

 WESTERN CONNECTICUT HEALTH NETWORK
DANBURY HOSPITAL

P-6

24 Hospital Ave
Danbury, CT 06810
203.739.7000
DanburyHospital.org

March 13, 2015

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

03001274

REC'D 1032145 AM 03/13/15

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

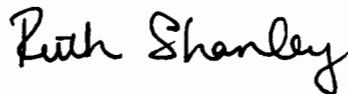
Dear Ms. Lanzisera:

Please find enclosed:

- Section 10 revision
- Confirmation of in vitro training for SIR-Spheres Y-90 for Dr. Seema Sanghavi
- Letter confirming that our RSO, Vladimir Monastyrchenko, Ph.D., was present for this training.

Dr. Sandhu is gathering his documentation for the 80 hours of didactic/lab training and I will forward that as soon as I receive it.

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

586115
NMSS/RGN1 MATERIALS 002

DANBURY HOSPITAL

24 Hospital Ave
Danbury, CT 06810
203.739.7000
DanburyHospital.org

March 12, 2015

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, Y-90 Revision

Dear Ms. Lanzisera:

As per your instruction, we have revised the wording of the first paragraph and the wording of 10.a., as well as changing 35.100 to 35.1000. The following is our revision of Section 10:

10. We request the authority through the Danbury Hospital's Radiation Safety Committee to allow for future changes and revisions to our Radiation Safety Program for Y-90 SIR-Spheres without the need for submitting an amendment request. These changes would be due to revisions to the NRC procedures for this use, including updated guidance publications for this radioactive material. In order to have this item request approved, we commit to the following conditions:
 - a. the program revision is in compliance with the regulations and
 - b. the revision is based on NRC's current guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC Web site; and
 - c. the program revision has been reviewed and approved by the Radiation Safety Officer and signed by the licensee's management; and
 - d. the affected individuals shall be instructed on the revisions to the program prior to the changes being implemented;
 - e. the licensee will retain a record of each program revision for five years; and
 - f. this record will contain a copy of the appropriate web site guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

Thank you for your prompt consideration of this matter. If you have any questions, please contact either Ruth Shanley, Radiation Safety Coordinator, at 203-739-7182, ruth.shanley@wchn.org or Vladimir Monastyrenko, RSO for Danbury Hospital at 203-739-7904, vladimir.monastyrenko@wchn.org.

Sincerely,

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

James Haynes

Vice President of Operations

24 Hospital Avenue

Danbury, CT 06810



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

Ref: 104US07

November 17, 2014

Dr. Seema Sanghavi
Radiation Oncologist
Danbury Hospital
24 Hospital Ave
Danbury, CT 06810

Dear Dr. Sanghavi,,

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


This letter certifies that on November 14, 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 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 oversee your first three (3) patient treatments at a minimum, including being on site for each case.

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

Yours sincerely,


Adam Paster
Regional Sales Manager



Sirtex Medical Inc.

300 Unicorn Park Drive
Woburn, MA 01801

Phone: +1 (781) 721-3800
+1 (888) 4-SIRTEX
Fax: +1 (781) 721-3880
Website: www.sirtex.com

March 13, 2015

To Whom It May Concern;

This letter is to confirm that Vladimir Monastyrenko was present for the Sirtex Authorized User Training that took place on November 17, 2014. Vladimir observed the training in its entirety. If you need any additional information concerning this matter please let me know.

Thank You,

A handwritten signature in cursive script that reads "Adam Paster".

Adam Paster
Regional Sales Manager
Sirtex Medical
apaster@sirtex.com
201-233-1778