

Indiana University Health LaPorte Hospital
1007 Lincolnway
LaPorte, Indiana 46350-0250

February 25, 2013

U.S. Nuclear Regulatory Commission
Radioisotopes Licensing Division
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Subject: Sir-Spheres

RE: NRC Radioactive Materials License #13-15151-01

Dear Sir or Madam:

1. We request the addition of Yttrium 90 (Y-90) microspheres under 35.1000.

Y-90 SIRTEX Medical Inc. Sir-spheres 1 Ci

2. We request the addition of Dr Syed I. Ali as the authorized user for this material. Dr Ali is currently authorized 35.300 uses on our license. Reference our current license amendment #47 for his AU qualifications. He meets the training requirements of 10CFR390 and is an ABR certified interventional radiologist. He has completed the training for the Y-90 Sir-spheres as documented in the attached letter from SIRTEX. This training included three supervised hands-on in-vitro simulated cases.
3. We understand and commit to all of the requirements as listed on the "Microsphere Brachytherapy Sources and Devices", Revised June 2012. Dr Ali has the training as listed in items A3) i, ii, iii and the requirements in B as provided by the manufacture.
4. Once the authority for this procedure is added to the license SIRTEX will provide a proctor on site for the first three cases.

If you have any questions regarding this notification, please contact me at (815) 370-6538.

Sincerely,



James C. Hatten
Radiation Safety Officer

jch

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

Ref: 104US07

November 12, 2012

Dr. Syed I. Ali
Interventional Radiologist
IU La Porte Hospital
1007 Lincolnway
La Porte, IN 46350

Dear Dr. Ali,

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

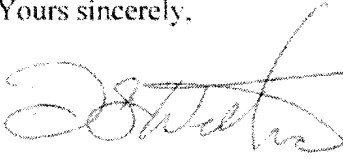
This letter certifies that on October 1, 2012 you successfully completed training in the operation of the delivery system, safety procedures and clinical use of SIR-Spheres yttrium-90 microspheres that are to be injected via the hepatic artery to treat patients with unresectable liver tumors in accordance 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,

A handwritten signature in cursive script, appearing to read "Derek S. Webster". The signature is written in black ink and is positioned above the printed name and title.

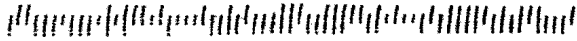
Derek S. Webster
Regional Sales Manager

cc:

Brad Boring
Central Area Manager

sahci Stan A. Huber Consultants, Inc.
Health Physics and Radiation Safety Services

200 North Cedar Road • New Lenox, Illinois 60451-1751



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