U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 30

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	
1. PharmaLogic Ltd.	In accordance with the letter dated June 23, 2016, 3. License number 44-30124-01MD is amended in its entirety to read as follows:
2. 1191 S. Brownell Road, Suite 40 Williston, Vermont 05495	4. Expiration date November 30, 2024 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
A. Any byproduct material with atomic numbers 3 through 83, except as listed below	A. Any, except sealed sources	A. 200 millicuries per radionuclide and 2 curies total
B. Fluorine 18	B. Any	B. 1 curie
C. Gallium 67	C. Any	C. 500 millicuries
D. Strontium 89	D. Any	D. 40 millicuries
E. Yttrium 90	E. Any	E. 500 millicuries
F. Molybdenum 99	F. Any	F. 100 curies
G. Technetium 99m	G. Any	G. 100 curies
H. Indium 111	H. Any	H. 300 millicuries
I. Iodine 123	I. Any	I. 50 millicuries
J. Iodine 131	J. Any	J. 2.5 curies
K. Xenon 133	K. Any	K. 1.5 curies
L. Samarium 153	L. Any	L. 750 millicuries
M. Thallium 201	M. Any	M. 1 curie
N. Any byproduct material permitted by 10 CFR 31.11(a)	N. Prepackaged units for in vitro diagnostic tests	N. 50 millicuries
O. Any byproduct material	O. Sealed Sources (Bristol-Myers	O. 500 millicuries

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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
permitted by 10 CFR 35.65(a)	Squibb Medical Imaging, formerly E.I. DuPont Model NES-356; International Isotopes, Inc. Models BM03-57L and BM03-57A; International Isotopes Idaho, Inc. Models BM06-37, BM06E Series, and BM06S Series; North American Scientific, Inc. Models MED3550, MED3400, and MED3402; Eckert & Ziegler Isotope Products dba Isotope Products Laboratories MED3503, GF Type R Series, RV-XXX Series, and EG-LVM Series)	
P. Any byproduct material permitted by 10 CFR 35.400	P. Sealed Sources (Bard Brachytherapy, Inc. Model STM 1251; IsoAid, L.L.C. Model IAI-125A; Theragenics Corporation TheraSeed Model 200; North American Scientific, Inc. Models MED3631 and MED3633)	P. 2,000 millicuries
Q. Any byproduct material with atomic numbers 2 through 83	Q. Analytical samples	Q. 50 millicuries
R. Depleted Uranium	R. Metal	R. 400 kilograms

9. Authorized use:

A. through M. Preparation and distribution of radioactive drugs, including compounding of iodine-131, to authorized recipients in accordance with 10 CFR 32.72 and to authorized recipients for nonmedical use.

F. and G. Redistribution of used and unused molybdenum 99/technetium 99m generators to authorized recipients for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.

N. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged.

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O. Calibration and checking of the licensee's 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.
P. Redistribution for medical use of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. Redistribution for non-medical use of sealed sources that have been registered either with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and 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.
Q. For possession incident to the performance of leak testing of customers' sealed sources.
R. Shielding for molybdenum-99/technetium-99m generators.

CONDITIONS

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

11. Licensed material shall 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: Glen Palmer, R.Ph., Richard Sucese, R.Ph., Richard L. Van Sant, R.Ph., Ruth Mary Wetzel, R.Ph., Zonker White, R.Ph. and Bynum L. Kimmons, 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., and Tamiko Ushio, R.Ph.

12. The Radiation Safety Officer for this license is Richard Sucese, R.Ph.

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 commercial distribution of licensed material to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.21, inclusive, or equivalent regulations of any Agreement State.

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15. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at 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 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, including leak test sample collection and analysis, 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 5 years.

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

17. The licensee shall conduct a physical inventory every six 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.

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18. 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

    C. Maintains records of the disposal of licensed materials for 3 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.

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. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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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. 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}

For the U.S. Nuclear Regulatory Commission

Date August 22, 2016

By ***Original signed by Tara L. Weidner***

Tara L. Weidner
Medical Branch
Division of Nuclear Materials Safety
Region I