Nuvance Health

Radiology
50 Hospital Hill Road,
Sharon, CT 06069

860.364.4000
NuvanceHealth.org

Br. 1

October 19, 2019

Farrah C. Gaskins
Health Physicist
U.S. NRC, Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406

Licensee: Sharon Hospital
License No.: 06-08020-02 03001272

Dear Ms. Gaskins:

Please amend our radioactive materials license number 06-08020-02 to include Anthony Dennis Mohabir, M.D. and Evan Kurz, M.D. as authorized users.

The physicians notes above are currently authorized users NYSDOH RAM License number 559 for Vassar Brothers Medical Center (A Health Quest Affiliate). See attached copy of this license.

We appreciate your efforts in this amendment request and we look forward to a continued safe and effective program with radioactive materials. If you have any questions or desire additional information, please contact me at (860)-364-4513.

Respectfully,

Kenneth DiVestea
Sharon Hospital
Director of Imaging Services

REC'D IN LAT 10-18-19

616953
NMSS/RGN1 MATERIALS-002

NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

License
Inspection

Pursuant to the Public Health Law, Part 16 of the New York State Sanitary Code, 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	3. LICENSE NUMBER
Vassar Brothers Medical Center Phone (845) 483-6229	559
	4. EXPIRATION DATE March 5, 2023
2. ADDRESS OF LICENSEE	5a. REFERENCE / b. AMENDMENT NO.
45 Reade Place Poughkeepsie, New York 12601	DHs 19-325 & 19-486 / 95

This license is subject to the following conditions:

Conditions 6 through 9 – Authorized Materials, Form, Possession Limits and Uses
Condition 10 – Authorized Users, Radiation Safety Officer, and Medical Physicists
Condition 11 – Documents Incorporated by Reference
Conditions 12 and beyond – License Conditions

In accordance with the requests dated April 30, 2019, signed by Benjamin Hentel, M.D., and August 8, 2018, signed by Alfonso DeCaro and Benjamin Hentel, M.D., New York State Department of Health Radioactive Materials License No. 559 is hereby amended.

Only the amended sections are included, with specific changes indicated in bold type. All previous license conditions not specifically addressed in this amendment shall remain valid and enforceable.

NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number 559 **5a. Reference** DHs 19-325 & 19-486 **b. Amendment No.** 95

AUTHORIZED MATERIALS, FORM, POSSESSION LIMITS AND USES

6. Radioactive Materials (element & mass no.)	7. Chemical and/or Physical Form	8. Maximum quantity licensee may possess at one time
A. Any radioactive material as approved under 10 NYCRR 16.123(c)(1), except alpha or positron emitting isotopes	A. Any radiopharmaceutical as approved under 10 NYCRR 16.123(c)(1)	A. As necessary for uses in Subitem 9A
B. **Any radioactive material as approved under 10 NYCRR 16.123(c)(2), except alpha emitting isotopes**	B. Any radiopharmaceutical or reagent kit as approved under 10 NYCRR 16.123(c)(2) (Restricted from molybdenum 99/technetium 99m generators)	B. As necessary for uses in Subitem 9B
C. Any radioactive material as approved under 10 NYCRR 16.123(c)(3), except positron emitting isotopes	C. Any radiopharmaceutical as approved under 10 NYCRR 16.123(c)(3). Iodine 131 restricted to capsule form only	C. As necessary for uses in Subitem 9C
D. Any radioactive material approved under 10 NYCRR 16.123(c)(4)	D. Any radioactive source approved under 10 NYCRR 16.123(c)(4)	D. 1.5 curies total for all radioactive material authorized in Subitem 9D
E. Iridium 192 as approved under 10 NYCRR 16.123(c)(6)	E. Sealed source (Elekta, Inc. [formerly Mallinckrodt] Model 105.002) manufactured by Mallinckrodt Medical B.V., QSA Global or Alpha-Omega Services, Inc.	E. 21 curies total. Two sources not to exceed 10 curies per installed source and 12 curies per source in its shipping container
F. Strontium 90	F. Sealed source (Victoreen Model 67-850)	F. 90 millicuries
G. Iodine 125	G. Sealed sources	G. As necessary for uses in Subitem 9G

NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number 559 **5a. Reference** DHs 19-325 & 19-486 **b. Amendment No.** 95

6. Radioactive Materials (element & mass no.)	7. Chemical and/or Physical Form	8. Maximum quantity licensee may possess at one time
H. Yttrium 90	H. Glass microsphere (Manufacturer as listed in Sealed Source and Device Registry NR-0220-D-131-S, TheraSphere)	H. 1 curie (not to exceed 540 millicuries per vial)
I. Any radioactive material as approved under 10 NYCRR 16.123(d)	I. Any calibration or reference source	I. Any quantity as approved under 10 NYCRR 16.123(d)

9. Authorized use (unless otherwise described, the authorized place of use is the licensee's address stated in Item 2, above).

