U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 41

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 March 04, 2025,	4. Expiration Date: March 31, 2038
1. PharmaLogic WV, Ltd. 2. 9 West Benedum Industrial Park Drive Bridgeport, WV 26330	3. License No.: 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, distribution, and redistribution 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. Same as 9.A
C. Gallium-67	C. Any	C. 500 millicuries total	C. Same as 9.A
D. Germanium-68	D. Any	D. 400 millicuries total	D. For use of Ge-68/Ga-68 generators to prepare Ga-68 radiopharmaceuticals for imaging and localization studies; and for preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72 and radiochemicals for non-medical use to authorized recipients.
E. Gallium-68	E. Any	E. 400 millicuries total	E. Same as 9.D

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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	9. Authorized use
F. Strontium-89	F. Any	F. 80 millicuries total	F. Same as 9.A
G. Yttrium-90	G. Any	G. 1 curie total	G. Same as 9.A
H. Molybdenum-99	H. Any	H. 200 curies total	H. For preparation, distribution, and redistribution of radioactive drugs and radiochemicals for medical use; and redistribution of unused molybdenum-99/technetium-99m generators to authorized recipients, in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
I. Technetium-99m	I. Any	I. 200 curies total	I. Same as 9.H
J. Indium-111	J. Any	J. 300 millicuries total	J. Same as 9.A
K. Iodine-123	K. Any	K. 500 millicuries total	K. Same as 9.A
L. Iodine-131	L. Any	L. 5 curies total	L. For preparation and distribution of radioactive drugs and radiochemicals, including compounding of iodine-131, for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
M. Xenon-133	M. Any	M. 3 curies total	M. Same as 9.A
N. Samarium-153	N. Any	N. 1.5 curies total	N. Same as 9.A
O. Thallium-201	O. Any	O. 1 curie total	O. Same as 9.A

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P. Iodine-125 permitted by 10 CFR 35.400	P. Sealed Sources	P. 500 millicuries total	P. 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.
Q. Palladium-103 permitted by 10 CFR 35.400	Q. Sealed Sources	Q. 250 millicuries total	Q. Same as 9.P
R. Any byproduct material permitted by 10 CFR 31.11 with half-life less than or equal to 120 days	R. Prepackaged Kits	R. 100 millicuries total	R. For redistribution to specific licensees or to general licensees in accordance with 10 CFR 31.11, provided the packaging and labeling remain unchanged.
S. Any byproduct material permitted by 10 CFR 35.65	S. Sealed Sources	S. 100 millicuries total	S. 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 with 10 CFR 32.74 to authorized recipients for medical use and to authorized recipients for non-medical use.
T. Gadolinium-153	T. Sealed Sources	T. 60 millicuries total	T. 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 with 10 CFR 32.74 to authorized recipients for medical use and to authorized recipients for non-medical use.
U. Uranium- depleted in Uranium-235	U. Metal	U. 400 kilograms total	U. For shielding for generators and shipping containers.

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CONDITIONS

10. Licensed material shall be used or stored at the licensee's facilities located at:

    A. 5842B Davis Creek Road, Barboursville, West Virginia, 25504

    B. 9 West Benedum Industrial Park Drive, (GPS Coordinates 39.295803,-80.220881 on Industrial Road West), Bridgeport, West Virginia, 26330

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:

David C. Alderson, Pharm.D.	William A. Boerger, R.Ph.	Jessica Comstock, Pharm.D.
Benjamin G. Fredrick, Pharm.D.	Reid Gadziala, Pharm.D.	Kimberly Gomez, Pharm.D.
Shelby Griffith, R.Ph.	Leah R. Hicks, R.Ph.	Jasmine Jenkins, Pharm.D.
Bynum L. Kimmons, R.Ph.	Garth Kistner, R.Ph.	Lawrence A. Lopez, Pharm.D.
Stephen R. Morrow, Pharm.D.	David M. Ostenberg, R.Ph.	Glen Palmer, R.Ph.
Kenna Spurlock, Pharm.D.		

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

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

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14. 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. Notwithstanding 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.

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.

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

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

16. 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.

17. 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.

18. 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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19. 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 statements, representations, and 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 impose on the licensee requirements that are more restrictive than or in addition to the regulations.

A. Application dated September 26, 2022 [ML22294A015]
B. Letter received February 16, 2023 [ML23048A025]
C. Letter dated February 28, 2023 [ML23060A023]
D. Letter dated December 17, 2023 [ML23360A028]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: June 6, 2025

By: JANICE NGUYEN Digitally signed by JANICE NGUYEN Date: 2025.06.06 11:18:24 -04'00'

Janice Nguyen
Region 1