

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 02

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.

Licensee

- 1. Spectron mrc, LLC
- 2. 17490 Dugdale Drive
South Bend, IN 46635

In accordance with letter dated July 29, 2016,

3. License number 13-32726-01MD is **amended** in its entirety to read as follows:

4. Expiration date **October 31, 2020**

5. Docket No. 030-38044
Reference No.

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 and with a half-life less than or equal to 120 days	A. Any	A. 200 millicuries per radionuclide and 2 curies total except as noted below:
B. Carbon-11	B. Any	B. 10 curies
C. Copper-62	C. Any	C. 300 millicuries
D. Fluorine-18	D. Any	D. 20 curies
E. Indium-113m	E. Any	E. 1 curie
F. Nitrogen-13	F. Any	F. 1 curie
G. Oxygen-15	G. Any	G. 1 curie
H. Rhenium-188	H. Any	H. 1 curie
I. Rubidium-82	I. Any	I. 300 millicuries

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

13-32726-01MD

Docket or Reference Number

030-38044

Amendment No. 02

J. Strontium-82	J. Any	J. 300 millicuries
K. Tin-113	K. Any	K. 1 curie
L. Tantalum-178	L. Any	L. 300 millicuries
M. Tungsten-178	M. Any	M. 300 millicuries
N. Tungsten-188	N. Any	N. 1 curie
O. Zinc-62	O. Any	O. 300 millicuries
P. Any byproduct material under 10 CFR 35.65	P. Sealed sources	P. 50 millicuries

9. Authorized use:

- A. through O. Preparation and distribution of radioactive drugs and redistribution of used and unused generators described in letter dated March 11, 2010, to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals, and redistribution of used and unused generators described in letter dated March 11, 2010, to authorized recipients for nonmedical use. Also, for research and development as described in 10 CFR 30.4.
- P. Calibration and checking of the licensee's instruments.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 17490 Dugdale Drive, South Bend, Indiana.
11. Licensed material shall be used by, or under the supervision of:
- A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) and (4).

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
13-32726-01MDDocket or Reference Number
030-38044

Amendment No. 02

- B. Authorized Nuclear Pharmacist(s): Greg Hiatt, R.Ph., Stanley Miller, R.Ph., Bettina Hickman, R.Ph., Todd Holiday, R.Ph., Mark Peters, R.Ph., and John A. Zehner, R.Ph.**
- C. David Trump, Ph.D., for licensed material listed in items 6.A. through 6.O for research and development.
12. **The Radiation Safety Officer for this license is Greg Hiatt, R.Ph.**
13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.
14. This license does not authorized distribution to persons exempt from licensing.
15. 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.
- 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.
16. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
17. The licensee shall conduct a physical inventory every six months, or at other intervals approved by NRC, to account for all sealed sources and/or devices received and possessed under the license.
18. 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 32.210 or by an Agreement State.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
13-32726-01MD

Docket or Reference Number
030-38044

Amendment No. 02

19. 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.
 - 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.
20. The licensee is authorized to retrieve, receive, and dispose of radioactive waste from its customers limited to radiopharmacy-supplied syringes and vials and their contents.
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. 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 April 29, 2009 (ML13256A308)
 - B. Letter dated September 30, 2009 (ML13256A25)
 - C. Letter dated December 14, 2009 (ML093491139)
 - D. Letter dated January 19, 2010 (ML100200911)
 - E. Letter dated March 11, 2010 (ML100710734)
 - F. Letter dated December 12, 2013 (ML13351A266)
 - G. Letter dated January 29, 2014 (ML14038A221)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date NOV 01 2016

By


Kevin G. Null
Materials Licensing Branch
Region III