



August 30, 2017

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

Attn: Mr. Frank Tran

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

Thank you for your time discussing the requirements to add a Ge68/Ga68 generator to Spectron mrc, LLC's material license. This generator is very important to me at this time because of a pending research contract to use the generator in developing a CMC and DMF for a compound this company wants us to help develop. I am asking for immediate verbal approval for the shipment of the IRE Ge68/Ga68 Galli Eo generator. The generator waiting to be shipped was manufactured last May and has decayed to under 40 mCi.

Again, thank you to you and your staff in any help you can provide for me.

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,

A handwritten signature in black ink, appearing to read "Gregory S. Hiatt". The signature is written in a cursive style with some loops and flourishes.

Gregory S. Hiatt R.Ph/ RSO OWNER

RECEIVED AUG 30 2017

Medical Radioisotope Center
17490 Dugdale Drive * South Bend * Indiana
574-271-2800



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

August 29, 2017

Attn: Mr. Frank Tran

RE: Amendment for license number: 13-32726-02

In reference to license number 13-32726-02: I would like to amend the following conditions.

- A. Please expedite adding Mr. Ali Abbasi PharmD, MD, as an authorized user. Mr. Ali is currently in the process of reciprocating as a pharmacist to the state of Indiana. The whole purpose is to provide relief for Greg Hiatt, currently the only pharmacist at Spectron.
- B. Add item 6S to the license to increase the Cu-64 possession limit to 3 Ci in any form. Because of the 12 hour half-life of this product I will have separate storage and waste areas.
- C. Add item 6V to the license to increase Cyclotron produced Ga-68 to 5.0 Ci in any form.

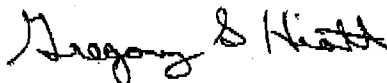
ITEM A.1. Additionally, I have included a copy of NCM USA Bronx, LLC's New York State Department of Health's Radioactive Materials License. This license shows Mr. Ali Abbasi qualifications to be an authorized user since he is shown on this license as an authorized user and Radiation Safety Officer.

ITEMS B.1 Spectron mrc, LLC will provide separate storage and waste area and/or containers so that there is control over the various radionuclides with their different half-lives. Cu-64 products and waste will be stored in separate labeled lead containers and/or bins from the F-18 and Ga-68 labeled lead containers and/or bins.

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: TAROY@sbcglobal.net

Yours truly,



Gregory S. Hiatt RSO, R.Ph

Page 1 of 4



August 29, 2017

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

Attn: Mr. Frank Tran

RE: Amendment for license number: 13-32726-01 MD

In reference to license number 13-32726-01 MD: I would like to amend the following conditions.

- A. Please expedite adding Mr. Ali Abbasi PharmD, MD, as an authorized user. Mr. Ali is currently in the process of reciprocating as a pharmacist to the state of Indiana. The whole purpose is to provide relief for Greg Hiatt, currently the only pharmacist at Spectron.
- B. Add item 6Q to the license to increase the Molybdenum-99/Technetium-99m generator possession limit to 20 curies any form. Waste and storage will be kept separate from the PET products and waste.
- C. Add item 6R to the license to increase the Technetium-99m possession limit to 20 curies in any form.
- D. Add item 6S to the license to increase the Cu-64 possession limit to 3 Ci in any form. Because of the 12 hour half-life of this product I will have separate storage and waste areas.
- E. Add item 6T to the license to increase the Uranium (depleted) possession limit to 100 kg
- F. Add item 6U to the license to increase the Ge-68/Ga-68 each as a generator to 99 mCi. The Ge-68/Ga-68 generator will be returned to the manufacturer for final disposal. Commitment letter attached.

Medical Radiolotope Center
17490 Dugdale Drive * South Bend * Indiana
574-271-2800

DM

Page 2 of 4

G. Add item 6V to the license to increase Cyclotron produced Ga-68 to 5.0 Ci in any form.

ITEM A.1. Additionally, I have included a copy of NCM USA Bronx, LLC's New York State Department of Health's Radioactive Materials License. This license shows Mr. Ali Abbasi's qualifications to be an authorized user since he is shown on this license as an authorized user and Radiation Safety Officer.

ITEMS B,C,D,F,G.1 Spectron mrc, LLC will provide separate storage and waste area and/or containers so that there is control over the various radionuclides with their different half-lives. Cu-64 products and waste will be stored in separate labeled lead containers and/or bins from the F-18 labeled lead containers and/or bins.

ITEM F.2 All Ge-68 waste, having a half-life greater than 120 days, will be stored in separate labeled lead containers. This waste will be reviewed annually for disposal and consolidated when appropriate. The intent is to have the Ge-68 waste removed for disposal within five (5) years but definitely removed for disposal within ten (10) years in the situation that the waste is low volume. Spectron mrc, LLC commits that the Ge68/Ga68 generator will be returned to the manufacturer for final disposal and the manufacturer has committed to Spectron that it will always accept their Ge-68/Ga-68 Generator. Commitment letter included

ITEM F.2 Spectron mrc, LLC has a DFP already in place along with a financial assurance in the form of a guaranteed letter of credit from First (1st) Source Bank of South Bend, Indiana.

