



Affiliate Columbia University College of Physicians and Surgeons
Member NewYork-Presbyterian Healthcare System
A Planetree Hospital

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To: USNRC, Region I Office
NMSB - Medical Licensing
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

June 11, 2018

Re: Amendment requested to Materials License #06-06697-02, Docket #030-01265

The following information is submitted for an amendment to the Materials License of our institution.

ITEM 1. Additional AU privileges.

Presently, Bryan Lazzara, MD, and, Josef Noga, MD are Authorized Users on the Materials License. We request to add the use of Yttrium-90 SIR-Spheres to both physicians. Enclosed are copies of the Sirtex Medical documentation for their training in the Y-90 SIR-Spheres program.

ITEM 2. Removal of AUs.

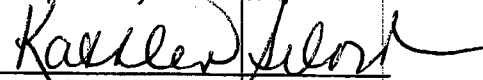
The following AUs are no longer required on the Materials License:

Steven Horowitz, MD
William Caragol, MD

If you have any questions or desire additional information please contact Ms. Elizabeth Manfredo, Cancer Center Director at 203-276-7886, or Mr. Mas at 203-276-4036 and email of pmas@stamhealth.org.

Thank you for your time and efforts with our requests.

Respectfully submitted,


Kathleen Silard, RN, BSN, MS, FACHE,
Executive VP, COO



SIRTEX MEDICAL INC.
300 Unicorn Park Drive
Woburn, MA 01801
Tel: +1 (781) 721 3800
Fax: +1 (781) 721 3880

Ref: 104US07

May 31st, 2018

Bryan Lazzara, M.D.
Stamford Hospital – Department of Radiology
1 Hospital Plaza, Stamford, CT 06902

Dear Dr. Lazzara,

Re: SIR-Spheres[®] Microspheres Authorized User Training and Certification

This letter certifies that on May 31st, 2018, you successfully completed training in the operation of the delivery system, safety procedures and clinical use of SIR-Spheres yttrium-90 microspheres that are to be injected via the hepatic artery to treat patients with unresectable liver tumors in accordance with the June 2012 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures as well as encompassing the following:

- a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- b) Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;
- c) Evaluation of each patient for the dose/activity of Y-90 microspheres to be administered to each treatment site;
- d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient;
- e) Using administrative controls to prevent a medical event involving the use of byproduct material;
- f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures; and
- g) Follow up and review of each patient's case history for Y-90 microspheres

Once your license has been appropriately amended, Sirtex will arrange with you to have a proctor oversee your first three (3) patient treatments at a minimum, including being on site for each case.

[®] SIR-Spheres is a Registered Trademark of Sirtex SIR-Spheres Pty Ltd

Sirtex would like to thank you for your support in this process.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'George Cross', written in a cursive style.

George Cross
Regional Sales Manager
Sirtex Medical



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300 Unicorn Park Drive
Woburn, MA 01801
Tel: +1 (781) 721 3800
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Ref: 104US07

May 31st, 2018

Josef Noga, M.D.
Stamford Hospital – Department of Radiology
1 Hospital Plaza, Stamford, CT 06902

Dear Dr. Noga,

Re: SIR-Spheres® Microspheres Authorized User Training and Certification

This letter certifies that on May 31st, 2018, you successfully completed training in the operation of the delivery system, safety procedures and clinical use of SIR-Spheres yttrium-90 microspheres that are to be injected via the hepatic artery to treat patients with unresectable liver tumors in accordance with the June 2012 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures as well as encompassing the following:

- a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- b) Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;
- c) Evaluation of each patient for the dose/activity of Y-90 microspheres to be administered to each treatment site;
- d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient;
- e) Using administrative controls to prevent a medical event involving the use of byproduct material;
- f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures; and
- g) Follow up and review of each patient's case history for Y-90 microspheres

Once your license has been appropriately amended, Sirtex will arrange with you to have a proctor oversee your first three (3) patient treatments at a minimum, including being on site for each case.

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George Cross
Regional Sales Manager
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ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee Kathy Silard Executive Vice President and Chief Operating Officer Stamford Hospital 1 Hospital Plaza Stamford, Connecticut 06904	Date June 27, 2018
	License Number(s) 06-06697-02
	Mail Control Number(s) 609204
	Licensing and/or Technical Reviewer or Branch Medical Branch

This is to acknowledge receipt of your: Letter and/or Application Dated: June 11, 2018

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 complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
 Follow the instructions on the form for submission.

The following administrative omissions have been identified:
 [Empty box for listing omissions]

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:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, (610) 337-5239