

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		In accordance with letter dated October 31, 2016,	4. Expiration Date: April 30, 2026
2. 14395 Bergen Boulevard Noblesville, IN 46060		3. License No.: 13-35179-03 is amended in its entirety to read as follows:	5. Docket No.: 030-38903 Reference No.:
6. Byproduct, source, and/or special nuclear material A. Any byproduct material with Atomic Numbers 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

 License Number
13-35179-03

Amendment No. 1

 Docket or Reference Number
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

AA. Indium-111

AA. Any

AA. 10 curies total

AA. Same as Item 9.A.

AB. Thallium-201

AB. Any

AB. 7.5 curies total

AB. Same as Item 9.A.

AC. Lead-202

AC. Any

AC. 90 curies total

AC. Same as Item 9.A.

AD. Gallium-67

AD. Any

AD. 9.9 curies total

AD. Same as Item 9.A.

AE. Gallium-68

AE. Any

AE. 50 curies total

AE. Same as Item 9.A.

AF. Cobalt-57

AF. Any

AF. 10 curies total

AF. Same as Item 9.A.

AG. Cobalt-58

AG. Any

AG. 120 curies total

AG. Same as Item 9.A.

AH. Germanium-68

AH. Any

AH. 50 curies total

AH. Same as Item 9.A.

AI. Zinc-62

AI. Any

AI. 100 curies total

AI. Same as Item 9.A.

AJ. Zinc-65

AJ. Any

AJ. 2000 curies total

AJ. Same as Item 9.A.

AK. Copper-62

AK. Any

AK. 100 curies total

AK. Same as Item 9.A.

B. Copper-64

B. Any

B. 100 curies total

B. Same as Item 9.A.

C. Copper-67

C. Any

C. 5 curies total

C. Same as Item 9.A.

D. Rubidium-81

D. Any

D. 30 curies total

D. Same as Item 9.A.

E. Rubidium-82

E. Any

E. 35 curies total

E. Same as Item 9.A.

F. Strontium-82

F. Any

F. 35 curies total

F. Same as Item 9.A.

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SUPPLEMENTARY SHEET**

 License Number
13-35179-03

Amendment No. 1

 Docket or Reference Number
030-38903

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material

G. Strontium-83

H. Strontium-85

I. Fluorine-18

J. Nitrogen-13

K. Carbon-11

L. Oxygen-15

M. Zirconium-89

N. Europium-154

O. Scandium-46

P. Iron-59

Q. Cobalt-60

R. Zinc-65

7. Chemical and/or physical form

G. Any

H. Any

I. Any

J. Any

K. Any

L. Any

M. Any

N. Incidentally activated products

O. Incidentally activated products

P. Incidentally activated products

Q. Incidentally activated products

R. Incidentally activated products

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

G. 35 curies total

H. 35 curies total

I. 300 curies total

J. 30 curies total

K. 16 curies total

L. 1 curie total

M. 20 curies total

N. 100 millicuries total

O. 100 millicuries total

P. 100 millicuries total

Q. 100 millicuries total

R. 100 millicuries total

9. Authorized use

G. Same as Item 9.A.

H. Same as Item 9.A.

I. Same as Item 9.A.

J. Same as Item 9.A.

K. Same as Item 9.A.

L. Same as Item 9.A.

M. Same as Item 9.A.

 N. For possession and storage of
byproduct materials incidental to
radionuclide production.

 O. For possession and storage of
byproduct materials incidental to
radionuclide production.

 P. For possession and storage of
byproduct materials incidental to
radionuclide production.

 Q. For possession and storage of
byproduct materials incidental to
radionuclide production.

 R. For possession and storage of
byproduct materials incidental to
radionuclide production.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

13-35179-03

Docket or Reference Number

030-38903

Amendment No. 1

6. Byproduct, source,
and/or special nuclear
material

S. Cesium-134

T. Europium-152

U. Manganese-54

V. Uranium - depleted in
Uranium-235

W. Cesium-137

X. Cobalt-57

Y. Barium-133

Z. Germanium-68

7. Chemical and/or physical form

S. Incidentally activated products

T. Incidentally activated products

U. Incidentally activated products

V. Metal

W. Sealed sources (International
Isotopes Idaho, Inc., Model
BM06E-37)X. Sealed sources (International
Isotopes Idaho, Inc., Model
BM06E-57)Y. Sealed sources (International
Isotopes Idaho, Inc., Model
BM06E-33)Z. Sealed sources (International
Isotopes Idaho, Inc., Model
BM06E-68)8. Maximum amount that licensee
may possess at any one time
under this license

S. 100 millicuries total

T. 100 millicuries total

U. 100 millicuries total

V. 5000 kilograms total

W. 0.212 millicuries total

X. 5.16 millicuries total

Y. 0.262 millicuries total

Z. 0.631 millicuries total

9. Authorized use

S. For possession and storage of
byproduct materials incidental to
radionuclide production.T. For possession and storage of
byproduct materials incidental to
radionuclide production.U. For possession and storage of
byproduct materials incidental to
radionuclide production.

V. Shielding for generators

W. Calibration and checking of the
licensee's instruments.X. Calibration and checking of the
licensee's instruments.Y. Calibration and checking of the
licensee's instruments.Z. 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
13-35179-03Docket or Reference Number
030-38903

Amendment No. 1

11. The Radiation Safety Officer (RSO) for this license is John Zehner, R.Ph.

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

Authorized User

John Zehner, R.Ph.

Scott Chance, PharmD

Maxim Kiselev, Ph.D.

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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
13-35179-03

Amendment No. 1

Docket or Reference Number
030-38903

- 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 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 32.240 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.

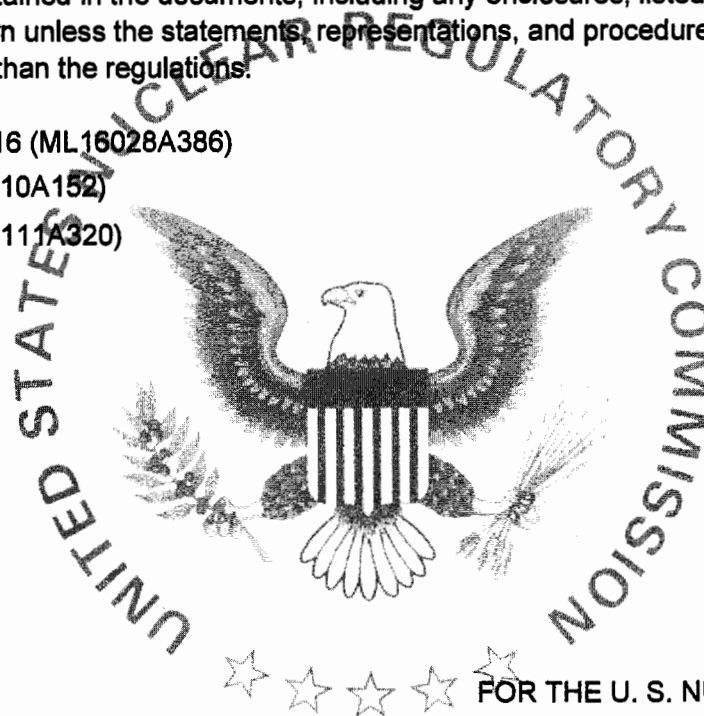
**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
13-35179-03

Amendment No. 1

Docket or Reference Number
030-38903

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. 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: JAN 17 2017By: B. A. ParkerBryan A. Parker
Region III