

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

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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, 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	
1. Lakeview Diagnostic 2. 36211 Jefferson Avenue Harrison Township, MI 48045	3. License number 21-32817-01MD 4. Expiration date May 31, 2021 5. Docket No. 030-38442 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, except as listed below, excluding radioactive drugs for Positron Emission Tomography:	A. Any	A. 100 millicuries per radionuclide and 1 curie total
B. Molybdenum-99	B. Any	B. 200 curies
C. Technetium-99m	C. Any	C. 200 curies
D. Iodine-131	D. Any	D. 3 curies
E. Xenon-133	E. Any	E. 2 curies
F. Any byproduct material listed in 10 CFR 31.11 (a)	F. Prepackaged units for <u>in vitro</u> diagnostic test kits	F. 20 millicuries
G. Any byproduct material authorized under 10 CFR 35.65(a)	G. Sealed sources	G. 200 millicuries
H. Uranium (depleted in the isotope Uranium 235)	H. Metal	H. 600 kilograms
I. Iodine-123	I. Any	I. 50 millicuries

Authorized use:

A. through E. and I.

Preparation and distribution of radioactive drugs including distribution of iodine-131 and xenon-133 and redistribution of used and unused molybdenum-99/technetium -99m generators to authorized recipients in accordance with 10 CFR 32.72.

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- F. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged.
- 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 to authorized recipients and to authorized recipients for non-medical use
- H. Shielding for molybdenum-99/technetium-99m generators.

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities located at 36211 Jefferson Avenue, Harrison Township, Michigan.
- 11. Licensed material shall be used by, or under the supervision of:
 - A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2) and (3), or
 - B. Authorized nuclear pharmacists: David W. Schmitt, R.Ph., Michael Grawburg, R.Ph. and Amanda M. Miller, Pharm.D.
- 12. The Radiation Safety Officer for this license is David W. Schmitt, R.Ph.
- 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.
- C. Sealed sources need not be leak 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.

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- D. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie 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. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Lisle, Illinois 60532, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.
- G. Tests for leakage and/or contamination shall be performed by the licensee or other 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 for analysis 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 3 years.
14. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
15. The licensee shall conduct a physical inventory every six months, or at other intervals approved by NRC, to account for all sources and/or devices received and possessed under the license.
16. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
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, 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. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal. **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 is authorized to retrieve, receive and dispose of radioactive waste from its customers, limited to radiopharmacy supplied syringes and vials and their contents.
19. 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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20. This license does not authorize distribution to persons exempt from licensing.
21. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from NRC before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.
22. 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 27, 2010 (with attachments, excluding all references to Hazmat and DOT training materials, sample bill of lading, and bar codes information); and,
- B. Letters dated December 27, 2010, April 18, 2011 (with attachments) and April 21, 2011.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

MAY 23 2011

Date _____

By _____

Colleen Carol Casey
Colleen Carol Casey
Materials Licensing Branch
Region III