015 [ML15048A172]
F. Letter received March 20, 2015 [ML15090A727]
G. Letter dated June 14, 2018 [ML18180A337]
H. Letter dated July 10, 2018 [ML18207A701]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: October 4, 2018

By: _____

Shawn Seeley
Region 1