Spectron
mrc l.l.c.

October 26, 2016

DNMS/Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Attn: Mr. Kevin Null

Pertaining to license numbers: 13-32726-01 MD and 13-32726-02

RE: Change of RSO

Mr. Null,

On July 29, 2016 Mr. Kirk Rozycki R.Ph. and RSO of Spectron mrc, LLC wrote a letter to your office indicating a change of the RSO from himself, Kirk Rozycki, to Gregory S. Hiatt R.Ph owner and President of Spectron mrc, LLC. This change in RSO is for two licenses operated by Spectron mrc, LLC. One license is for the radiopharmacy under license number 13-32726-01 MD and the other license is for a cyclotron under the license number 13-32726-02.

Gregory S. Hiatt's qualifications are in part met by being an authorized user on both of the existing licenses since 2009. Additionally, Gregory S. Hiatt was RSO for the radiopharmacy Spectrum Pharmacy, Inc., license number 13-26367-01 MD beginning in 1992 and continuing on for several years when he stepped down and worked as an authorized user. Prior to Spectrum Pharmacy, Inc., Gregory S. Hiatt was listed as an authorized user on the Syncor, Intl., master license.

If you need additional information please feel free to call or email me.

My cell phone number is: 574-298-9616
My email address is: TARQY@sbcglobal.net

Yours truly,

Gregory S Hiatt R.Ph

Gregory S. Hiatt R.Ph/ President

Indiana

Online Licensing

New Search
Litigation Documents
Digital Certification
Pharmacy Board

Person Information

JOHN ANDREW ZEHNER

Address Information

Indianapolis IN 46236

License Information

License No:	26017457A
Profession:	Pharmacy Board
License Type:	Pharmacist
Obtained By Method:	Examination
Issue Date:	10/23/1991
Expiration Date:	6/30/2018
License Status:	Active

Previous Action

No Data Available

Violations

No Data Available

Related Licenses

License No:	60006489A	Name:	Global Isotopes, LLC. dba Zevacor Molecular		
License Type:	Pharmacy	Status:	Active	Relationship:	Managing Pharmacist
License No:		Name:	Global Isotopes, LLC. dba Zevacor Molecular		
License Type:	Pharmacy	Status:	Withdrawn Application	Relationship:	Managing Pharmacist

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 09

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	In accordance with **letter dated May 1, 2015,**
1. Global Isotopes, LLC d/b/a Zevacor Molecular 2. 1968 Innerbelt Business Center Drive Overland, **MO** 63114	3. License No. 24-32827-01MD is amended in its entirety to read as follows: 4. Expiration Date: December 31, 2018 5. Docket No. 030-38460/030-37831 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, except as listed below:	A. Any	A. 100 millicuries per radionuclide for a total of 1 curie
B. Technetium-99m	B. Any	B. 60 curies
C. Thallium-201	C. Any	C. 500 millicuries
D. Fluorine-18	D. Any	D. 30 curies
E. Yittrium-90	E. Any	E. 500 millicuries
F. Molybdenum-99	F. Any	F. 60 curies
G. Iodine-131	G. Any; unopened non-manipulated containers	G. 950 millicuries
H. Iodine-131	H. Any	H. 8.95 curies
I. Iodine-123	I. Any; unopened non-manipulated containers	I. 20 millicuries
J. Iodine-123	J. Any	J. 100 millicuries
K. Xenon-133	K. Any; unopened non-manipulated containers	K. 3 curies
L. Xenon-133	L. Any	L. 2 curies
M. Strontium-90	M. Any	M. 1 curie

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N. Samarium-153	N. Any	N. 1 curie
O. Indium-111	O Any	O. 1 curie
P. Gallium-67	P. Any	P. 1 curie
Q. Strontium-89	Q. Any	Q. 1 curie
R. Chromium-51	R. Any	R. 5 millicuries
S. Any byproduct material listed in 10 CFR 31.11(a)	S. Prepackaged units for *in vitro* diagnostic tests	S. 10 millicuries
T. Any byproduct material in a brachytherapy source as listed in 10 CFR 35.400	T. Sealed sources	T. 500 millicuries
U. Any byproduct material in a sealed source for diagnosis as listed in 10 CFR 35.500	U. Sealed sources	U. 1.5 curies per source for a total of 5.5 curies
V. Depleted Uranium	V. Metal	V. 999 kilograms
W. Any byproduct material authorized under 10 CFR 35.65	W. Sealed sources	W. 30 millicuries

9. Authorized use:

A. through R. Preparation and distribution of radioactive drugs including compounding of iodine-131 and redistribution of used and unused molybdenum-99/technetium-99m and rubidium/strontium-82 generators to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals, including compounding of iodine-131 and redistribution of used and unused molybdenum-99/technetium-99m and rubidium/strontium-82 generators to authorized recipients for nonmedical use.

S. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11, provided the packaging and labeling remain unchanged.

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T. and U. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. Redistribution of sealed sources that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess, and use the devices.

V. Shielding for molybdenum-99/technetium-99m generators.

W. Calibration and checking of the licensee's instruments. Redistribution of sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for nonmedical use.

CONDITIONS

10. A. Licensed material listed in Subitem Nos. 6.A.-G., 6.I., 6.K. and 6.M.-W. may be used at the licensee's facilities located at 1968 Innerbelt Business Center, Overland, Missouri **and at Zevacor Molecular – Noblesville, 14395 Bergen Boulevard, Noblesville, Indiana.**

B. Licensed material listed in Subitem Nos. 6.A.-W. may be used at the licensee's facilities located at 2220-2240 West Sunset Street, Springfield, Missouri.

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) or (4); and,

B. Authorized Nuclear Pharmacists: Rachel Ziegler, R.Ph., Rita Gentilcore, M.S., R.Ph., Corey Sorrell, R.Ph, Steven H. Alvey, R.Ph, William Boerger, R.Ph., Michael Dunn, Pharm.D., Michael Roberts, Pharm D., **Scott D. Chance, R.Ph., and John A. Zehner, R.Ph.**

12. **A. The Site Radiation Safety Officer (RSO) for the Overland, Missouri and Springfield, Missouri locations is Rachel Ziegler, R.Ph.**

B. The Site Radiation Safety Officer for the Noblesville, Indiana location is John A. Zehner, R.Ph.

13. This license does not authorize distribution to persons exempt from licensing.

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.

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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 (Bq)) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels (Bq)) 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 shall be performed by the licensee or other persons specifically licensed by the Commission or an Agreement State to perform such services. In addition, the licensee is authorized to collect leak test samples for analysis by persons specifically licensed by the Commission or an Agreement State to perform such services.

F. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.

15. Sealed sources 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 NRC, to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 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. 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 an 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.

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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 radioactive 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.

18. 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.

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."

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. Applications dated September 4, 2008, **and July 7, 2015**;

B. Letters dated October 8, 2008, August 21, 2009, November 4, 2009, June 18, 2013, July 29, 2013, November 8, 2013, November 18, 2013, February 6, 2014, August 7, 2014 (with attachments), October 2, 2014 (with attachments), November 24, 2014 (with attachments), January 8, 2015 (with attachment), **May 1, 2015 (with attachments), July 17, 2015 (with attachments), July 23, 2015 (with attachments), and July 31, 2015 (with attachments); and,**

C. Facsimiles dated November 21, 2008, and July 24, 2009.

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Date AUG 04 2015

By Colleen Carol Casey
Colleen Carol Casey
Materials Licensing Branch
Region III

Tomczak, Tammy

From: Null, Kevin
Sent: Thursday, October 27, 2016 12:18 PM
To: Tomczak, Tammy
Subject: FW: Rso update
Attachments: Indiana Pharmacist License 2016 (1).pdf; NRC License 2016.pdf; NRCAmendRSO10261620161026_21434012.pdf

Tammy, See attached signed letter and other related documentation. This info needs to get into ADAMS as additional info to C/N's 591630 and 591631.

Thanks

From: Gregory Hiatt [mailto:tarqy@sbcglobal.net]
Sent: Wednesday, October 26, 2016 9:02 PM
To: Null, Kevin <Kevin.Null@nrc.gov>
Cc: Gregory Hiatt <tarqy@sbcglobal.net>
Subject: [External_Sender] Rso update

Kevin,

Attached is a signed letter hopefully covering the missing pieces you wanted to see on the RSO change. Additionally, I have attached two additional documents. These documents were going to be used an another amendment I was going to write for the the same license numbers that involves Spectron mrc, LLC.

What I was going to ask for is to add Mr. John Zehner to my authorized users as a back-up pharmacist. Since Kirk is not available yet John has offered to cover if I needed some time off.

Do I need to submit this information as an amendment or will attaching them to this RSO change work?

It was great talking with you and make sure you keep my cell phone number to use when you come to Indy or South Bend.

BTW: was this quick or what! I got lucky and found the old Spectrum Pharmacy, Inc. license number. I also was on an old Pharmatopes, Inc license as RSO from 1980 to 1985 but I don't have that number anymore. Getting OLD.

Thanks,

Greg