ITEM F.3 The Ge-68/Ga-68 Generators I am seeking approval for is:
IRE ELiT Galli Eo™ Gallium-68 generator

ITEM F.4. Commitments and Protocols for Safe Handling the Ge68/Ga68 Generator

Staff training and manufacturer's procedures:

- ✓ Provide instructions and/or training on the manufacturer's procedures to all individuals involved in Ge-68/Ga-68 generator use
- ✓ Employees will not open, breach, or physically modify the IRE ELiT Galli Eo™ Ga86 generator.
- ✓ Employees will follow manufacturer's procedures including generator set-up, generator elution, drug preparation, Ge-68 breakthrough testing, and final disposition when the Ge68/Ga68 generator is being used for human use.

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Discarding materials:

- ✓ We will not use an expired generator for preparation of materials except for research where no humans will be involved.
- ✓ We will only use a generator with a clearly marked expiration date unless it is for research use only
- ✓ After installation, we will elute the generator and properly dispose of the eluate prior to the first use of eluate for testing or human use.
- ✓ If the generator has not been eluted within 48 hours, we will discard the first eluate prior to use.

NOTE: Spectron mrc, LLC commits that the IRE Galli Eo™ Ge68/Ga68 generator will be returned to the manufacturer for final disposal and the manufacturer has committed to Spectron that it will always accept their Ge-68/Ga-68 Generator. Commitment letter included

Quality Standards and SOPs:

- ✓ We will not knowingly administer to a patient or human research subject any material containing Ga-68 which is determined to exceed the manufacturer's 0.001 percent breakthrough limit.
- ✓ We will develop and implement written procedures to determine Ge-68 breakthrough that detects whether the eluate exceeds the manufacturer's 0.001 percent breakthrough limit.
- ✓ We will measure the breakthrough of the generator upon initial installation and at least once every 7 calendar days when in use.
- ✓ We will remove a generator from use if the measured Ge-68 breakthrough exceeds the manufacturer's stated breakthrough limit.
- ✓ We will not return a generator to service for human use until the breakthrough has been measured again in a new elution and determined to be below the manufacturer's stated breakthrough limit.

Page 4 of 4

Quality Standards and SOPs continued:


- ✓ Maintain a record of the breakthrough tests for at least 3 years. Should include:
 - *ratio of the measured activity of Ge-68 per Ga-68 corrected for the time of elution
 - *time and date of the elution
 - *time and date of the measurement
 - *name of the individual who made the measurement
- ✓ Develop and implement written emergency procedures for leaking or damaged generators.
- ✓ Send a written report to the appropriate NRC Regional Office within 30 days after discovery of an eluate that exceeded the manufacturer's breakthrough limits of Ge-68.
- ✓ Report in writing, within 30 days, any doses to humans prior to the results of a failed breakthrough calculation in accordance with the rules for medical events and reportable events.
- ✓ Survey test all areas of licensed material use, including the generator storage and kit preparation areas, for contamination using a survey instrument each day of use.
- ✓ Wipe test the generator casing semi-annually, along with the sealed sources, for expired or unused generators that have been in storage for more than six (6) months.

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

My cell phone number is: 574-298-9616

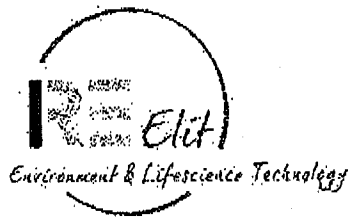
My email address is: TAROY@sbcglobal.net

Yours truly,



Gregory S. Hiatt RSO, R.Ph

Attachment: IRE Commitment letter
New York State Department of Health Radioactive Materials License No. C5496
Cover page



Fleurus, August 17th 2017

Subject : Recovery of Gallium ^{68}Ga ($^{68}\text{Ge}/^{68}\text{Ga}$) generator after use.

To whom it may concern

Dear Sir,

By this letter, the undersigned, Philippe van Put, duly authorized to sign this Statement in his capacity of Business Development Manager, hereby declares that IRE ELiT is committed to take back the above mentioned generator at its end of use by the user. This obligation of returning the generator is part of the commercial Terms & Conditions signed by the user (or the local distributor) and IRE ELiT at the time of purchase.

