

**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.

<p>Licensee</p> <p>1. PharmaLogic Ltd.</p>	<p>In accordance with letters dated August 8, 2016 and October 21, 2016</p>	<p>4. Expiration Date: November 30, 2024</p>	
<p>2. 1191 S. Brownell Road, Suite 40 Williston, VT 05495</p>	<p>3. License number: 44-30124-01MD is amended in its entirety to read as follows:</p>	<p>5. Docket No.: 030-33449 Reference No.:</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material between atomic numbers 3 and 83 with exceptions listed below</p> <p>B. Fluorine-18</p> <p>C. Gallium-67</p>	<p>7. Chemical and/or physical form</p> <p>A. Any except sealed sources</p> <p>B. Any</p> <p>C. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 200 millicuries per source and 2 curies total</p> <p>B. 1 curie total</p> <p>C. 500 millicuries total</p>	<p>9. Authorized use</p> <p>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.</p> <p>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.</p> <p>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.</p>

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
44-30124-01MD

Amendment No. 31

Docket or Reference Number  
030-334496. Byproduct, source,  
and/or special nuclear  
material

D. Strontium-89

E. Yttrium-90

F. Molybdenum-99

G. Technetium-99m

7. Chemical and/or physical form

D. Any

E. Any

F. Any

G. Any

8. Maximum amount that licensee  
may possess at any one time  
under this license

D. 40 millicuries total

E. 500 millicuries total

F. 100 curies total

G. 100 curies total

9. Authorized use

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. 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. 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. 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.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
44-30124-01MD

Amendment No. 31

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030-334496. Byproduct, source,  
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material

H. Indium-111

I. Iodine-123

J. Iodine-131

K. Xenon-133

L. Samarium-153

7. Chemical and/or physical form

H. Any

I. Any

J. Any

K. Any

L. Any

8. Maximum amount that licensee  
may possess at any one time  
under this license

H. 300 millicuries total

I. 50 millicuries total

J. 2.5 curies total

K. 1.5 curies total

L. 750 millicuries total

9. Authorized use

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. 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. 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. 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. 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.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
44-30124-01MD

Amendment No. 31

Docket or Reference Number  
030-334496. Byproduct, source,  
and/or special nuclear  
material

M. Thallium-201

7. Chemical and/or physical form

M. Any

8. Maximum amount that licensee  
may possess at any one time  
under this license

M. 1 curie total

9. Authorized use

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  
35.65O. 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.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
44-30124-01MDDocket or Reference Number  
030-33449

Amendment No. 31

6. Byproduct, source,  
and/or special nuclear  
materialP. Any byproduct material  
identified in 10 CFR  
35.400Q. Any byproduct material  
between atomic numbers  
2 & 83 with exceptionsR. Uranium- depleted in  
Uranium-235

7. Chemical and/or physical form

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)

Q. Analytical Samples

R. Metal

8. Maximum amount that licensee  
may possess at any one time  
under this license

P. 2 curies total

Q. 50 millicuries total

R. 400 kilograms total

9. Authorized use

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. For possession incident to the  
performance of tests for leakage on  
customers sealed sources.R. For shielding of  
molybdenum-99/technetium-99m  
generators .**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).

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
44-30124-01MD

Amendment No. 31

Docket or Reference Number  
030-33449

- B. Authorized Nuclear Pharmacist(s): Glen Palmer, R.Ph., Richard L. Van Sant, R.Ph., Ruth Mary Wetzel, R.Ph., Zonker White, R.Ph., Bynum L. Kimmons, R.Ph., and Robert S. Hickman, Pharm.D.
- 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 (RSO) for this license is Zonker White, 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 distribution to persons exempt from licensing.
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.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
44-30124-01MD

Amendment No. 31

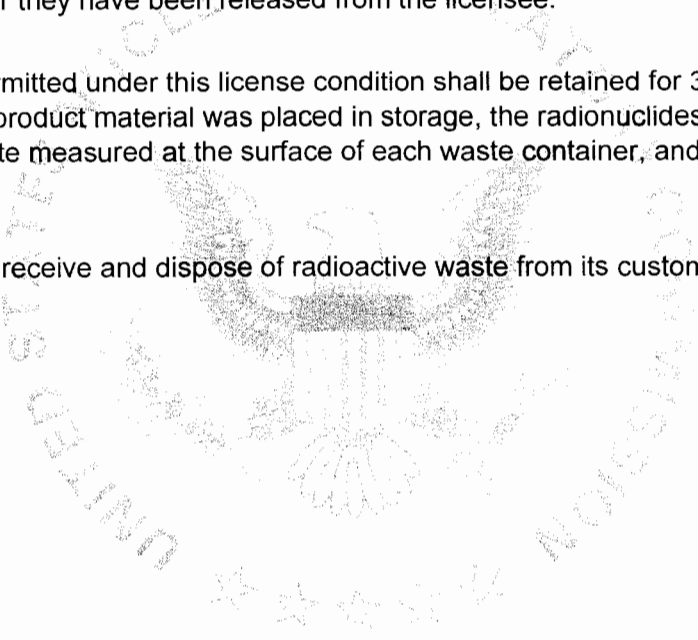
Docket or Reference Number  
030-33449

- 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.
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:

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
44-30124-01MD

Amendment No. 31

Docket or Reference Number  
030-33449

- 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.
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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
44-30124-01MD

Amendment No. 31

Docket or Reference Number  
030-33449

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. 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]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

By: Farrah Gaskins  
Region 1Date: November 3, 2016