U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 23

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 25, 2020,	4. Expiration Date: June 30, 2021
1. Radiopharmacy Incorporated		5. Docket No.: 030-31910 Reference No.:
2. 1409 East Virginia Street Evansville, IN 47711	3. License No.: 13-26246-01MD 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 Nos. 1 through 83 with exceptions	A. Any	A. 1000 millicuries total	A. Preparation and distribution 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. Preparation and distribution of radioactive drugs and radiochemicals, including compounding of iodine-131 and redistribution of unused molybdenum-99/technetium-99m generators, to authorized recipients for non-medical use.
B. Molybdenum-99	B. Any	B. 100 curies total	B. Same as Item 9.A.
C. Technetium-99m	C. Any	C. 100 curies total	C. Same as Item 9.A.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No. 13-26246-01MD

Amendment No. 23

Docket or Reference No. 030-31910

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. Iodine-131	D. Any	D. 2 curies total	D. Same as Item 9.A.
E. Xenon-133	E. Any	E. 800 millicuries total	E. Same as Item 9.A.
F. Any byproduct material permitted in 10 CFR 35.400	F. Sealed Sources	F. 1 curie total	F. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. 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 NRC or an Agreement State specific license authorizing distribution to persons specifically authorized by NRC or an Agreement State license to receive, possess, and use the sources.
G. Any byproduct material permitted by 10 CFR 35.65	G. Sealed Sources	G. 75 millicuries total	G. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 or under an equivalent license of an Agreement State to authorized recipients and to authorized recipients for non-medical use.
H. Uranium - depleted in uranium-235	H. Metal	H. 999 kilograms total	H. Shielding for molybdenum-99/technetium-99m generatorss

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No. 13-26246-01MD

Amendment No. 23

Docket or Reference No. 030-31910

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
I. Radium-223	I. Liquid	I. 5 millicuries total	I. For the preparation, distribution, and redistribution of radium-223 dichloride radioactive drugs to authorized recipients.
J. Germanium-68	J. Any	J. 100 millicuries total	J. For use of the Eckert and Ziegler GalliaPharm™ and IRE Galli-Eo® Ge-68/Ga-68 generators to prepare Ga-68 radiopharmaceuticals for imaging and localization studies.
K. Gallium-68	K. Any	K. 100 millicuries total	K. 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 shall be used or stored only at the licensee's facilities located at 1409 East Virginia Street, Evansville, Indiana, 47711.

11. A. Licensed material shall only be used by, or under the supervision of:

1) 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. 13-26246-01MD	Docket or Reference No. 030-31910
	Amendment No. 23	

2) Authorized Nuclear Pharmacists:

Alexander J. Bassemier, PharmD	Matthew O. Broshears, R.Ph.	Andrew Scott Day, R.Ph.
E. Dean Dome, R.Ph.	John E. Haney, R.Ph.	Phillip B. Harris, R.Ph.
Bynum L. Kimmons, R.Ph.	Kyle Kuczmanski, PharmD	Timothy M. Quinton, R.Ph.
Nicole M. Spurling, R.Ph.	John Vardsveen, PharmD	Ruth Mary Wetzel, R.Ph.
Jason J. Wilson, R.Ph.		

B. The Radiation Safety Officer (RSO) for this license is Jason J. Wilson, R.Ph.

12. A. Sealed sources and detector cells 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 six 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.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No. 13-26246-01MD	Docket or Reference No. 030-31910
	Amendment No. 23	

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 three years.

13. Sealed sources containing licensed material shall not be opened.

14. The licensee shall conduct a physical inventory every six months to account for all sources and/or devices received and possessed under the license.

15. 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.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No. 13-26246-01MD	Docket or Reference No. 030-31910
	Amendment No. 23	

B. A record of each such disposal permitted under this license condition shall be retained for three 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.

16. 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.

17. 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 August 26, 2019 (ML19240B407) and October 2, 2019 (ML19275G305).

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No. 13-26246-01MD	Docket or Reference No. 030-31910
	Amendment No. 23	

18. 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 February 15, 2011 (ML110470562)
B. Letter dated March 7, 2014 (ML14066A489)
C. Letter dated October 27, 2016 (ML16301A437)
D. Letter dated December 16, 2016 (ML16354A124)
E. Letter dated August 26, 2019 (ML19240B407)
F. Letter dated October 2, 2019 (ML19275G305)
G. Letter dated November 20, 2019 (ML19324G109)

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Bryan A. Parker

Digitally signed by Bryan A. Parker
Date: 2020.04.16 10:55:33 -04'00'

Date: April 16, 2020

By: _____

Bryan A. Parker
Region III