U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 14

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 October 10, 2018.	4. Expiration Date: January 31, 2021
1. Molecular Imaging, Inc. d/b/a MI Bioresearch 2. 800 Technology Dr. Ann Arbor, MI 48108	3. License number: 21-32816-01 is amended in its entirety to read as follows:	5. Docket No.: 030-38386 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. Fluorine-18	A. Liquid	A. 240 millicuries total	A. For research and development as defined in 10 CFR 30.4 in rodents.
B. Cobalt-57	B. Sealed Sources (Eckert & Ziegler, Model PHI-0119)	B. 5 millicuries per source and 10 millicuries total	B. For use in instrument calibration.
C. Germanium-68	C. Sealed Sources (Siemens , Model CS-6-14)	C. 2 sources not to exceed 5 millicuries total	C. For use in instrument calibration.
D. Cesium-137	D. Sealed Sources (Eckert & Ziegler, Model RV-137-200U)	D. 300 microcuries per source and 600 microcuries total	D. For use in instrument calibration.
E. Technetium-99m	E. Any	E. 50 millicuries total	E. Same as Item 9.A.
F. Indium-111	F. Any	F. 100 millicuries total	F. Same as Item 9.A.
G. Iodine-123	G. Any	G. 50 millicuries total	G. Same as Item 9.A.
H. Iodine-125	H. Any	H. 60 millicuries total	H. Same as Item 9.A.

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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
I. Gallium-67	I. Any	I. 50 millicuries total	I. Same as Item 9.A.
J. Thallium-201	J. Any	J. 50 millicuries total	J. Same as Item 9.A.
K. Copper-64	K. Any	K. 50 millicuries total	K. Same as Item 9.A.
L. Yttrium-86	L. Any	L. 50 millicuries total	L. Same as Item 9.A.
M. Cobalt-55	M. Any	M. 50 millicuries total	M. Same as Item 9.A.
N. Iodine-124	N. Any	N. 100 millicuries total	N. Same as Item 9.A.
O. Zirconium-89	O. Any	O. 100 millicuries total	O. Same as Item 9.A.
P. Gallium-68	P. Any	P. 150 millicuries total	P. Same as Item 9.A.
Q. Lutetium-177	Q. Any	Q. 100 millicuries total	Q. Same as Item 9.A.
R. Tin-117m	R. Any	R. 20 millicuries total	R. Same as Item 9.A.
S. Iodine-131	S. Labeled Compounds	S. 125 millicuries total	S. Same as Item 9.A.
T. Actinium-225	T. Liquid (non-volatile)	T. 50 microcuries per vial and 500 microcuries total	T. Same as Item 9.A.

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at: 800 Technology Drive, Ann Arbor, Michigan, 48108.

11. Licensed material shall only be used by, or under the supervision of, Sarah Krueger, Ph.D. and Kevin Guley.

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12. The Radiation Safety Officer (RSO) for this license is John Harvey, Ph.D., CHP.

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 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.

D. 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.

E. Analysis of leak test samples and/or contamination shall be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. The licensee is authorized to collect leak test samples but not perform the analysis.

F. 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 by the licensee.

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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 shall not use the licensed material in or on humans.

17. Experimental animals, or the products from experimental animals, that have been administered licensed material shall not be used for human consumption.

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.

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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 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 June 9, 2010 (ML101740179)
    B. Letter dated March 16, 2012 (ML120790252)
    C. Letter dated March 23, 2012 (ML120830256)
    D. Letter dated April 27, 2012 (ML12121A674)
    E. Letter dated October 15, 2012 (ML12293A103)
    F. Letter dated March 11, 2013 (ML13073A889)
    G. Letter dated July 1, 2013 (ML13189A080)
    H. Letter dated September 13, 2013 with the exception of authorizing a location of use outside U.S. Nuclear Regulatory Commission jurisdiction (ML13260A520)
    I. Letter dated November 18, 2013 (ML13337A438)
    J. Letter dated February 24, 2014 (ML14105A052)
    K. Letter dated May 13, 2014 (ML14133A698)
    L. Letter dated July 17, 2014 (ML14203A294)

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M. Letter dated February 10, 2016 (ML16041A492)
N. Letter dated September 13, 2016 (ML16264A382)
O. Letter dated December 16, 2016 (ML16354A120)
P. Letter dated October 10, 2018 (ML18283A067)
Q. Letter dated December 5, 2018 (ML18340A049)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: December 12, 2018

By: _____
Frank P. D. Tran
Region 3