

May 5, 2020

US NRC
Licensing Assistance Team
2100 Renaissance Boulevard
Suite 100
King of Prussia, PA 19406-2713

Re: Amendment request to materials license number 06-00843-03

Dear License Reviewer:

Please accept this letter as our request to re-instate Dr. Adam Kaye as an Authorized User to the license. Attached is a previous amendment of our license listing him as an AU.

Sincerely,



Brooke A. Karlsen
Regional Vice President, Operations

Enclosures: SVMC License #75

REC RG 1 0518 20 PM 02:43

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Amendment No. 75

U.S. NUCLEAR REGULATORY COMMISSION

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		In accordance with letter dated November 14, 2018.	4. Expiration Date: March 31, 2024
1. St. Vincent's Medical Center			5. Docket No.: 030-01245 Reference No.: 06-30182-01
2. 2800 Main Street Bridgeport, CT 06606		3. License number: 06-00843-03 is amended in its entirety to read as follows:	

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
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As Needed	A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As Needed	B. For use in imaging and localization studies permitted by 10 CFR 35.200.
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 500 millicuries total	C. For any use permitted by 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75.

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From: USNRC Region I DNMS

6103378266

02/14/2019 15:22

#197 P.002/007

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

06-00843-03

Docket or Reference Number

030-01245 06-30162-01

Amendment No. 75

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
D. Palladium-103 permitted by 10 CFR 35.400	D. Sealed Sources (IsoAid, L.L.C., Model IAPD-103A; North American Scientific, Inc., Model MED3633; Theragenics Corporation TheraSeed, Model 200)	D. 750 millicuries total	D. For any manual brachytherapy procedure permitted by 10 CFR 35.400 for which the patient can be released under the provisions of 10 CFR 35.75.
E. Iodine-125 permitted by 10 CFR 35.400	E. Sealed Sources (IsoAid, L.L.C., Model IAI-125A; Medi-Physics Inc., d/b/a GE Healthcare, Model 6711; North American Scientific, Inc., Model MED3631)	E. 750 millicuries total	E. For any manual brachytherapy procedure permitted by 10 CFR 35.400 for which the patient can be released under the provisions of 10 CFR 35.75.
F. Iridium-192 permitted by 10 CFR 35.600	F. Sealed Sources (Elekta, Inc. - formerly Nucletron [manufactured by Mallinckrodt Medical B.V., QSA Global, Inc., or Alpha-Omega Services, Inc.], Model 105.002)	F. 12 curies per source and 20 curies total	F. One source for medical use permitted by 10 CFR 35.600, in a Nucletron B.V. Model microSelectron 106.990 HDR remote afterloader. The source activity may not exceed 12 curies at the time of medical use. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.
G. Yttrium-90 permitted by 10 CFR 35.1000	G. Microspheres (Sirtex Wilmington LLC [manufactured by Sirtex Wilmington LLC, Sirtex Medical Limited, or Sirtex Singapore Manufacturing Pte Ltd.], Model SIR-Spheres)	G. 296 millicuries per vial and 592 millicuries total	G. For use in permanent manual brachytherapy using Sirtex Medical Limited SIR-Spheres Yttrium-90 microspheres and delivery system permitted by 10 CFR 35.1000.

