U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 3

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	In accordance with letter dated June 18, 2018,	4. Expiration Date: December 31, 2025
1. Zevacor Molecular		5. Docket No.: 030-38841 Reference No.:
2. 14395 Bergen Boulevard Noblesville, IN 46060	3. License No.: 13-35179-02 is amended in its entirety to read as follows:	

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
A. Any byproduct material with Atomic Nos. 1 through 83 with exceptions	A. Any	A. 100 millicuries per source and 1 curie total	A. For research and development in the pre-production of radiopharmaceuticals for testing, validation, and qualification of FDA regulated drug products for submission of data for drug protocols.
B. Molybdenum-99	B. Any	B. 300 curies total	B. Same as Item 9.A.
C. Technetium-99m	C. Any	C. 300 curies total	C. Same as Item 9.A.
D. Rubidium-82	D. Any	D. 2 curies total	D. Same as Item 9.A.
E. Strontium-82	E. Any	E. 2 curies total	E. Same as Item 9.A.
F. Strontium-85	F. Any	F. 500 millicuries total	F. Same as Item 9.A.
G. Indium-111	G. Any	G. 1 curie total	G. Same as Item 9.A.
H. Germanium-68	H. Any	H. 2 curies total	H. Same as Item 9.A.

MATERIALS LICENSE SUPPLEMENTARY SHEET

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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
I. Gallium-68	I. Any	I. 2 curies total	I. Same as Item 9.A.
J. Cesium-137	J. Sealed sources (International Isotopes Idaho, Inc., Model BM06E-37	J. 420 microcuries total	J. For use in calibration and checking of the licensee's instruments.
K. Cobalt-57	K. Sealed sources (International Isotopes Idaho, Inc., Model BM06E-57)	K. 10.6 millicuries total	K. Same as Item 9.J.
L. Barium-133	L. Sealed sources (International Isotopes Idaho, Inc., Model BM06E-33)	L. 525 microcuries total	L. Same as Item 9.J.

CONDITIONS

10. Licensed material shall 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.

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

Authorized Users	Material and Use
Scott D. Chance, PharmD	All
John Zehner, R.Ph.	All

13. Licensed material shall not be used in or on humans except as provided otherwise by specific condition of this license.

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14. The licensee shall not use licensed material in field applications where activity is release except as provided otherwise by specific condition of this license.

15. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

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. Records of inventories shall be maintained for three 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.

17. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.

18. 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.

19. 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 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 six 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 three 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.

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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 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.

G. Analysis of leak test samples and/or contamination shall be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. The licensee is authorized to collect leak test samples but not perform the analysis.

H. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for three years.

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.

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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.

21. 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 27, 2015 (ML15152A156)
B. Letter dated October 16, 2015 (ML15292A558)
C. Letter dated July 11, 2017 (ML17198A357)
D. Letter dated July 31, 2018 (re: new RSO) (ML18220B174)

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Date: AUG 22 2018

By: _____

Bryan A. Parker
Region III