

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 1. Karmanos Cancer Center 2. 4100 John R St. Mail Code GE00RO Detroit, MI 48201		In accordance with letter dated October 28, 2019. 3. License number: 21-03298-06 is amended in its entirety to read as follows:	4. Expiration Date: July 31, 2022 5. Docket No.: 030-38328 Reference No.:
6. Byproduct, source, and/or special nuclear material A. Fluorine-18	7. Chemical and/or physical form A. Any	8. Maximum amount that licensee may possess at any one time under this license A. 40 curies total	9. Authorized use A. (1) For production, possession, or handling of radiochemicals for transfer to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State. (2) For packaging and distribution of produced radiochemicals to persons authorized to receive licensed materials pursuant to the terms and conditions of specific licenses issued by the U. S. Nuclear Regulatory Commission or Agreement States. This should not be distributed as a radiopharmaceutical or radioactive drug. (3) For research and development as defined in 10 CFR 30.4.

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21-03298-06

Amendment No. 6

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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 |
| B. Carbon-11 | B. Any | B. 8 curies total | B. Same as 9.A. |
| C. Nitrogen-13 | C. Any | C. 8 curies total | C. Same as 9.A. |
| D. Oxygen-15 | D. Any | D. 8 curies total | D. Same as 9.A. |
| E. Any byproduct material with Atomic Numbers 1 through 83 | E. Incidentally Activated Products | E. 1 curie total | E. For possession and storage of byproduct materials incidental to radionuclide production. |
| F. Iodine-124 | F. Any | F. 50 millicuries total | F. Same as 9.A. |

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 3901 Beaubien Blvd., Detroit, Michigan, 48201.
11. The Radiation Safety Officer (RSO) for this license is Thomas J. Mangner, Ph.D.
12. Licensed material shall be used by, or under the supervision of, Thomas J. Mangner, Ph.D.
13. This license does not authorize distribution pursuant to 32.72 or 32.74; to persons exempt from licensing; or to general licensees.
14. 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.

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- 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. 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.
- F. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for 3 years.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
16. 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.

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17. 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.
18. The licensee shall provide acceptable decommissioning financial assurance (DFA) as required by 10 CFR Part 30, Section 30.35. The licensee shall submit DFA progress reports to the U.S. Nuclear Regulatory Commission, Region III, Attention: Chief, Nuclear Materials Licensing Branch, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532 to update the NRC on the status of their DFA. The licensee shall submit DFA progress reports every 30 days until such time that the DFA is submitted to the NRC for review. If the NRC determines that the DFA is not acceptable, the licensee shall continue to submit DFA progress reports every 30 days until an acceptable DFA is provided to the NRC.
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 July 11, 2010 (ML102080612)
 - B. Letter dated March 23, 2012 (ML12090A396)
 - C. Letter dated June 22, 2012 (ML12177A382)

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- D. Letter dated June 10, 2014 Item 1 re: Room G108 transfer (ML14162A358)
E. Letter dated July 31, 2014 Item 1 re: Room G108 transfer (ML14251A560)
F. Letter dated November 11, 2014 (ML14317A769)
G. Letter dated February 16, 2015 (ML15049A594)
H. Letter dated July 10, 2017 (ML17201Q133)
I. Letter dated October 28, 2019 (ML19323C779)
J. Letter dated January 2, 2020 (ML20009D107)
K. Letter dated January 13, 2020 (ML20014E725)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____

FEB 03 2020

By: _____

Cassandra F. Frazier
Region 3