CONDITIONS

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MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 06-00843-03	Docket or Reference Number 030-01245 06-30162-01												
	Amendment No. 75													
<p>10. A. Licensed material may be used or stored at the licensee's facilities located at 2800 Main Street, Bridgeport, Connecticut.</p> <p>B. Licensed material listed in Subitem No. 6.B. may be used or stored at the licensee's facilities located at the St. Vincent's Regional Heart and Vascular Center, 2979 Main Street, Bridgeport, Connecticut, and Cardiology Physicians of Fairfield County, LLC, d/b/a The Cardiology Group, 1952 Whitney Avenue, 1st Floor, Hamden, Connecticut.</p> <p>C. Licensed material listed in Subitem Nos. 6.A. and 6.B. may be used or stored at the licensee's facilities located at 40 Cross Street, Norwalk, Connecticut; and 1177 Summer Street, Stamford, Connecticut.</p> <p>11. The Radiation Safety Officer (RSO) for this license is Jason Bond, M.S., DABR.</p> <p>12. Licensed material shall only be used by, or under the supervision of:</p> <p>A. Individuals permitted to work as authorized users and/or authorized medical physicists in accordance with 10 CFR 35.13 and 10 CFR 35.14.</p> <p>B. Physicians permitted to work as authorized users for Yttrium 90 SIR-Spheres in accordance with the commitments for notification to the NRC in the letter dated December 2, 2010.</p> <p>C. The following individuals are authorized users for the material and medical uses as indicated:</p> <table style="width: 100%; border: none;"> <thead> <tr> <th style="text-align: left;"><u>Authorized Users</u></th> <th style="text-align: left;"><u>Material and Use</u></th> </tr> </thead> <tbody> <tr> <td>Jonathan Brier, M.D.</td> <td>10 CFR 35.200</td> </tr> <tr> <td>Steven M. Cohen, M.D.</td> <td>10 CFR 35.100, 10 CFR 35.200; Oral administration of sodium iodide I-131</td> </tr> <tr> <td>Thomas DiBartholomeo, M.D.</td> <td>10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300; Yttrium 90 SIR-Spheres</td> </tr> <tr> <td>Terence W. Hughes, M.D.</td> <td>Yttrium 90 SIR-Spheres</td> </tr> <tr> <td>Christopher M. Ianuzzi, M.D.</td> <td>10 CFR 35.400; Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required; Iridium 192 in a High Dose Rate Remote Afterloader Unit</td> </tr> </tbody> </table>			<u>Authorized Users</u>	<u>Material and Use</u>	Jonathan Brier, M.D.	10 CFR 35.200	Steven M. Cohen, M.D.	10 CFR 35.100, 10 CFR 35.200; Oral administration of sodium iodide I-131	Thomas DiBartholomeo, M.D.	10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300; Yttrium 90 SIR-Spheres	Terence W. Hughes, M.D.	Yttrium 90 SIR-Spheres	Christopher M. Ianuzzi, M.D.	10 CFR 35.400; Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required; Iridium 192 in a High Dose Rate Remote Afterloader Unit
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SUPPLEMENTARY SHEET

License Number

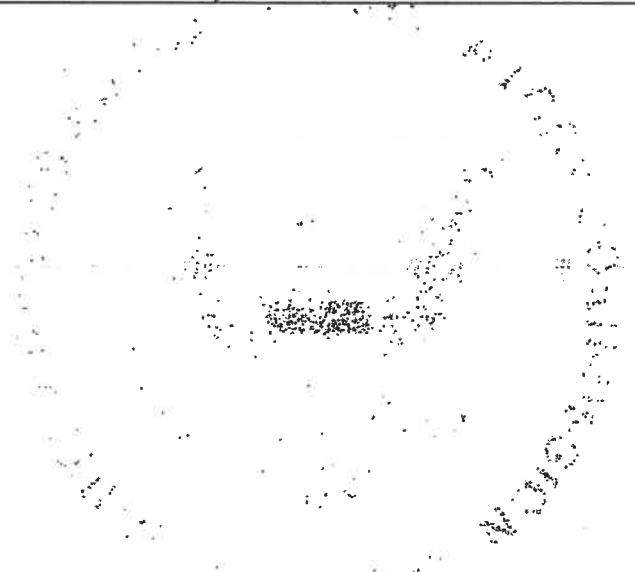
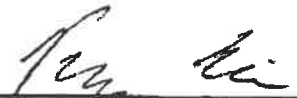
06-00843-03

Docket or Reference Number

030-01245 06-30162-01

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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) for establishing decommissioning financial assurance.
14. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26 and applicable guidance updates for 10 CFR 35.1000 uses. 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. Letter dated January 28, 2009 [ML090420463]
 - B. Letter dated December 7, 2009 [ML093410532]
 - C. Letter dated December 2, 2010 [ML103470499]
 - D. Application dated September 30, 2013 [ML13296A778], except 115 Technology Drive & 4675 Main Street Facilities
 - E. Letter dated February 20, 2014 [ML14083A283], except 115 Technology Drive & 4675 Main Street equipment
 - F. Letter dated March 14, 2014 [ML14078A426], except 115 Technology Drive Facility
 - G. Letter dated March 26, 2014 [ML14087A213]
 - H. Letter dated April 30, 2014 [ML14134A107]
 - I. Letter dated June 4, 2014 [ML14164A473]
 - J. Letter dated August 18, 2014 [ML14239A339]
 - K. Letter dated September 4, 2014 [ML14259A239]
 - L. Letter dated October 16, 2014 [ML14297A365]

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continued M. Letter dated December 4, 2017 [ML17347A056]		
		
FOR THE U.S. NUCLEAR REGULATORY COMMISSION		
Date: <u>January 25, 2019</u>	By: <u></u> Penny Lanzisera Region 1	
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