

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, and 70, 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 letters dated May 4, 2012, May 29, 2013, and March 7, 2014,	
1. Radiopharmacy Incorporated		3. License number 13-26246-01MD is amended in its entirety to read as follows:	
2. 1409 East Virginia Street Evansville, IN 47711		4. Expiration date June 30, 2021	
		5. Docket No. 030-31910 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	
A. Any byproduct material with atomic numbers 1 through 83	A. Any	A. 1000 millicuries total except for the following:	
B. Molybdenum-99	B. Any	B. 100 curies	
C. Technetium-99m	C. Any	C. 100 curies	
D. Iodine-131	D. Any	D. Two curies	
E. Xenon-133	E. Any	E. 800 millicuries	
F. Any byproduct material in a brachytherapy source as listed in 10 CFR 35.400	F. Sealed sources	F. One curie total	
G. Any byproduct material authorized under 10 CFR 35.65(a)(b)	G. Sealed sources	G. 75 millicuries total	
H. Depleted uranium	H. Metal	H. 999 kilograms total	
I. Radium-223	I. Liquid	I. Five millicuries	

9. Authorized use:

- A. through E.** 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.

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- 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 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 sources.
- 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. Shielding for molybdenum 99/technetium-99m generators.
- I. **For the preparation, distribution, and redistribution of radium-223 dichloride radioactive drugs to authorized recipients.**

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1409 East Virginia Street, Evansville, Indiana.
11. A. Licensed material shall 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) and (4).
 - 2) Authorized Nuclear Pharmacists: Timothy M. Quinton, R.Ph., E. Dean Dome, R.Ph., Nicole M. Spurling, R.Ph., Matthew O. Broshears, R.Ph., Jason J. Wilson, R.Ph., John E. Haney, R.Ph., Phillip B. Harris, R.Ph., and John Vardsveen, Pharm.D.
- B. The Radiation Safety Officer for this license is Timothy M. Quinton, R.Ph.
12. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals **specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.**
- B. In the absence of a certificate from a transferor indicating that a leak test has been made within the six months 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 leak tested if 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 ten years without being tested for leakage and/or contamination.

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- E. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) 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 shall be performed by the licensee or by 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 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 may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
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.
- 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.
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.
18. 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.

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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. The 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; and,

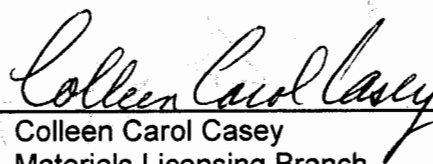
B. Letter dated **March 7, 2014**.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

MAY 29 2014

By



Colleen Carol Casey
Materials Licensing Branch
Region III