

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. Zevacor Molecular 2. 14395 Bergen Boulevard Noblesville, IN 46060		In accordance with letter dated May 22, 2018, 3. License No.: 13-35179-03 is amended in its entirety to read as follows:	4. Expiration Date: April 30, 2026 5. Docket No.: 030-38903 Reference No.:
6. Byproduct, source, and/or special nuclear material A. Any byproduct material with Atomic Nos. 1 through 83	7. Chemical and/or physical form A. Any	8. Maximum amount that licensee may possess at any one time under this license A. 2 curies total	9. Authorized use A. (1) For production, possession, or handling of radiochemicals and sealed sources for transfer to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the NRC or an Agreement State. (2) Research and development as defined in 10 CFR 30.4. (3) For packaging and distribution of produced radiochemicals and sealed sources to persons authorized to receive licensed materials pursuant to the terms and conditions of a specific license issued by the NRC or an Agreement State. This should not be distributed as a radiopharmaceutical or radioactive drug.

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SUPPLEMENTARY SHEET**License No.
13-35179-03

Amendment No. 2

Docket or Reference No.
030-38903

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. Indium-111	B. Any	B. 10 curies total	B. Same as Item 9.A.
C. Thallium-201	C. Any	C. 7.5 curies total	C. Same as Item 9.A.
D. Lead-202	D. Any	D. 90 curies total	D. Same as Item 9.A.
E. Gallium-67	E. Any	E. 9.9 curies total	E. Same as Item 9.A.
F. Gallium-68	F. Any	F. 50 curies total	F. Same as Item 9.A.
G. Cobalt-57	G. Any	G. 10 curies total	G. Same as Item 9.A.
H. Cobalt-58	H. Any	H. 120 curies total	H. Same as Item 9.A.
I. Germanium-68	I. Any	I. 50 curies total	I. Same as Item 9.A.
J. Zinc-62	J. Any	J. 100 curies total	J. Same as Item 9.A.
K. Zinc-65	K. Any	K. 2000 curies total	K. Same as Item 9.A.
L. Copper-62	L. Any	L. 100 curies total	L. Same as Item 9.A.
M. Copper-64	M. Any	M. 100 curies total	M. Same as Item 9.A.
N. Copper-67	N. Any	N. 5 curies total	N. Same as Item 9.A.
O. Rubidium-81	O. Any	O. 30 curies total	O. Same as Item 9.A.
P. Rubidium-82	P. Any	P. 35 curies total	P. Same as Item 9.A.
Q. Strontium-82	Q. Any	Q. 35 curies total	Q. Same as Item 9.A.
R. Strontium-83	R. Any	R. 35 curies total	R. Same as Item 9.A.

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S. Strontium-85	S. Any	S. 35 curies total	S. Same as Item 9.A.
T. Fluorine-18	T. Any	T. 300 curies total	T. Same as Item 9.A.
U. Nitrogen-13	U. Any	U. 30 curies total	U. Same as Item 9.A.
V. Carbon-11	V. Any	V. 16 curies total	V. Same as Item 9.A.
W. Oxygen-15	W. Any	W. 1 curie total	W. Same as Item 9.A.
X. Zirconium-89	X. Any	X. 20 curies total	X. Same as Item 9.A.
Y. Europium-154	Y. Incidentally Activated Products	Y. 100 millicuries total	Y. For possession and storage of byproduct materials incidental to radionuclide production.
Z. Scandium-46	Z. Incidentally Activated Products	Z. 100 millicuries total	Z. For possession and storage of byproduct materials incidental to radionuclide production.
AA. Iron-59	AA. Incidentally Activated Products	AA. 100 millicuries total	AA. For possession and storage of byproduct materials incidental to radionuclide production.
AB. Cobalt-60	AB. Incidentally Activated Products	AB. 100 millicuries total	AB. For possession and storage of byproduct materials incidental to radionuclide production.
AC. Zinc-65	AC. Incidentally Activated Products	AC. 100 millicuries total	AC. For possession and storage of byproduct materials incidental to radionuclide production.
AD. Cesium-134	AD. Incidentally Activated Products	AD. 100 millicuries total	AD. For possession and storage of byproduct materials incidental to radionuclide production.