Your's sincerely,

(For, IRE ELiT)

Philippe van Put

Business Development Manager

Philippe.vanout@ire.eu / tel: +32 71 82 94 91 / fax: +32 71 81 38 12

NEW YORK
state department of
HEALTH

Nirav R. Shah, M.D., M.P.H.
Commissioner

Sue Kelly
Executive Deputy Commissioner

NCM USA Bronx, LLC
390 Concord Avenue
Bronx, New York 10454

SEP 17 2012

Attention: Ali Abbasi, M.D., Pharm.D.
Radiation Safety Officer

Re: NYS Dept. of Health Radioactive
Materials License No. C5496
DH No. 12-623

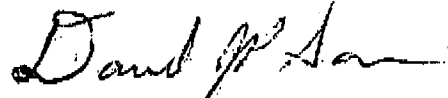
Dear Dr. Abbasi:

Enclosed is Amendment No. 2 to New York State Department of Health Radioactive Materials License No. C5496, which authorizes the production of Zirconium 89 for pharmaceutical distribution under NYS DOH License No. C5494. This amendment also adds Zirconium 88 that is produced as contaminant as a result of the (p,2n) activation of Yttrium.

If I may be of assistance, please contact this office at (518) 402-7590 or:

New York State Department of Health
Bureau of Environmental Radiation Protection
Radioactive Materials Section
ESP, Corning Tower, Room 1245
Albany, New York 12237

Sincerely,



Daniel J. Samson, CHP
Associate Radiophysicist

CJB/DJS:ks

Enclosure: Amendment No. 2



**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

Pursuant to the Public Health Law, Part 16 of the New York State Sanitary Code, Industrial Code Rule 38, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing radioactive material(s) for the purpose(s), and at the place(s) designated below. The license is subject to all applicable rules, regulations, and orders now or hereafter in effect of all appropriate regulatory agencies and to any conditions specified below.

1. NAME OF LICENSEE <p align="center">NCM USA Bronx, LLC</p> <p align="right">Phone (212) 719-2322</p>	3. LICENSE NUMBER <p align="center">C5496</p>		
2. ADDRESS OF LICENSEE <p align="center">390 Concord Avenue Bronx, New York 10454</p>	4. EXPIRATION DATE <p align="center">March 31, 2021</p> <table border="1"> <tr> <td data-bbox="938 884 1247 1085"> 5a. REFERENCE <p align="center">DH 12-623</p> </td> <td data-bbox="1247 884 1472 1085"> b. AMENDMENT NO. <p align="center">2</p> </td> </tr> </table>	5a. REFERENCE <p align="center">DH 12-623</p>	b. AMENDMENT NO. <p align="center">2</p>
5a. REFERENCE <p align="center">DH 12-623</p>	b. AMENDMENT NO. <p align="center">2</p>		

6. Radioactive Materials (elements in mass number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
A. Fluorine 18	A. Any	A. 50 curies
B. Nitrogen 13	B. Any	B. 4 curies
C. Cesium 137	C. Sealed sources	C. 5 millicuries (No single source to exceed 1 millicurie)
D. Sodium 22	D. Sealed sources	D. 5 millicuries (No single source to exceed 1 millicurie)
E. Germanium 68	E. Sealed sources	E. 5 millicuries (No single source to exceed 1 millicurie)
F. Cobalt 57	F. Sealed sources	F. 20 millicuries (No single source to exceed 1 millicurie)



**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

3. License Number C54965a. Reference DH.12-623b. Amendment No. 2

6. Radioactive Materials (elements in mass number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
G. Any radioactive material with atomic numbers 1 through 83	G. Activated cyclotron parts and associated shielding	G. 1 curie total possession (No single isotope to exceed 50 millicuries, except as noted below)
H. Iron 55	H. Activated cyclotron parts and associated shielding	H. 200 millicuries
I. Cobalt 57	I. Activated cyclotron parts and associated shielding	I. 300 millicuries
J. Cobalt 60	J. Activated cyclotron parts and associated shielding	J. 100 millicuries
K. Zinc 65	K. Activated cyclotron parts and associated shielding	K. 100 millicuries
L. Cadmium 109	L. Activated cyclotron parts and associated shielding	L. 400 millicuries
M. Zirconium 89	M. Any	M. 4 curies
N. Zirconium 88	N. Any	N. 1 curie

9. Authorized use.

Conditions 6.A., 6.M. and 6.N.:

As produced incident to the operation of the General Electric PETtrace Cyclotron (NYS Dept. of Health Registration No. 94000009); for the preparation and distribution of radiopharmaceuticals authorized under NYS DOH License No. C5494.

Condition 6.B.:

As produced incident to the operation of the General Electric PETtrace Cyclotron (NYS Dept. of Health Registration No. 94000009); for conditioning of cyclotron components and for the calibration of the exhaust monitoring system.



NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

3. License Number C5496

5a. Reference DH 12-623

b. Amendment No. 2

(Condition 9, continued)

Conditions 6.C. through 6.F.:
As reference and calibration standards.

