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 July 14, 2022,	4. Expiration Date: July 31, 2035
1. PharmaLogic Michigan, L.L.C.		5. Docket No.: 030-35125 Reference No.:
2. 1501 Cass St. Traverse City, MI 49684	3. License No.: 21-32190-01MD is amended in its entirety to read as follows:	

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	A. Any except sealed source	A. 200 millicuries per radionuclide; 2 curies total	A. For preparation, distribution and redistribution of radioactive drugs, including compounding of Iodine-131 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.
B. Molybdenum-99	B. Any except sealed source	B. 200 curies total	B. Same as Subitem No. 9.A.
C. Technetium-99m	C. Any except sealed source	C. 200 curies total	C. Same as Subitem No. 9.A.
D. Iodine-131	D. Any except sealed source	D. 5 curies total	D. Same as Subitem No. 9.A.
E. Any byproduct material permitted by 10 CFR 31.11	E. Prepackaged Kits	E. 100 millicuries total	E. 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 No.: 21-32190-01MD

Amendment No. 25

Docket or Reference No.: 030-35125

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. Any byproduct material permitted in 10 CFR 35.400	F. Sealed Sources	F. 500 millicuries total	F. For redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. 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 and to authorized recipients for non-medical use.
G. Any byproduct material permitted by 10 CFR 35.500	G. Sealed Sources	G. 1.5 curies per source and 5.5 curies total	G. Same as Subitem No. 9.F.
H. Any byproduct material permitted by 10 CFR 35.65	H. Sealed Sources	H. 100 millicuries total	H. For use in calibration and checking of licensee's instruments and radiation detection and measuring equipment. For redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 and for non-medical use to authorized recipients.
I. Samarium-153	I. Any except sealed source	I. 1.5 curies total	I. For preparation and distribution of drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
J. Yttrium-90	J. Any except sealed source	J. 1 curie total	J. Same as Subitem No. 9.I.
K. Fluorine-18	K. Any Except Sealed Sources	K. 1 curie total	K. Same as Subitem No. 9.I.
L. Gallium-67	L. Any Except Sealed Sources	L. 500 millicuries total	L. Same as Subitem No. 9.I.
M. Indium-111	M. Any Except Sealed Sources	M. 300 millicuries total	M. Same as Subitem No. 9.I.
N. Thallium-201	N. Any Except Sealed Sources	N. 1 curie total	N. Same as Subitem No. 9.I.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No.: 21-32190-01MD

Amendment No. 25

Docket or Reference No.: 030-35125

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
O. Strontium-89	O. Any Except Sealed Sources	O. 80 millicuries total	O. Same as Subitem No. 9.I.
P. Xenon-133	P. Any Except Sealed Sources	P. 3 curies total	P. Same as Subitem No. 9.I.
Q. Uranium- depleted in Uranium-235	Q. Metal	Q. 600 kilograms total	Q. For shielding for generators and shipping containers.
R. Germanium-68	R. Any	R. 100 millicuries total	R. For use of Ge-68/Ga-68 generators to prepare Ga-68 radiopharmaceuticals for imaging and localization studies. For preparation and distribution of radioactive drugs for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
S. Gallium-68	S. Any	S. 100 millicuries total	S. Same as Subitem No. 9.R.

CONDITIONS

10. Licensed material shall be used or stored at the licensee's facilities located at 1501 Cass St., Traverse City, Michigan, 49684.

11. The Radiation Safety Officer (RSO) for this license is Dana L. Suttle, R.Ph.

12. 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 No.: 21-32190-01MD	Docket or Reference No.: 030-35125
	Amendment No. 25	

B. Authorized Nuclear Pharmacists:

David R. Allen, Pharm.D.	Aaron A. Barnes, Pharm.D.	Allen R. Doan, R.Ph.
Jacob D. Dorie, Pharm.D.	Bynum L. Kimmons, R.Ph.	David Osterberg, R.Ph.
Glen Palmer, R.Ph., BCNP	Logan William Payne, R.Ph.	Gerald Strugala, R.Ph., BCNP
Dana Suttle, R.Ph.	Ruth Mary Wetzel, R.Ph.	Anna K. Wierzbicki, R.Ph.

13. 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.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No.: 21-32190-01MD	Docket or Reference No.: 030-35125
	Amendment No. 25	

F. Tests for leakage and/or contamination 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. In addition, the licensee is authorized to collect leak test samples for analysis by persons specifically licensed by the 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.

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

15. 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.

16. 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.

17. 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 No.: 21-32190-01MD	Docket or Reference No.: 030-35125
	Amendment No. 25	

18. Except for maintaining labeling as required by 10 CFR Part 20, or Part 71, the licensee shall obtain authorization from the U.S. Nuclear Regulatory Commission before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective certificate of registration issued either by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or by an Agreement State.

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

20. Notwithstanding the requirements of License Condition 21, the licensee is authorized to make program changes and changes to procedures specifically identified in the letter dated September 29, 2020 (ML20290A506), which were previously approved by the U.S. Nuclear Regulatory Commission and incorporated into the license without prior Commission approval as long as:

    A. The revision does not require a license amendment under 10 CFR 35.13;

    B. The revision is based upon NRC's current guidance for use of Ge-68/Ga-68 generators to prepare Ga-68 radiopharmaceuticals for the imaging and localization studies under 10 CFR 35.1000 posted on the NRC Medical Uses Licensee Toolkit;

    C. The revision has been reviewed and approved by the licensee's Radiation Safety Officer and management;

    D. The affected individuals are instructed on the revised program before the change is implemented;

    E. The licensee will maintain a record of each change for 5 years; and

    F. The record will include a copy of the current guidance for use of Ge-68/Ga-68 generators to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under 10 CFR 35.1000, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management representative who reviewed and approved the change.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No.: 21-32190-01MD	Docket or Reference No.: 030-35125
	Amendment No. 25	

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 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 January 10, 2020 (ML20024G445)
B. Letter dated July 16, 2020 (ML20198M549)
C. Letter dated September 29, 2020 (ML20290A506)
D. Letter dated April 20, 2021 (including attachment letter dated March 22, 2021) (ML21112A239)
E. Letter dated July 14, 2022 (ML2207B847)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: September 13, 2022

By: Sara A. Forster

Digitally signed by Sara A. Forster
Date: 2022.09.13 16:14:26 -05'00'

Sara A. Forster
Region III