

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 align="center">Licensee</p> <p>1. US Department of Health and Human Services Food and Drug Administration</p>	<p>In accordance with application dated July 22, 2018.</p>	<p>4. Expiration Date: November 30, 2026</p>
<p>2. 109 Holton Street Public Health Service, FDA Winchester, MA 01890-1197</p>	<p>3. License number: 20-08361-01 is amended in its entirety to read as follows:</p>	<p>5. Docket No.: 030-04675 Reference No.: 04-09759-01;04-09763-01;05-09749-01;10-09754-01;19-09760-01;31-09753-02;31-28300-01;46-09750-01</p>

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|---|---|---|---|
| <p>6. Byproduct, source, and/or special nuclear material</p> | <p>7. Chemical and/or physical form</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> | <p>9. Authorized use</p> |
| <p>A. Any byproduct material with Atomic Numbers 1 through 83 with half-life less than or equal to 120 days</p> | <p>A. Any</p> | <p>A. 250 millicuries per radionuclide and 2 curies total</p> | <p>A. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments.</p> |
| <p>B. Any byproduct material with Atomic Numbers 1 through 83 with half-life greater than 120 days</p> | <p>B. Any</p> | <p>B. 10 millicuries per radionuclide and 1 curie total</p> | <p>B. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments.</p> |

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Amendment No. 45

Docket or Reference Number

030-04675

04-09759-01;04-09763-01;05-09749-01;1
0-09754-01;19-09760-01;31-09753-02;31
-28300-01;46-09750-01

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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 |
| C. Any byproduct material with Atomic Numbers 84 through 96 | C. Any | C. 1 millicurie per radionuclide and 5 millicuries total | C. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments. |
| D. Hydrogen-3 | D. Any | D. 10 curies total | D. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments. |
| E. Molybdenum-99 | E. Any | E. 50 curies total | E. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments. |
| F. Technetium-99m | F. Any | F. 50 curies total | F. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments. |
| G. Iodine-131 | G. Any | G. 3 curies total | G. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments. |

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-28300-01;46-09750-016. 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

H. Xenon-133

H. Any

H. 1.5 curies total

H. For research and development as
defined in 10 CFR 30.4 and 70.4;
teaching and training of students;
instrument development; and calibration
and checking of the licensee's
instruments.

I. Samarium-153

I. Any

I. 2 curies total

I. For research and development as
defined in 10 CFR 30.4 and 70.4;
teaching and training of students;
instrument development; and calibration
and checking of the licensee's
instruments.

J. Thorium-228

J. Any

J. 500 microcuries total

J. For research and development as
defined in 10 CFR 30.4 and 70.4;
teaching and training of students;
instrument development; and calibration
and checking of the licensee's
instruments.

K. Thorium-229

K. Any

K. 50 microcuries total

K. For research and development as
defined in 10 CFR 30.4 and 70.4;
teaching and training of students;
instrument development; and calibration
and checking of the licensee's
instruments.

L. Thorium-230

L. Any

L. 500 microcuries total

L. For research and development as
defined in 10 CFR 30.4 and 70.4;
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instrument development; and calibration
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and/or special nuclear
material

