

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. Covance Laboratories, Inc.</p> <p>2. 8211 Scicor Dr. Indianapolis, IN 46214</p>		<p>In accordance with letter dated April 08, 2021,</p>	<p>4. Expiration Date: June 30, 2034</p>
		<p>3. License No.: 13-32713-01 is amended in its entirety to read as follows:</p>	<p>5. Docket No.: 030-37840 Reference No.:</p>
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with Atomic Numbers 3 through 83</p> <p>B. Carbon-14</p> <p>C. Hydrogen-3</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</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. 50 millicuries per radionuclide and 200 millicuries total</p> <p>B. 500 millicuries total</p> <p>C. 500 millicuries total</p>	<p>9. Authorized use</p> <p>A. For research and development as defined in 10 CFR 30.4, including animal studies and preparation of drug formulations containing radiolabeled compounds. The licensee may transfer (on a non-commercial basis) radiolabeled drug compounds (for medical use in human research subjects) to persons authorized to receive the material pursuant to the terms and conditions of a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.</p> <p>B. Same as Item 9.A.</p> <p>C. Same as Item 9.A.</p>



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 13-32713-01

Docket or Reference No.:
030-37840

Amendment No. 10

- | | | | |
|---|----------------------------------|--|---|
| 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. Iodine-125 | D. Non-volatile | D. 50 millicuries total | D. Same as Item 9.A. |
| E. Phosphorus-33 | E. Any | E. 100 millicuries total | E. Same as Item 9.A. |
| F. Nickel-63 | F. Foils or plated sources | F. 150 millicuries total | F. For use in gas chromatography devices for sample analysis. |



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 13-32713-01

Docket or Reference No.:
030-37840

Amendment No. 10

CONDITIONS

10. A. Licensed material shall be used or stored at the licensee's facilities located at 671 S Meridian Rd., Greenfield, IN 46140.
- B. Licensed material listed in Item No. 6.A. shall be used or stored at the licensee's facilities located at 8211 Scicor Dr., Indianapolis, IN 46214.
11. The Radiation Safety Officer (RSO) for this license is Brian Davidson.
12. Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.
13. 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 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. 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 3 months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 13-32713-01

Docket or Reference No.:
030-37840

Amendment No. 10

- F. 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.
- G. 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.
- H. Tests for leakage and/or contamination 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.
- I. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for 3 years.
14. 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.
15. Sealed sources, foil sources, or detector cells containing licensed material shall not be opened or sources removed from source holders, or foil sources removed from detector cells by the licensee, except as specifically authorized.
16. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 13-32713-01

Docket or Reference No.:
030-37840

Amendment No. 10

17. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
18. 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.
19. Experimental animals, or the products from experimental animals, that have been administered licensed material shall not be used for human or animal consumption.
20. In addition to the possession limits in Item 8, as specified in 10 CFR 30.35(d), the licensee shall further restrict the possession of unsealed byproduct material to quantities less than or equal to 10^4 of the applicable limits in Appendix B of 10 CFR Part 30.
21. The licensee shall not use the licensed material in or on humans.

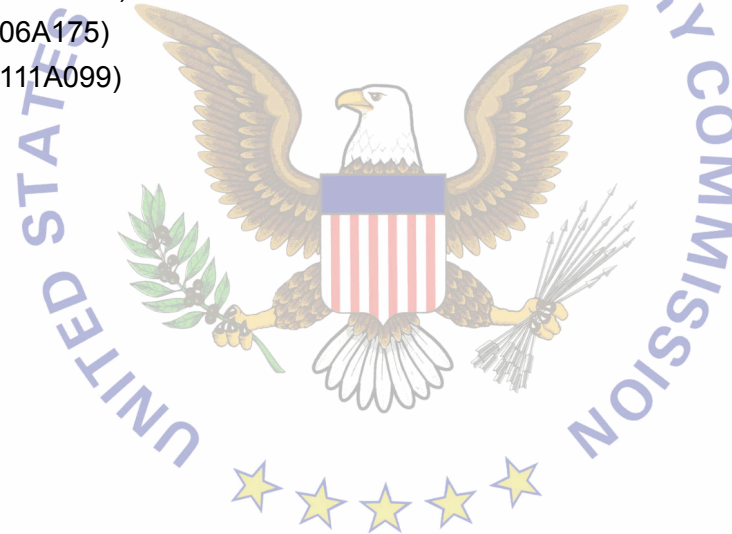
**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 13-32713-01

Docket or Reference No.:
030-37840

Amendment No. 10

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. This license condition applies only to those statements, representations, and 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 impose on the licensee requirements that are more restrictive than or in addition to the regulations.
- A. Application dated December 18, 2018 (ML18360A581)
 - B. Letter dated April 15, 2019 (ML19105B233)
 - C. Letter dated April 8, 2021 (ML21106A175)
 - D. Letter dated April 20, 2021 (ML21111A099)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: April 25, 2021By: _____
Cassandra F. Frazier
Region 3