

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.

<p>Licensee</p> <p>1. Ionetix Corporation</p> <p>2. 3130 Sovereign Dr. Lansing, MI 48911</p>		<p>In accordance with letter dated November 03, 2021,</p>	<p>4. Expiration Date: July 31, 2027</p>
		<p>3. License No.: 04-35412-01 is amended in its entirety to read as follows:</p>	<p>5. Docket No.: 030-39033 Reference No.:</p>
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with Atomic Numbers 1 through 83</p> <p>B. Nitrogen-13</p> <p>C. Fluorine-18</p>	<p>7. Chemical and/or physical form</p> <p>A. Incidentally Activated Products</p> <p>B. Any</p> <p>C. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 200 millicuries per source and 800 millicuries total</p> <p>B. 200 millicuries total</p> <p>C. 1.5 curies total</p>	<p>9. Authorized use</p> <p>A. For possession and storage of byproduct materials incidental to radionuclide production resulting from the manufacture and operation of cyclotrons.</p> <p>B. Research and development, as defined in 10 CFR 30.4, of cyclotron and targetry performance tests. Testing of production cyclotrons both in-house and at customer locations. Servicing of cyclotrons at customer locations as described in letter dated December 31, 2018 (ML19002A549).</p> <p>C. Same as Subitem No. 9.B.</p>



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SUPPLEMENTARY SHEET**

License No.:
04-35412-01

Docket or Reference No.:
030-39033

Amendment No. 9

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
D. Cesium-137	D. Sealed Sources (Eckert & Ziegler Isotopes Products, Model GF-137-R3 and RV-137-200U)	D. 1 millicurie total	D. For possession and storage of calibration sealed sources prior to redistribution to Ionetix manufacturing facilities.
E. Astatine-210	E. Any	E. 200 millicuries total	E. Research and development, as defined in 10 CFR 30.4, of cyclotron and targetry performance tests, with in-house testing only.
F. Astatine-211	F. Any	F. 500 millicuries total	F. Same as Subitem No. 9.E.
G. Gallium-68	G. Any	G. 250 millicuries total	G. Same as Subitem No. 9.B.

CONDITIONS

10. Licensed material shall be used or stored only at the licensee's facilities located at 3130 Sovereign Dr., Lansing, Michigan, 48911 and may be used at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate state regulatory agency.

11. A. The Radiation Safety Officer (RSO) for this license is Eric L. Mollon.

B. The Alternate RSO for this license is Michael A. Levy, R.Ph.

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12. Licensed material shall only be used by, or under the supervision of:

Gary Horner
Jay Paquette
Xiaoyu Wu, Ph.D.

Michael A. Levy, R.Ph.
Chris Shreves

Eric L. Mollon
John Vincent, Ph.D.

13. The licensee shall not use the licensed material in or on humans.

14. 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.

15. 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 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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16. 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 February 22, 2017 (ML17061A694)
- B. Letter dated June 22, 2017 (ML17181A509)
- C. Letter dated October 1, 2018 (ML18277A101)
- D. Letter dated December 31, 2018 (ML19002A549)
- E. Letter dated March 6, 2019 (ML19065A259)
- F. Letter dated June 14, 2020 (ML20169A265)
- G. Letter dated April 29, 2021 excluding Item 3 (ML21123A082)
- H. Letter dated July 14, 2021 (ML21196A001)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: November 8, 2021By: _____
Sara A. Forster
Region III