

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.

<p>Licensee</p> <p>1. Molecular Imaging, Inc.</p> <p>2. 800 Technology Drive Ann Arbor, Michigan 48108</p>	<p>In accordance with letter dated February 10, 2016,</p> <p>3. License number 21-32816-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date January 31, 2021</p> <p>5. Docket No. 030-38386 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Fluorine-18</p> <p>B. Cobalt-57</p> <p>C. Germanium-68</p> <p>D. Cesium-137</p> <p>E. Technetium-99m</p> <p>F. Indium-111</p> <p>G. Iodine-123</p> <p>H. Iodine-125</p> <p>I. Gallium-67</p> <p>J. Thallium-201</p> <p>K. Copper-64</p> <p>L. Yttrium-86</p> <p>M. Cobalt-55</p> <p>N. Iodine-124</p> <p>O. Zirconium-89</p> <p>P. Gallium-68</p> <p>Q. Lutetium-177</p> <p>R. Tin-117m</p>	<p>7. Chemical and/or physical form</p> <p>A. Solution</p> <p>B. Sealed sources (Eckert & Ziegler Model PHI-0119)</p> <p>C. Sealed sources (Siemens Model CS-6-14)</p> <p>D. Sealed sources (Eckert & Ziegler Model RV-137-200U)</p> <p>E. Any</p> <p>F. Any</p> <p>G. Any</p> <p>H. Any</p> <p>I. Any (Bound)</p> <p>J. Any (Bound)</p> <p>K. Any (Bound)</p> <p>L. Any (Bound)</p> <p>M. Any (Bound)</p> <p>N. Any (Bound)</p> <p>O. Any (Bound)</p> <p>P. Any (Bound)</p> <p>Q. Any (Bound)</p> <p>R. Any (Bound)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 240 millicuries</p> <p>B. 2 sources not to exceed 5 millicuries each</p> <p>C. 2 sources not to exceed 5 millicuries total</p> <p>D. 2 sources not to exceed 300 microcuries each; 600 microcuries total</p> <p>E. 50 millicuries</p> <p>F. 100 millicuries</p> <p>G. 50 millicuries</p> <p>H. 60 millicuries</p> <p>I. 50 millicuries</p> <p>J. 50 millicuries</p> <p>K. 50 millicuries</p> <p>L. 50 millicuries</p> <p>M. 50 millicuries</p> <p>N. 100 millicuries</p> <p>O. 100 millicuries</p> <p>P. 150 millicuries</p> <p>Q. 100 millicuries</p> <p>R. 20 millicuries</p>

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
21-32816-01Docket or Reference Number
030-38386

Amendment No. 11

9. Authorized use:

- A. and E. through R. For research and development as defined in 10 CFR 30.4 in rodents.
- B. through D. For instrument calibration.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 800 Technology Drive, Ann Arbor, Michigan.
11. Licensed material shall be used only by, or under the supervision of Patrick McConville, Ph.D., Deanne Lister, B.Sc, and **Kevin Guley**.
12. The Radiation Safety Officer (RSO) for this license is Catherine M. Anderko, M.S.
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 NRC under 10 CFR 32.210 or by an Agreement State.
- 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 NRC 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 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.
- E. Tests for leakage and/or contamination shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services. In addition, the licensee is authorized to collect leak test samples but not perform the analysis: analysis of leak samples must be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
- F. Records of leak tests results shall be kept in units of microcuries and shall be maintained for three years.

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14. Sealed sources containing licensed material shall not be opened.
15. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
17. Licensed material shall not be used in or on humans.
18. Experimental animals or the products from experimental animals that have been administered licensed materials shall not be used for human consumption.
19. 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.

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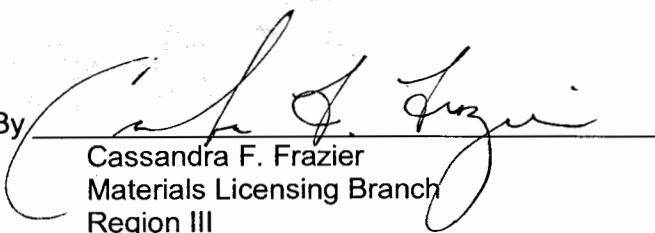
20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are 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 (with attachment) (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)
- M. Letter dated **February 10, 2016** (ML16041A492)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAR 30 2016

By


Cassandra F. Frazier
Materials Licensing Branch
Region III