



DANBURY HOSPITAL

24 Hospital Ave
Danbury, CT 06810
203.739.7000
DanburyHospital.org

Br.1

February 8, 2016

Penny Lanzisera
Senior Health Physicist
U.S. NRC Region 1
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

SUBJECT: DANBURY HOSPITAL, LICENSE AMENDMENT, LICENSE # 06-08544-01 /03001274

Dear Ms. Lanzisera:

Please find enclosed the letter from the manufacturer's representative, Adam Paster, documenting the completion of three proctored Y-90 cases by Fatejeet Sandhu, M.D.

If there is anything further that is needed please contact me. Thank you!

Ruth Shanley
Radiation Safety Coordinator, WCHN
203-739-7182
ruth.shanley@wchn.org

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590303
INNOVATION MATERIALS-002



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

Ref: 104US07

December 3, 2014

Dr. Jeet Sandhu
Interventional Radiology
Danbury Hospital
24 Hospital Ave
Danbury, CT 06810

Dear Dr. Sandhu,

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

This letter certifies that on November 14, 2013 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 by-product material;
- f) Using procedures to control and to contain spilled by-product 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 and/or manufacturer representative oversee your first three (3) patient treatments at a minimum, including being on site for each case.

Manufacturer representative was onsite for 3 proctored cases, including the final infusion that took place on 1/11/16.

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

Yours sincerely,


Adam Paster
Regional Sales Manager

This is to acknowledge the receipt of your letter/application dated

02/08/2016, and to inform you that the initial processing which includes an administrative review has been performed.

☒ 06-08544-01 (Notification)
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 590303.
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.