

**SAINT JOSEPH**  
Regional Medical Center

July 24, 2013

Dennis P. O'Dowd, Health Physicist  
United States Nuclear Regulatory Commission  
Region III, Materials Licensing  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

RE: Control #580601  
Amendment to NRC License No. 13-02650-02  
**Saint Joseph Regional Medical Center**  
**Additional Information**

Mr. O'Dowd:

Please find the attached training documentation from SIRTex for Dr. King. This letter certifies that on October 1, 2012, Dr. King successfully completed training which included (3) supervised hands-on in-vitro simulated set-up and delivery procedures that demonstrate possible issues encountered during the yttrium-90 microsphere administration.

In addition, the SIR-Spheres yttrium-90 microspheres will be used and stored at the 5215 Holy Cross Parkway, Mishawaka, Indiana facility. The maximum Yttrium-90 activity per vial is 189 mCi. We are requesting a possession limit of 1 Ci. If you need additional information, please contact our Radiation Safety Officer, Sharon Updike, at 734-662-3197.

Sincerely,



Christopher Karam, Chief Operating Officer  
Saint Joseph Regional Medical Center

**Mishawaka**  
5215 Holy Cross Parkway  
Mishawaka, IN 46545  
574.335.5000

**Plymouth**  
1915 Lake Avenue  
Plymouth, IN 46563  
574.936.3181

**South Bend**  
837 East Cedar Street  
South Bend, IN 46617  
574.335.5000

**Rehabilitation Institute**  
60205 Bodnar Boulevard  
Mishawaka, IN 46544  
574.335.8800

**Physician Network**  
810 East Park Place  
Mishawaka, IN 46545  
574.335.8758

**The Foundation**  
837 East Cedar Street, Suite 350  
South Bend, IN 46617  
574.237.7377

**Outreach Services**  
215 West 4th Street, Suite LL201  
Mishawaka, IN 46544  
574.335.3888

**Graduate Medical Education**  
611 E Douglas Rd., Ste. 412  
Mishawaka, IN 46545  
574.335.6550



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

Ref: 104US07

October 8, 2012

Dr. Scott King  
Interventional Radiologist  
Saint Joseph Regional Medical Center  
5215 Holy Cross Parkway  
Mishawaka, IN 46545

Dear Dr. King,

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

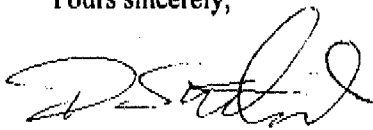
This letter certifies that on October 1, 2012, you successfully completed training in the operation of the delivery system, safety procedures and clinical use of SIR-Spheres yttrium-90 microspheres that are to be injected via the hepatic artery to treat patients with unresectable liver tumors in accordance 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 black ink, appearing to read "D. Webster", written in a cursive style.

**Derek S. Webster**  
**Regional Sales Manager**

cc:

**Brad Boring**  
**Central Area Manager**