Conditions 6.G through 6.L.:
As produced incident to the operation of the General Electric PETtrace Cyclotron (NYS Dept. of Health Registration No. 94000009).

10. A. The Radiation Safety Officer (RSO) for this License is Ali Abbasi, M.D., Pharm.D.
- B. The GE PETtrace Cyclotron may be operated for the purpose of producing fluorine 18 and/or Nitrogen 13 by or under the direct supervision of Ali Abbasi, M.D., Pharm.D., Maxim Kiselev and Mark Soffing, Pharm.D.
- C. The RSO will be provided with regular on-site health physics support by Greg Hisel, CHP. This individual shall be physically available and able to respond to accidents and incidents in a timely manner, and shall visit this facility for at least ten (10) hours per week to provide the routine support described in Appendix A of the Radiation Guide 1.8. This individual shall also conduct or participate in the required annual audits of the licensee's radiation protection program and performance of the RSO.
11. Except as specifically provided otherwise in the 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 Department'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 July 11, 2011, signed by Anwer Rizvi, with attachments.
- B. Shielding Design Report dated October 2011, by K&N Physics Consulting, LLC.
- C. Letter received November 2, 2011, signed by Anwer Rizvi, with attachments.
- D. Letters received June 21, 2012 and August 28, 2012, signed by Ali Abbasi, M.D., Pharm.D., with attachments.
12. Licensed material shall be stored and used at the licensee's installation located at the address indicated in Condition 2, above.
13. A. The licensee shall instruct persons before they engage in work under the license, in accordance with 10 NYCRR 16.13(c), and shall provide annual refresher training. Such instruction shall include the licensee's operating and emergency procedures and other information contained in documents incorporated in Condition 11.



NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

3. License Number C5496

5a. Reference DH 12-623

b. Amendment No. 2

13. B. Records of training received pursuant to paragraph A of this Condition shall be maintained for a period of three (3) years and shall include:
- i) the name of the individual who conducted the training;
 - ii) the name of the individual who received the training;
 - iii) the dates and duration of the training; and
 - iv) a list of topics covered.
14. A. The licensee shall submit to the Department a detailed description of any proposed changes to the facilities and equipment, described in the license application and supporting documents, before making any such changes. This shall include, but not be limited to, changes in use, floor plans, ventilation systems and usage of areas contiguous to areas where radioactive materials are used and stored.
- B. Plans of facilities which the licensee intends to dedicate to operations involving the use of radioactive material shall be submitted to the Department for review and approval prior to such use.
15. The licensee shall submit complete decontamination procedures to the Department for approval ninety (90) days prior to the termination of authorized operations involving radioactive material in controlled areas and/or vacating installations pursuant to 12 NYCRR 38, section 38.23.
16. The licensee shall maintain records of information important to safe and effective decommissioning at the location specified in Condition 2 and at other locations as the licensee chooses. The records shall be maintained until this license is terminated by the Department and shall include:
- A. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site;
 - B. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination, such as buried pipes that may be subject to contamination.
 - C. Records of the cost estimate performed for decommissioning funding plan or the amount certified for decommissioning, and records of the funding method used for assuring funds, if either a funding plan or certification is used.
17. The licensee shall submit full information on any proposed changes of ownership or control of licensed premises, at least 90 days prior to the proposed action.



NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

3. License Number C5496

5a. Reference DH 12-623

b. Amendment No. 2


18. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 days for decay-in-storage before disposal in ordinary trash, provided:
- A. Affected radioactive waste shall be held for decay a minimum of ten (10) half-lives; and
 - B. Prior to disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
19. The licensee shall have available appropriate survey meters which shall be maintained operational and shall be calibrated before initial use and at subsequent intervals not exceeding twelve months by a person specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. Records of all calibrations shall be kept a minimum of three years.
20. A. The licensee shall not release any licensed radioactive materials into the environment except as allowed by the New York State Department of Environmental Conservation.
- B. Before use or disposal of any licensed radioactive material in a manner that could result in discharge or release to the environment, the licensee shall obtain from the New York State Department of Environmental Conservation either:
- i) A valid permit, or
 - ii) A letter stating that no permit is required.
- C. The licensee shall maintain the letter or valid permit required in paragraph B of this condition on file for the duration of the license and make such letter or permit available for inspection by the Department upon request.

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Date: SEP 17 2012

CJB/DJS:ks

By


Charles J. Burns, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

From: Greg Hiatt
Spectron mfg, LLC
 Fax: 574/271-3523
 Phone: 574-298-9616 (cell)

FAX

To: Mr. Frank TRAN
 Fax: 630/515-1078
 Phone: _____
 Pages: 14 Pages including fax cover
 Re: NRC License Amendments

CONFIDENTIAL

Special Verbal request for
6268/6268 Generator for Research

Greg Hiatt

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