A. Any uptake, dilution, or excretion study approved under 10 NYCRR 16.123(c)(1).

B. Any imaging and localization study approved under 10 NYCRR 16.123(c)(2). **The licensee shall limit its use of positron emitting tomography (PET) radionuclides administration of no more than 700 millicuries total per week for diagnostic studies. Records indicating the number of PET scans performed per week, including activity injected per patient, must be maintained for inspection by the Department.**

C. Any use approved under 10 NYCRR 16.123(c)(3) for which a written directive is required.

D. Any manual brachytherapy procedure approved under 10 NYCRR 16.123(c)(4).

E. One source for medical use approved under 10 NYCRR 16.123(c)(6) in an Elekta Inc. (formerly Nucletron) microSelectron Model 106.990 high dose rate remote afterloader unit for the treatment of humans. One source in its shipping container to be in possession of the licensee as necessary for the replacement of the source in the remote afterloader unit only.

F. For treatment of superficial eye conditions.

G. For use in localization of nonpalpable breast lesions.

H. For use in a MDS Nordion Yttrium-90 microsphere brachytherapy afterloader single use device for the treatment of unresectable hepatocellular carcinoma.

I. The licensee may receive, possess and use calibration and reference standards approved under 10 NYCRR 16.123 (d).

AUTHORIZED USERS, RADIATION SAFETY OFFICER, AND MEDICAL PHYSICISTS

10. A. Medical use of byproduct material shall be used by, or under the supervision of, the following individuals for the specified uses approved under New York State Sanitary Code, Chapter 1, Part 16, "Ionizing Radiation", Section 123:

Laurie Abrams, M.D.	16.123(c)(1) and 16.123(c)(2)
Philip Amatulle, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(7) limited to seed localization
Joseph C. Antonio, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(7) limited to seed localization
Michael Bromley, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(7) limited to seed localization
Michael A. Burke, M.D.	16.123(c)(3), 16.123(c)(4) including eye applicator, and 16.123(c)(6) limited to remote afterloader units
M. Saleem Choudhry, M.D.	16.123(c)(1) and 16.123(c)(2)
Muhaddis Choudhury, M.D.	16.123(c)(1) and 16.123(c)(2)
Lynn Clements-Northland, M.D.	16.123(c)(1) and 16.123(c)(2)
Nancy Cooper, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodide I-131 in any quantity
Jonathan J. Crystal, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(7) limited to seed localization and TheraSphere Yttrium-90 microspheres
Ronald Cuffe, M.D.	16.123(c)(1) and 16.123(c)(2)
Krishna Das, M.D.	16.123(c)(1) and 16.123(c)(2)
John Ditzenberger, M.D.	16.123(c)(1) and 16.123(c)(2)
Elizabeth Dubovsky, M.D.	16.123(c)(1) and 16.123(c)(2)

10. A. (Continued)

Edward M. Farhangi, M.D.	16.123(c)(3), 16.123(c)(4) including eye applicator, and 16.123(c)(6) limited to remote afterloader units
Richard Friedland, M.D.	16.123(c)(1), 16.123(c)(2), 16.123(c)(3) limited to oral administration of sodium iodide I-131 in any quantity, and 16.123(c)(7) limited to seed localization
Victor D. Gaines, M.D.	16.123(c)(1), 16.123(c)(2), 16.123(c)(3), and 16.123(c)(7) limited to seed localization
Bruce R. Gendron, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(7) limited to seed localization
Glenn Gerber, D.O.	16.123(c)(1) and 16.123(c)(2)
Simon Gorwara, M.D.	16.123(c)(1) and 16.123(c)(2)
Ethan L. Gundeck, M.D.	16.123(c)(1) and 16.123(c)(2)
Kamran Haleem, M.D.	16.123(c)(1) and 16.123(c)(2)
Benjamin M. Hentel, M.D.	16.123(c)(1), 16.123(c)(2),16.123(c)(3) limited to oral administration of sodium iodide I-131 in any quantity, and 16.123(c)(7) limited to seed localization
Mira Herman, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(7) limited to TheraSphere Yttrium-90 microspheres
M. Zubair Jafar, M.D.	16.123(c)(1) and 16.123(c)(2)
Vikas Jindal, M.D.	16.123(c)(1) and 16.123(c)(2)
Louis W. Kantaros, M.D.	16.123(c)(1) and 16.123(c)(2)
Russell Karp, M.D.	16.123(c)(1), 16.123(c)(2), 16.123(c)(3) limited to oral administration of sodium iodide I-131 in any quantity, and 16.123(c)(7) limited to seed localization