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AE. Europium-152	AE. Incidentally Activated Products	AE. 100 millicuries total	AE. For possession and storage of byproduct materials incidental to radionuclide production.
AF. Manganese-54	AF. Incidentally Activated Products	AF. 100 millicuries total	AF. For possession and storage of byproduct materials incidental to radionuclide production.
AG. Uranium- depleted in Uranium-235	AG. Metal	AG. 5000 kilograms total	AG. Shielding for generators
AH. Cesium-137	AH. Sealed sources (International Isotopes Idaho, Inc., Model BM06E-37)	AH. 0.212 millicuries total	AH. Calibration and checking of the licensee's instruments.
AI. Cobalt-57	AI. Sealed sources (International Isotopes Idaho, Inc., Model BM06E-57)	AI. 5.16 millicuries total	AI. Calibration and checking of the licensee's instruments.
AJ. Barium-133	AJ. Sealed sources (International Isotopes Idaho, Inc., Model BM06E-33)	AJ. 0.262 millicuries total	AJ. Calibration and checking of the licensee's instruments.
AK. Germanium-68	AK. Sealed sources (International Isotopes Idaho, Inc., Model BM06E-68)	AK. 0.631 millicuries total	AK. Calibration and checking of the licensee's instruments.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 14395 Bergen Boulevard, Noblesville, Indiana, 46060.
11. The Radiation Safety Officer (RSO) for this license is Matthew Trusner.

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

Authorized Users

Scott Chance, PharmD

Maxim Kiselev, Ph.D.

John Zehner, R.Ph.

Material and Use

All

All

All

13. This license does not authorize distribution, pursuant to 32.72 or 32.74, to persons exempt from licensing or to general licensees.

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 NRC under 10 CFR 32.210 or by an Agreement State
- 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 NRC under 10 CFR 32.210 or by an Agreement State prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested and the test results received.
- C. 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.
- D. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) 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.
- E. 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.

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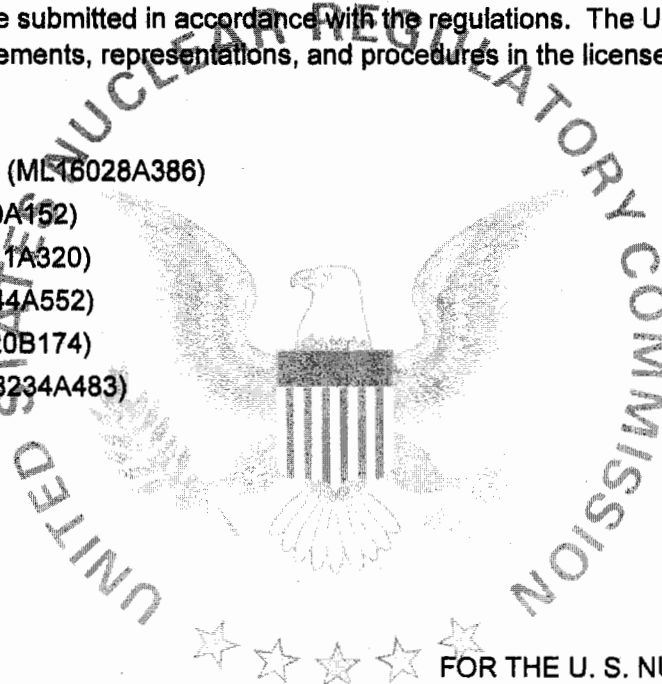
- F. Records of leak tests results shall be kept in units of microcuries and shall be maintained for three years.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.
17. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from NRC before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant 10 CFR 32.210 or by an Agreement State.
18. The licensee is authorized to hold radioactive material with a physical half-life of less than 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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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 January 25, 2016 (ML16028A386)
- B. Letter dated April 7, 2016 (ML16110A152)
- C. Letter dated April 19, 2016 (ML16111A320)
- D. Letter dated May 22, 2018 (ML18144A552)
- E. Letter dated July 31, 2018 (ML18220B174)
- F. Letter dated August 22, 2018 (ML18234A483)



FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Date: AUG 22 2018By: BAPBryan A. Parker
Region III