NRC FORM 374

Amendment No. 33

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, 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		
1. PharmaLogic WV, Ltd.	In accordance with letter dated July 24, 2019.	4. Expiration Date: October 31, 2022
2. 9 W. Benedum Industrial Park Drive Bridgeport, WV 26330	3. License number: 47-25375-01MD is amended in its entirety to read as follows:	5. Docket No.: 030-34289 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 with Atomic Numbers 1 through 83 with half-life less than or equal to 120 days	A. Any	A. 200 millicuries per radionuclide 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.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 47-25375-01MD	Docket or Reference Number 030-34289
	Amendment No. 33	

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
D. Strontium-89	D. Any	D. 80 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. 1 curie 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. 200 curies total	F. For preparation and distribution of radioactive drugs and radiochemicals, and redistribution of used and unused Molybdenum-99/Technetium-99m generators for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
G. Technetium-99m	G. Any	G. 200 curies total	G. For preparation and distribution of radioactive drugs and radiochemicals, and redistribution of used and unused Molybdenum-99/Technetium-99m generators for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number
47-25375-01MD

Amendment No. 33

Docket or Reference Number
030-34289

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
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. 5 curies total	J. For preparation, including compounding of iodine-131, 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.
K. Xenon-133	K. Any	K. 3 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. 1.5 curies 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.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 47-25375-01MD	Docket or Reference Number 030-34289
	Amendment No. 33	

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
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. Iodine-125 permitted by 10 CFR 35.400	N. Sealed Sources (Bard Brachytherapy Inc., Model STM 125I; Best Medical, Model 2301-2308 or 2309-2316; IsoAid L.L.C., Model IAI-125; North American Scientific, Model MED 3631)	N. 0.5 curies total	N. For redistribution of sealed sources initially distributed by a manufacturer licensed in accordance with 10 CFR 32.74 to authorized recipients for medical use and to authorized recipients for non-medical use.
O. Palladium-103 permitted by 10 CFR 35.400	O. Sealed Sources (Best Medical, Model 2331-2335; North American Scientific, Model MED 3633; Theragenics Coporation, Model Theraseed Model 200)	O. 250 millicuries total	O. For redistribution of sealed sources initially distributed by a manufacturer licensed in accordance with 10 CFR 32.74 to authorized recipients for medical use and to authorized recipients for non-medical use.
P. Any byproduct material permitted by 10 CFR 31.11 with half-life less than or equal to 120 days	P. Prepackaged Kits	P. 100 millicuries total	P. For redistribution to specific licensees or to general licensees in accordance with 10 CFR 31.11, provided the packaging and labeling remain unchanged.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 47-25375-01MD Amendment No. 33	Docket or Reference Number 030-34289

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
Q. Any byproduct material permitted by 10 CFR 35.65	Q. Sealed Sources (International Isotopes Idaho Inc., Model BM06E, BM06S, BM03-XXA, or BM03-XXL Series; Isotopes Product Laboratories, Model RV-XXX, EG-XXX, or GF Type R Series; North American Scientific Inc., Model MED 3503, MED 3550, MED 3400 or MED 3402)	Q. 100 millicuries total	Q. For use in calibration and checking of the licensee's instruments and for redistribution of sealed sources initially distributed by a manufacturer licensed in accordance to 10 CFR 32.74 to authorized recipients for medical use and to authorized recipients for non-medical use.
R. Uranium- depleted in Uranium-235	R. Metal	R. 400 kilograms total	R. For shielding for generators.
S. Germanium-68	S. Any	S. 100 millicuries total	S. For use of the Ge-68/Ga-68 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.

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at 5842B Davis Creek Road, Barboursville, West Virginia and 9 W. Benedum Industrial Park Drive, Bridgeport, West Virginia.

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 47-25375-01MD	Docket or Reference Number 030-34289
	Amendment No. 33	

B. Authorized Nuclear Pharmacists:

James Cordonier, II, R.Ph.	Benjamin G. Fredrick, Pharm.D.	Reid Gadziala, Pharm.D.
Steven C. Green, R.Ph.	Shelby Griffith, R.Ph.	Kevin Hart, R.Ph.
Garth Kistner, R.Ph.	Glen Palmer, R.Ph.	Laurie Stallings, R.Ph.; BCNP
Richard Sucese, R.Ph.	Timothy Summers, R.Ph.	Dana Suttle, R.Ph.
Dustin Van Dyke, Pharm.D.	Zonker White, R.Ph.	Anna K. Wierzbicki, R.Ph.
Amanda Wilfong, Pharm.D.		

12. The Radiation Safety Officer (RSO) for this license is Shelby Griffith, R.Ph.

13. 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 and IRE Galli-Eo generators), based on the commitments between the licensee and manufacturer (Eckert and Ziegler for the GalliaPharm) and between the licensee and distributor (Cardinal Health for the Galli-Eo). The licensee shall return the generators to the manufacturer/distributor in accordance with the generator return agreements described in the letters dated March 6, 2017 and July 24, 2019.

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. Not withstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 47-25375-01MD	Docket or Reference Number 030-34289
	Amendment No. 33	

C. 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.

D. 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.

E. 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.

F. 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.

G. 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.

H. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for 3 years.

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

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 47-25375-01MD Amendment No. 33	Docket or Reference Number 030-34289

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.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 47-25375-01MD	Docket or Reference Number 030-34289
	Amendment No. 33	

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 April 26, 2012 [ML12122A214]
    B. Letter dated June 19, 2012 [ML12178A539]
    C. Letter dated September 6, 2012 [ML12263A215]
    D. Application dated November 16, 2012 [ML12342A305]
    E. Letter dated January 10, 2013 [ML13029A564]
    F. Letter dated January 23, 2013 [ML13024A257]
    G. Letter dated January 20, 2015 [ML15048A157]
    H. Letter received March 20, 2015 [ML15090A750]
    I. Letter dated November 11, 2016 [ML16341C333]
    J. Letter dated February 7, 2017 [ML17052A016]
    K. Facility diagram received February 7, 2017 [ML17052A072]
    L. Letter dated February 8, 2017 [ML17055B624]
    M. Letter dated March 6, 2017 [ML17072A106]
    N. Letters dated March 10 and 13, 2017 [ML17086A144]

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 47-25375-01MD	Docket or Reference Number 030-34289
	Amendment No. 33	

continued

O. Letter dated March 31, 2017 [ML17093A698]

P. Letter dated July 24, 2019 [ML19211C586]

Q. Letter dated August 12, 2019

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: August 22, 2019

By: Janice Nguyen

Janice Nguyen
Region 1