10. A. (Continued)

Taik H. Kim, M.D.	16.123(c)(3) limited to parenteral administration of unsealed byproduct material, 16.123(c)(4) including eye applicator, and 16.123(c)(6) limited to remote afterloader units
David Michael Krakowski, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(7) limited to seed localization
Douglas Kroll, M.D.	16.123(c)(1) and 16.123(c)(2)
Evan Kurz, M.D.	**16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodine I-131 in any quantity**
Vincent Lau, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodine I-131 in any quantity
William Lee, M.D.	16.123(c)(1) and 16.123(c)(2)
Jon Michael Lewis, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(7) limited to seed localization
Stephen B. Lichtenberg, M.D.	16.123(c)(1) and 16.123(c)(2)
Donald Lien, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries, and 16.123(c)(7) limited to seed localization
Julie Ling, M.D.	16.123(c)(1) and 16.123(c)(2)
Kathleen Llewellyn, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodine I-131 in any quantity
Thomas Mazzilli, M.D.	16.123(c)(3) limited to parenteral administration of unsealed byproduct material, 16.123(c)(4) including eye applicator, and 16.123(c)(6) limited to remote afterloader units

10. A. (Continued)

Anthony Messina, M.D.	16.123(c)(1) and 16.123(c)(2)
Anthony Dennis Mohabir, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodine I-131 in any quantity
Syed Hasan Mahboob Naqvi, M.D.	16.123(c)(1) and 16.123(c)(2)
Gary William Nathanson, M.D.	16.123(c)(1) and 16.123(c)(2)
Daniel J. O'Dea, M.D.	16.123(c)(1) and 16.123(c)(2)
Dimitrios Papadopoulos, M.D.	16.123(c)(3) limited to parenteral administration of unsealed byproduct material, 16.123(c)(4) including eye applicator, and 16.123(c)(6) limited to remote afterloader units
Mahesh Patel, M.D.	16.123(c)(1) and 16.123(c)(2)
John Portelli III, M.D.	16.123(c)(1) and 16.123(c)(2)
Mahboobur Rahman, M.D.	16.123(c)(1) and 16.123(c)(2)
Shashidar Reddy, M.D.	16.123(c)(1) and 16.123(c)(2)
John T. Respass, M.D.	16.123(c)(1) and 16.123(c)(2)
Fatos Rugova, M.D.	16.123(c)(1) and 16.123(c)(2)
Benjamin D. Seckler, M.D.	16.123(c)(1) and 16.123(c)(2)
Emil Shih, M.D.	16.123(c)(1) and 16.123(c)(2)
Robert Smith, M.D.	16.123(c)(3) limited to parenteral administration of unsealed byproduct material, 16.123(c)(4) including eye applicator, and 16.123(c)(6) limited to remote afterloader units
Lawrence W. Solomon, M.D.	16.123(c)(1) and 16.123(c)(2)
Fara Tafazoli, M.D.	16.123(c)(1) and 16.123(c)(2)

10. A. (Continued)

Camilo Torres, M.D.	16.123(c)(3) limited to parenteral administration of unsealed byproduct material, 16.123(c)(4) including eye applicator, and 16.123(c)(6) limited to remote afterloader units
Harshan Weerackody, M.D.	16.123(c)(1) and 16.123(c)(2)
David Weinreich, M.D.	16.123(c)(1) and 16.123(c)(2)
Danielle S. Williams, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodide I-131 in any quantity
Bryan Yen, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(7) limited to seed localization
Michael H. Yen, M.D.	16.123(c)(1) and 16.123(c)(2)
Shah Manir Zaman, M.D.	16.123(c)(1) and 16.123(c)(2)
Sarah Zeb, M.D.	16.123(c)(1) and 16.123(c)(2)
Yiping Zhang, M.D.	16.123(c)(1) and 16.123(c)(2)

B. Radioactive material listed in Item 6 shall be used by Benjamin M. Hentel, M.D., as appropriate to fulfill the responsibilities of the Radiation Safety Officer.

C. The Radiation Therapy Physicists for this license are Jason Gong, Ph.D., Sergey Kriminski, Ph.D., and Parthena Sansourekidou, M.S. Only these persons may perform full calibrations of the HDR brachytherapy unit and provide decay-corrected output values.

DOCUMENTS INCORPORATED BY REFERENCE

11. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7 and 8 of this license, in accordance with statements, representations, and procedures contained in the documents (including any enclosures) listed below:

A. Application for New York State Department of Health Radioactive Materials License dated June 4, 2012, signed by Janet Ready.

