

U.S. NUCLEAR REGULATORY COMMISSION

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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, and 70, 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. Zevacor Molecular</p> <p>2. 14395 Bergen Boulevard Noblesville, IN 46060</p>	<p>3. License number 13-35179-03</p> <p>4. Expiration date April 30, 2026</p> <p>5. Docket No. 030-38903 Reference No.</p>
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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
A. Any byproduct material with atomic numbers 1 through 83	A. Any	A. 1 curie per nuclide, 2 curie total possession, except as noted.
B. Indium-111	B. Any	B. 10 curies
C. Thallium-201	C. Any	C. 7.5 curies
D. Lead-202	D. Any	D. 90 curies
E. Gallium-67	E. Any	E. 9.9 curies
F. Gallium-68	F. Any	F. 50 curies
G. Cobalt-57	G. Any	G. 10 curies
H. Cobalt-58	H. Any	H. 120 curies
I. Germanium-68	I. Any	I. 50 curies
J. Zinc-62	J. Any	J. 100 curies
K. Zinc-65	K. Any	K. 2000 curies
L. Copper-62	L. Any	L. 100 curies
M. Copper-64	M. Any	M. 100 curies
N. Copper-67	N. Any	N. 5 curies
O. Rubidium-81	O. Any	O. 30 curies
P. Rubidium-82	P. Any	P. 35 curies
Q. Strontium-82	Q. Any	Q. 35 curies
R. Strontium-85	R. Any	R. 35 curies
S. Fluorine-18	S. Any	S. 300 curies
T. Nitrogen-13	T. Any	T. 30 curies

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U. Carbon-11	U. Any	U. 16 curies
V. Oxygen-15	V. Any	V. 1 curie
W. Zirconium-89	W. Any	W. 20 curies
X. Europium-154	X. Incidentally activated isotopes	X. 100 millicuries
Y. Scandium-46	Y. Incidentally activated isotopes	Y. 100 millicuries
Z. Iron-59	Z. Incidentally activated isotopes	Z. 100 millicuries
AA. Cobalt-60	AA. Incidentally activated isotopes	AA. 100 millicuries
BB. Zinc-65	BB. Incidentally activated isotopes	BB. 100 millicuries
CC. Cesium-134	CC. Incidentally activated isotopes	CC. 100 millicuries
DD. Europium-152	DD. Incidentally activated isotopes	DD. 100 millicuries
EE. Manganese-54	EE. Incidentally activated isotopes	EE. 100 millicuries
FF. Depleted Uranium	FF. Metal	FF. 5000 kilograms
GG. Cesium-137	GG. Sealed source (RadQual model number BM06E-37)	GG. 0.212 millicurie
HH. Cobalt-57	HH. Sealed source (RadQual model number BM06E-57)	HH. 5.16 millicuries
II. Barium-133	II. Sealed source (RadQual model number BM06E-33)	II. 0.262 millicurie

9. Authorized use:

- A. through W. (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 U.S. Nuclear Regulatory Commission or an Agreement State.

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(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 specific licenses issued by the Nuclear Regulatory Commission or Agreement States. This should not be distributed as a radiopharmaceutical or radioactive drug.

X. through EE. For possession and storage of byproduct materials incidental to radionuclide production.

FF. Shielding for generators

GG. through II. Calibration and checking of the licensee's instruments.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 14395 Bergen Blvd., Noblesville, Indiana.
11. The Radiation Safety Officer for this license is John Zehner.
12. Licensed material shall be used by, or under the supervision of John Zehner, RPh, Scott Chance, PharmD, or Maxim Kiselev, PhD.
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.

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- 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.
- F. Records of leak tests results shall be kept in units of microcuries and shall be maintained for 3 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 to 10 CFR 31.210 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, byproduct material shall be surveyed at the container surface with the appropriate survey meter 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.
- B. A record of each 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.
19. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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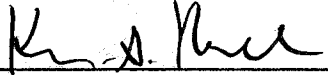
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20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear 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).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date OCT 17 2016

By



Kevin G. Null
Materials Licensing Branch
Region III