M. Thorium-232

N. Uranium-232

O. Uranium-236

P. Uranium-237

Q. Uranium-238

7. Chemical and/or physical form

M. Any

N. Any

O. Any

P. Any

Q. Any

8. Maximum amount that licensee
may possess at any one time
under this license

M. 500 microcuries total

N. 100 microcuries total

O. 30 microcuries total

P. 3 microcuries total

Q. 5 microcuries total

9. Authorized use

M. For research and development as
defined in 10 CFR 30.4 and 70.4;
teaching and training of students;
instrument development; and calibration
and checking of the licensee's
instruments.N. For research and development as
defined in 10 CFR 30.4 and 70.4;
teaching and training of students;
instrument development; and calibration
and checking of the licensee's
instruments.O. For research and development as
defined in 10 CFR 30.4 and 70.4;
teaching and training of students;
instrument development; and calibration
and checking of the licensee's
instruments.P. For research and development as
defined in 10 CFR 30.4 and 70.4;
teaching and training of students;
instrument development; and calibration
and checking of the licensee's
instruments.Q. For research and development as
defined in 10 CFR 30.4 and 70.4;
teaching and training of students;
instrument development; and calibration
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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
R. Uranium- depleted in Uranium-235	R. Any	R. 10 kilograms total	R. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments.
S. Uranium (Natural)	S. Any	S. 20 kilograms total	S. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments.
T. Thorium	T. Any	T. 20 kilograms total	T. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments.
U. Uranium-233	U. Any	U. 400 microcuries total	U. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments.
V. Uranium-235	V. Any	V. 100 microcuries total	V. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments.

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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 |
| W. Plutonium-238 and/or Plutonium-239 | W. Any | W. 4 millicuries per radionuclide and 20 millicuries total | W. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments. |
| X. Nickel-63 | X. Sealed, Plated, or Foil Sources | X. 15 millicuries per source and 150 millicuries total | X. For research and development as defined in 10 CFR 30.4; sample analysis; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments. |
| Y. Americium-241 | Y. Sealed Sources (Isotope Products Laboratory, Model 553-61) | Y. 20 microcuries total | Y. For possession and storage only with intent to dispose. |
| Z. Nickel-63 | Z. Sealed, Plated, or Foil Sources (Eckert & Ziegler/Isotope Products Laboratory, Model NER-004 or NER-004P) | Z. 15 millicuries per source and 15 millicuries total | Z. For use in Excellims RA4100 Electrospray Ionization High Resolution Ion Mobility Spectrometer for sample analysis. |
| AA. Hydrogen-3 | AA. Any | AA. 500 millicuries total | AA. For research and development as defined in 10 CFR 30.4 and 70.4; teaching and training of students; instrument development; and calibration and checking of the licensee's instruments. |

CONDITIONS

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10. A. Licensed material may be used or stored at the licensee's facilities located at Winchester Engineering and Analytical Center, 1090 Holton Street, Winchester, Massachusetts 01890-1197. Licensed material in the form of sealed sources may be used at temporary job sites 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.
- B. Licensed material listed in Subitem No. 6.Z. may be used at the licensee's facilities located at the Center for Drug Evaluation and Research, 645 South Newstead Avenue, St. Louis, Missouri 63101
- C. Licensed material listed in Subitem No. 6.AA. may be used at the licensee's facilities located at the Northeast Regional Laboratory, 158-15 Liberty Avenue, Jamaica, New York 11433.
11. Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the licensee's Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.
12. The Radiation Safety Officer (RSO) for this license is Elon Malkin, Ph.D.
13. The licensee shall not use licensed material in or on human beings.
14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
15. 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.

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- 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 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.
- D. 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.
- E. 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.
- F. The leak test shall be capable of detecting the presence of 0.005 microcuries (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcuries (185 becquerels) or more of a removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with Appendix D of 10 CFR Part 20, and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- G. Tests for leakage and/or contamination, including leak test sample collection and analysis, 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.
- H. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for 3 years.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

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17. 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.
18. 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.
19. A. Detector cells containing a titanium tritide foil or scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations from an Agreement State.
- B. When in use, detector cells containing a titanium tritide foil or scandium tritide foil shall be vented to the outside.
20. 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.

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21. Notwithstanding the requirements of License Condition 22, the licensee is authorized to make program changes and changes to procedures specifically identified in the application dated May 17, 2016, and the letter dated September 8, 2016, which were previously approved by the U.S. Nuclear Regulatory Commission and incorporated into the license without prior Commission approval as long as:
- A. The proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation;
 - B. The revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program;
 - C. The licensee's staff is trained in the revised procedures prior to implementation; and
 - D. The licensee's audit program evaluates the effectiveness of the change and its implementation.

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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 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 May 17, 2016 (ML16159A342)
- B. Letter dated September 8, 2016 (ML16257A405)
- C. Application dated July 2, 2018 (ML18194A928)

Date: September 19, 2018

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

By: Michael Reichard
Region 1