11. B. Letter dated April 18, 2002, signed by Debra L. Rossi.

C. Letter dated July 8, 2002, signed by Kenneth Chu, Ph.D.

D. Letter dated November 10, 2004, signed by Daniel Aronzon, M.D., and Kenneth Chu, Ph.D., DABR.

E. Letter dated March 13, 2006, signed by Kenneth Chu, Ph.D., and D. Aronzon, M.D.

F. Facsimile dated April 22, 2006, signed by Kenneth Chu, Ph.D.

G. Letter dated February 27, 2007, signed by Kenneth Chu, Ph.D., and D. Aronzon, M.D.

H. Letter dated July 10, 2008, signed by D. Aronzon, M.D., and Dan Pavord.

I. Letter dated August 24, 2012, from Dan Pavord, M.S.

J. Documents received October 10, 2012, sent by Dan Pavord, M.S.

K. Letter dated November 8, 2012, signed by Dan Pavord, M.S., and Janet Ready, and attached documents received November 13, 2012.

L. Letter dated November 8, 2013, signed by Dan Pavord, M.S., and Sandi Cassese.

M. Letter dated May 13, 2015, signed by Dan Pavord, M.S., and Robert Friedberg.

N. Letter dated February 27, 2017, signed by Dan Pavord, M.S., and Ann McMackin with attachments.

O. Letter dated August 8, 2019, signed by Alfonso DeCaro and Benjamin Hentel, M.D.

P. Letter dated August 21, 2019, signed by Alfonso DeCaro and Benjamin Hentel, M.D.

LICENSE CONDITIONS

12. Radioactive materials shall not be stored in the same facilities with materials which might substantially increase the fire or explosion hazard of the storage space and its radioactive contents.

13. All use of radioactive materials at this institution shall be coordinated with and approved by the Radiation Safety Committee of Vassar Brothers Medical Center.

14. The licensee shall have available an appropriate survey meter 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 five years.

15. For a period not to exceed sixty (60) days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

A. Has the prior written permission of the hospital's administrator and its Radiation Safety Committee;

B. Is specifically named as a user on a U.S. Nuclear Regulatory Commission or Agreement State license authorizing human use; and

C. Performs only those procedures for which he is specifically authorized by a U.S. Nuclear Regulatory Commission or Agreement State license.

The licensee shall maintain for inspection by the Department, copies of the written permission specified in Subitem A above and of the license(s) specified in Subitems B and C above. These records shall be maintained for five years from the time the licensee grants its permission under Subitem A above.

16. Leak tests of sealed sources shall be performed in accordance with Section 16.10 (a) (4), New York State Sanitary Code (10 NYCRR 16). Off-site analysis of leak test samples shall be performed by persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. On-site analysis of leak test samples shall be in accordance with procedures approved by the Department.

17. The licensee shall cease treatment of patients with any therapy unit if a safety related system of the therapy unit is found to be malfunctioning; including source drive mechanisms, treatment timing systems, safety interlocks and radiation field alarms. The licensee shall report to the Department any such malfunction which requires the suspension of patient treatments for more than 24 hours and shall submit a written report of the incident and corrective actions within thirty (30) calendar days.

18. Remote control brachytherapy units shall be inspected and serviced in accordance with the manufacturer's recommendations. This inspection and servicing must be performed by persons specifically authorized to do so by the Department, and Agreement State, or the U.S. Nuclear Regulatory Commission. A report of the inspection and servicing must be kept on file for inspection by the Department.

19. The licensee shall, within 30 days of the effective date of the amendment, implement the procedures and record keeping requirements in the LICENSE ADDENDUM - High Dose Rate Remote Afterloader Units, dated 12/20/06.

20. The licensee shall follow the camera manufacturer's recommendations for radiation safety and quality assurance.

21. A. The licensee shall monitor the external surfaces of a package labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440, for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4;

B. The licensee shall monitor the external surfaces of a package labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440, for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Appendix A to 10 CFR 71.

22. **The licensee shall maintain doses to members of the public from licensed activities such that the total effective dose equivalent to an individual shall not exceed 100 millirem in one year. The total effective dose equivalent to an individual member of the public shall include doses resulting from exposure to patients administered radioactive materials while those patients remain on the licensee's premises.**

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Date: SEP 1 8 2019

By Daniel P Samson

Daniel J. Samson, CHP, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

DJS/AMM

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Sharon George
President
Vassar Health Connecticut, Inc.
d/b/a Sharon Hospital
50 Hospital Hill Road
Sharon, Connecticut 06069

Date
November 13, 2019

License Number(s)
06-08020-02

Mail Control Number(s)
616953

Licensing and/or Technical Reviewer or Branch
Medical Branch

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** October 19, 2019

The initial processing, which included an administrative review, has been performed.

☑ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, Request for Taxpayer Identification Number, located at the following link:**

http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Select a location (Use keyboard arrows to select). . .