

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 style="text-align: center;">Licensee</p> <p>1. Department of Health & Human Services Food and Drug Administration</p> <p>2. Harvey W. Wiley Bldg. HFS-657 5001 Campus Drive College Park, MD 20740</p>		<p>In accordance with the letter dated December 17, 2020,</p>	<p>4. Expiration Date: December 31, 2025</p>
		<p>3. License No.: 19-30771-01 is amended in its entirety to read as follows:</p>	<p>5. Docket No.: 030-36120 Reference No.: 08-00482-03/03003917</p>
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen-3</p> <p>B. Carbon-14</p> <p>C. Phosphorus-32</p> <p>D. Phosphorus-33</p> <p>E. Sulfur-35</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 50 millicuries total</p> <p>B. 50 millicuries total</p> <p>C. 25 millicuries total</p> <p>D. 25 millicuries total</p> <p>E. 25 millicuries total</p>	<p>9. Authorized use</p> <p>A. For research and development as defined in 10 CFR 30.4, including animal studies</p> <p>B. For research and development as defined in 10 CFR 30.4, including animal studies</p> <p>C. For research and development as defined in 10 CFR 30.4, including animal studies</p> <p>D. For research and development as defined in 10 CFR 30.4, including animal studies</p> <p>E. For research and development as defined in 10 CFR 30.4, including animal studies</p>

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 19-30771-01

Docket or Reference No.:

030-36120

08-00482-03/03003917

Amendment No. 17

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

F. Chromium-51

F. Any

F. 25 millicuries total

F. For research and development as defined in 10 CFR 30.4, including animal studies

G. Iodine-125

G. Bonded to nonvolatile agent

G. 10 millicuries total

G. For research and development as defined in 10 CFR 30.4, including animal studies



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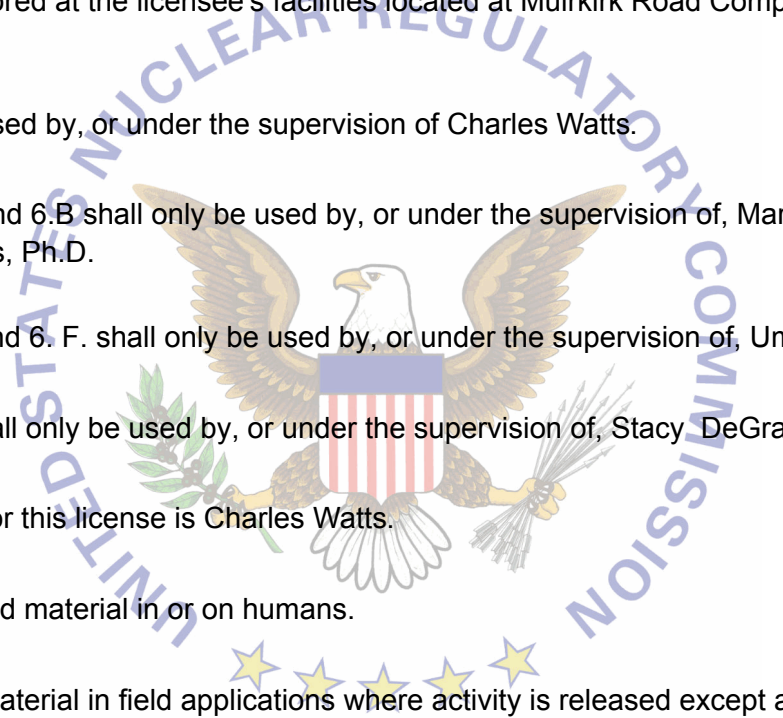
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CONDITIONS

10. Licensed material shall be used or stored at the licensee's facilities located at Muirkirk Road Complex, 8301-8501 Muirkirk Road, Laurel, Maryland.
 11.
 - A. Licensed material shall only be used by, or under the supervision of Charles Watts.
 - B. Licensed material in Items 6.A. and 6.B shall only be used by, or under the supervision of, Margaret Kraeling, Pak Chu, Ph.D., Jeff Yourick, Ph.D., or Michael Meyers, Ph.D.
 - C. Licensed material in items 6.A. and 6. F. shall only be used by, or under the supervision of, Uma Babu, Ph.D.
 - D. Licensed material in item 6.A. shall only be used by, or under the supervision of, Stacy DeGrasse, Ph.D.
 12. The Radiation Safety Officer (RSO) for this license is Charles Watts.
 13. The licensee shall not use the licensed material in or on humans.
 14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
 15. Experimental animals, or the products from experimental animals, that have been administered licensed material shall not be used for human or animal consumption.
 16. 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:
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- 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.
17. 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. Letter dated August 24, 2015 (ML15267A695)
- B. Letter dated October 30, 2015 (ML15310A403)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: March 12, 2021By: _____
Elizabeth Ullrich
Region 1