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

To: Licensing Assistance Team – Division of Nuclear Materials
USNRC, Region I Office
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

March 1st 2016

Re: Amendment requested for Materials License #06-06697-02 & #06-06697-03

Our Hospital would like to make an address change to our existing licenses. We would also like to submit the final physician Sirtex source sphere Y-90 credentialing for Dr's Masino and Stainken. License #06-06697-02 will have two changes – address and Y-90 AU's. License #06-06697-03 is only an address change.

To better serve our community Stamford Hospital is in the process of building a new patient care building. While none of our current licensed nuclides are moving to the new building we would like to change our address for the entire campus prior to opening the new facility. As of April 1st 2016 the new address will be:

Stamford Hospital
1 Hospital Plaza
Stamford, CT 06902

The paperwork for Dr Masino, third case Y-90, and Dr Stainken, previously approved user at Rodger Williams Medical Center has been submitted by email and is included as an attachment to this letter.

If you have any questions or desire additional information, please contact our RSO Sarah Bull at 203- 276-4036 or 203-417-3996, or via email; SBULL1@stamhealth.org.

Thank you for your time and efforts with our requests.

Respectfully submitted,

Kathy Silard, Executive VP & Chief Operating Officer

REC'D IN LIT 03/04/2016

590405/590406
NMSS/RGNI MATERIALS-002

Roger Williams Medical Center

AUTHORIZATION TO USE RADIOACTIVE MATERIALS

An authorization is hereby issued allowing the user to receive, acquire, and possess the radioactive material listed below; and to use such material for the purpose(s) and at the place(s) designated below. This authorization is subject to the applicable rules, regulations, and conditions of the Roger Williams Medical Center Radiation Safety Policy Manual and to any conditions specified below.

1. Name of Principal User: Dr. Gary Marecek

4. Amendment Number: 32

2. Department: Radiology

5. Expiration Date: September 30, 2016

3. Authorization Number: R301-033

6. Radioisotope	7. Form of Material	8. Maximum Activity (Unit)	9. Authorized Use
I-131	Sodium Iodine (Capsule Form)	250.00000 mCi	For thyroid ablation therapy, cancer, and treatment of hyperthyroidism
P-32	Chloride (Liquid)	50.00000 mCi	For infusions as pain mitigation
Sm-153	Chloride (Liquid)	20.00000 mCi	For relief of pain in patients with confirmed osteoblastic metastatic bone lesions
Sr-89	Chloride (Liquid)	15.00000 mCi	Treatment of cancer related bone pain
Y-90	Ibritumomab tiuxetan (liquid)	65.00000 mCi	For treatment of non-Hodgkin's Lymphoma
Y-90	Microspheres	550.00000 mCi	Treatment of Malignant Hepatic Tumors

10. Use Labs

Roger Williams Medical Center

NUG Med

11. Independent Users

Dr. BRIAN STAINKEN

Dr. JOSEPH R TUCCI

Conditions

Joseph Tucci, M.D. (Limited to I-131)

Brian Stainken, M.D. (Limited to Y-90)

12. The above radioactive material may be used by, or under the supervision of Gary Marecek, M.D., Joseph R. Tucci, M.D. (only 131I), or Brian Stainken M.D. (Y-90 only), in accordance with statements made in amendment application dated 10/29/2007, renewal application dated 8/20/2014, and prior related application amendments (March 1999, September 2003 and February 2004). Written directives are required for all patient administrations.

13. 131I patients may not receive more than 33 mCi on an outpatient basis without prior approval of the Radiation Safety Officer. 89Sr patients may not receive more than 4 mCi per treatment.

14. 90Y Ibritumomab tiuxetan radiopharmaceutical must be a unit dose from an authorized nuclear pharmacy.

15. All technologists and physicians involved in 131I therapies will submit to thyroid bioassay procedures as prescribed by RSO.

16. Staff to receive vendor specific training prior to use of Y-90 microspheres. Physicians shall be approved for use by the credentialing office.

Roger Williams Medical Center
AUTHORIZATION TO USE RADIOACTIVE MATERIALS

For the RWMC Radiation Safety Committee

September 26, 2014

Approval Date

Roger Williams Medical Center



Radiation Safety Officer

Form RS-5-5/92



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

Ref: 104US07

March 18, 2014

Dr. Frank Masino
Radiation Oncologist
Stamford Hospital
34 Shelburne Road
Stamford, CT 06902

Handwritten signature and date: 3/28/16

Dear Dr. Masino

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

This letter certifies that on March 18, 2014 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.

This is to acknowledge the receipt of your letter application dated

03/01/2016, and to inform you that the initial processing which includes an administrative review has been performed.

06-06697-03
06-06697-03 (Amendment)
☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 590405/590406
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader.