

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. Essential Isotopes 2. 1513 Research Park Dr. Columbia, MO 65211		In accordance with letter dated July 30, 2019. 3. License number: 24-32762-02 is amended in its entirety to read as follows:	4. Expiration Date: August 31, 2021 5. Docket No.: 030-38132 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. 20 curies total	9. Authorized use A. (1) For production, possession, or handling of radiochemicals for transfer to persons authorized to receive the licensed material in accordance with the terms and conditions of a specific license issued by the U.S. NRC or an Agreement State. (2) For packaging and distribution of produced radiochemicals to persons authorized to receive licensed materials in accordance with the terms and conditions of specific licenses issued by the U.S. NRC or Agreement States. This material should not be distributed as a radiopharmaceutical or radioactive drug.

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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. 2 curies total	B. Same as Subitem No. 9.A.
C. Nitrogen-13	C. Any	C. 2 curies total	C. Same as Subitem No. 9.A.
D. Oxygen-15	D. Any	D. 1 curie total	D. Same as Subitem No. 9.A.
E. Indium-111	E. Any	E. 100 millicuries total	E. Same as Subitem No. 9.A.
F. Copper-64	F. Any	F. 1 curie total	F. Same as Subitem No. 9.A.
G. Gallium-68	G. Any	G. 200 millicuries total	G. Same as Subitem No. 9.A.
H. Any byproduct material with Atomic Numbers 1 through 83	H. Incidentally Activated Products	H. 20 millicuries per radionuclide; 1 curie total	H. For possession and storage of byproduct materials incidental to radionuclide production.
I. Cobalt-60	I. Incidentally Activated Products	I. 50 millicuries total	I. Same as Subitem No. 9.H.
J. Manganese-54	J. Incidentally Activated Products	J. 100 millicuries total	J. Same as Subitem No. 9.H.
K. Cadmium-109	K. Incidentally Activated Products	K. 100 millicuries total	K. Same as Subitem No. 9.H.
L. Cobalt-57	L. Sealed Sources	L. 10 millicuries total	L. For use in calibration and checking of the licensee's instruments.
M. Cesium-137	M. Sealed Sources	M. 300 microcuries total	M. Same as Subitem No. 9.L.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 1513 Research Park Dr., Columbia, Missouri, 65211.

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11. The Radiation Safety Officer (RSO) for this license is Ronald Dobey, CHP.

12. Licensed material shall only be used by, or under the supervision of authorized individuals as noted below:

Authorized Users

Andrew Borrok, R.Ph.

Scott C. Brower, R.Ph.

Nicholas E. Roberts, R.Ph., Pharm.D.

Lawrence Saale

Marc D. Weichelt, R.Ph.

Jon Woodward, R.Ph.

Material and Use

All

All

All

All

All

All

13. This license does not authorize commercial distribution of licensed material pursuant to 10 CFR 32.72 or 10 CFR 32.74 to persons generally licensed pursuant to 10 CFR Part 31 or equivalent regulations of any Agreement State; or to persons exempt from licensing pursuant to 10 CFR 30.14 through 10 CFR 30.21 inclusive, or equivalent regulations of any Agreement State.

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.

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.

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- C. 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 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
- D. 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.
- E. 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.
- F. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- G. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for 3 years.
15. Sealed sources 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 Rd., Ste. 210, Lisle, IL 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 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 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 August 10, 2009 (ML092300628)

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- B. Letter dated April 15, 2010 (ML112500044)
C. Letter dated October 22, 2010 (ML112500041)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: OCT 28 2019By: B. A. ParkerBryan A. Parker
Region 3