

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 37

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 style="text-align: center;">Licensee</p> <p>1. MPI Research, Inc.</p> <p>2. 54943 North Main Street Mattawan, MI 49071</p>	<p>In accordance with letter dated November 9, 2015,</p> <p>3. License number 21-11315-02 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date June 30, 2024</p> <hr/> <p>5. Docket No. 030-08546 Reference No.</p>
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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
A. Any byproduct material with Atomic Numbers between 1-83, inclusive, with a half-life less than or equal to 120 days, except as specified below	A. Any	A. 50 millicuries per radionuclide with a total possession limit of 500 millicuries
B. Fluorine-18	B. Any	B. 10 curies
C. Carbon-11	C. Any	C. 5 curies
D. Nitrogen-13	D. Any	D. 1 curie
E. Oxygen-15	E. Any	E. 2 curies
F. Zirconium-89	F. Any	F. 2 curies
G. Iodine-124	G. Non-volatile	G. 2 curies
H. Iodine-124	H. Volatile	H. 1 curie
I. Iodine-125	I. Non-volatile	I. 1 curie
J. Iodine-125	J. Volatile	J. 350 millicuries
K. Copper-64	K. Any	K. 100 millicuries
L. Indium-111	L. Any	L. 250 millicuries
M. Hydrogen-3	M. Any	M. 500 millicuries
N. Carbon-14	N. Any	N. 890 millicuries
O. Calcium-45	O. Any	O. 5 millicuries
P. Radium-223	P. Any	P. 50 millicuries

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Q. Thorium-227	Q. Any	Q. 50 millicuries
R. Actinium-225	R. Any	R. 100 millicuries
S. Rhenium-186	S. Any	S. 250 millicuries
T. Molybdenum-99	T. Any	T. 32 curies
U. Technetium-99m	U. Any	U. 32 curies
V. Cobalt-57	V. Sealed sources (Eckert & Ziegler Isotope Products d/b/a IPL, Model 1911, UPET Series, International Isotopes, Idaho, Inc., Model BM06E Series and BM06S Series, IPL Model USM Series and 374 Series)	V. 15 millicuries total (10 millicuries per source for the model 1911 Series, UPET Series and USM Series, and 10 microcuries per source for the 374 series)
W. Germanium-68	W. Sealed sources (Eckert & Ziegler Isotope Products d/b/a IPL, Model 1911, UPET Series for the Germanium-68/Gallium-68, Siemens Medical Solutions USA, Inc., Molecular Imaging, Model LS, International Isotopes Idaho, Inc., Model BM06E and BM06S, IPL USM Series and 374 Series)	W. 5 millicuries total (0.5 millicuries per source for Model No. BM06E Series and BM06S Series, 10 microcuries per source for Model No. 374 Series)
X. Americium-241	X. Calibration or reference sources (Eckert & Ziegler Analytics, Model AM1-EAB-FP)	X. No single source to exceed 0.054 microcuries. Total activity not to exceed 0.162 microcuries
Y. Cesium-137	Y. Sealed sources (Eckert & Ziegler Analytics, Model GF-137-D)	Y. 1 millicurie
Z. Cesium-137	Z. Sealed sources (Isotope Products Laboratories, Inc. Model RV-XXX)	Z. 250 microcuries
AA. Germanium-68	AA. Sealed sources (Sanders Medical Products Model PET-180/0.8)	AA. No single source to exceed 1.5 millicuries. Total activity not to exceed 5 millicuries
BB. Iodine-123	BB. Non-volatile	BB. 2 curies
CC. Iodine-123	CC. Volatile	CC. 1 curie

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9. Authorized use:

A. through **W. and BB., CC.** For research and research and development as defined in 10 CFR 30.4, including animal studies and in-vitro studies.

X. and Y. For instrument calibration.

Z. and AA. For PET scanner calibration.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 54943 North Main Street, Mattawan, Michigan.
11. The Radiation Safety Officer (RSO) for this license is Richard D. Granberg, CHP.
12. Licensed material is only authorized for use by, or under the supervision of, individuals designated by the Radiation Safety Officer.
13. Licensed material shall not be used in or on human beings.
14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
15. Experimental animals, or the products from experimental animals that have been administered licensed materials, shall not be used for human consumption.
16. This license does not authorize commercial distribution of licensed material.
17.
 - 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 under equivalent regulations of an Agreement State
 - B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
 - C. 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 under equivalent regulations of an Agreement State, prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested and the test results received.
 - D. 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 thirty days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than ten microcuries of alpha-emitting material.

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- E. Sealed sources need not be tested if they are not designed to emit alpha particles, 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.
- F. 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.
- G. The licensee is authorized to collect leak test samples for analysis by the device manufacturer. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
- H. Records of leak test results shall be kept in units of microcuries and shall be maintained for three years.
18. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by U.S. Nuclear Regulatory Commission.
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
19. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
20. The licensee shall conduct a physical inventory every six months to account for all sources and/or devices received and possessed under the license.
21. 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, byproduct material shall be surveyed at the container surface with the appropriate meter 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 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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22. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
23. 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 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 December 20, 2013 (ML13360A321) excluding SDR sheets
 - B. Letter dated December 4, 2013 (ML13339A988)
 - C. Letter dated January 15, 2014 (ML14027A388)
 - D. Letter dated February 17, 2014 (ML14050A441)
 - E. Letter dated February 21, 2014 (ML14056A230)
 - F. Letter dated April 28, 2014 (ML14120A163) excluding Attachment 6, RSC Training and Experience
 - G. Letter dated April 28, 2014 (ML14120A167) excluding the MediSmarts Radiation Monitoring System Operating Manual
 - H. Letter dated June 16, 2014 (ML14169A270)
 - I. Letter dated September 8, 2014 (ML14252A338)
 - J. Letter dated September 10, 2014 (ML14267A273)
 - K. Letter dated March 6, 2015 (ML15071A381)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date FEB 16 2016

By


Cassandra F. Frazier
Materials Licensing Branch
Region III