

April 26, 2010

Penny Lanzisera  
Senior Health Physicist  
U.S Nuclear Regulatory Commission, Region 1  
Division of Nuclear Materials Safety  
475 Allendale Road  
King of Prussia, PA 19406-1415

MS 16

P-6

2010 APR 28 AM 10:44

RECEIVED  
REGION 1

**RE: *Bridgeport Hospital Amendment Request for License No: 06-01060-01  
Docket Number 030-01247  
Mail Control No. 144426***

Dear Penny Lanzisera,

Please find below the responses to your request for additional information to support the addition of SirSpheres.

1. We were just notified by SIRTex (see attached memo dated March 31, 2010) that they are changing their delivery schedule resulting in product delivered one day prior to calibration. As a result the new minimum activity for the Individual Source Limit is 4.89GBq (132mCi) per vial of SIR-Spheres microspheres. Our maximum activity request per vial is 132mCi per vial. Our total possession limit will be 264mCi.
2. At this time we would like to withdraw our request, without prejudice, for Dr Hughes to be an authorized user.
3. Please find attached signed vendor training certifications for Drs. Zinn and Williams.
4. This is to confirm that we will submit documentation to NRC Region 1 within 30 days following completion of three hands-on clinical cases supervised in the presence of the manufacturer's representative.

267 Grant Street  
P.O. Box 5000  
Bridgeport, CT 06610-0120  
203.384.3000

144426

5. This is to confirm that we will be following the manufacturer's procedures for calculating/documenting the dose to the treatment site and other sites, preparing the dose, and performing pre/post vial dose measurements as stated in our procedure as submitted.
6. We confirm that:
  - a. When Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer, we, the licensee, will label the vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres) and label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).
  - b. We will comply with medical event reporting and notification requirements as described in 10 CFR 35.3045(b) – (g) in addition to reporting requirements identified in the licensing guidance.
  - c. We will, as the authorized user, consult, as necessary, with individuals with expertise in cancer management (e.g., radiation or medical oncology), catheter placement, radiation dosimetry, and safe handling of unsealed byproduct material.

If you should have any questions please feel free to contact me at 203-384-3169.

Sincerely,



Michael R. Tatta  
Director Imaging Services

Cc: Scott Williams, MD  
Patrick Schmincke



**Sirtex Medical Inc.**  
16 Upton Drive, #2-4  
Wilmington, MA 01887

Telephone: (888) 474-7839  
Fax: (978) 229-9585  
Web: [www.sirtex.com](http://www.sirtex.com)

**\*\* IMMEDIATE ATTENTION REQUIRED \*\***

March 31, 2010

**URGENT: Sirtex SIR-Spheres® microspheres Users and  
Radiation Safety Officers (RSOs)**

In order to meet customer requests and minimize shipping delays, Sirtex is preparing to change the delivery schedule of SIR-Spheres microspheres. This change will result in the product being received the day prior to calibration.

In order to be able to receive the product, you will need to amend your license in relation to our product and the new Individual Source Limit, Total Possession Limit or both. The new minimum activity for the Individual Source Limit is 4.89GBq (132mCi) per vial of SIR-Spheres microspheres. In addition to your Individual Source Limit changing, you will need to amend the total amount of SIR-Spheres microspheres you have on-hand at any one point in time. This is dependent on how many doses you expect to receive at one time.

We will send you additional information on this product change as the date for implementation gets closer, but please **submit the appropriate paperwork immediately** so that your facility can continue to receive SIR-Spheres microspheres. If this change in your license is not completed, you will no longer be able to receive SIR-Spheres microspheres once the earlier delivery schedule is implemented. We are anticipating a "go live" date of July 2010.

You may require the following information:

**Distributor:** Sirtex Wilmington LLC  
16 Upton Drive., #2-4 Wilmington, MA 01887

**Sealed Source Model Designation:** Sirtex Medical Limited  
SIR-Spheres® microspheres Y001

**Isotope:** Yttrium-90

**Required Activity:** 4.89 GBq (132 mCi) per vial (minimum requirements)

Thank you in advance for your assistance with this matter. Please contact your local representative if you need assistance or have any questions.

---

® SIR-Spheres is a Registered Trademark of Sirtex SIR-Spheres Pty Ltd



SIRTEX MEDICAL, INC.  
16 Upton Drive, #2-4  
Wilmington, MA 01887  
Tel: 978 642 3000

Ref: 104US03

June 9, 2009

Kenneth Zinn, M.D.  
Interventional Radiologist/AU  
267 Grant Street  
Bridgeport, CT 06610

Dear Dr. Zinn:

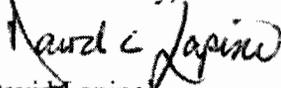
**Re: SIR-Spheres® Microspheres Authorized User Training and Certification**

This letter certifies that on June 9, 2009 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 September 2008 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures that demonstrate possible issues encountered during the yttrium-90 microsphere administration.

Following the license amendment that names you as an AU for SIR-Spheres yttrium-90 microspheres use, Sirtex will arrange for the first three (3) *in-vivo* patient cases to be performed in the physical presence of a Sirtex proctor.

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

Yours sincerely,

  
David Lapine  
Regional Sales Manager

cc: Scott Williams, MD – Nuclear Medicine/AU



SIRTEX MEDICAL, INC.  
16 Upton Drive, #2-4  
Wilmington, MA 01887  
Tel: 978 642 3000

Ref: 104US03

June 9, 2009

Scott Williams, MD  
Nuclear Medicine/AU  
267 Grant Street  
Bridgeport, CT 06610

Dear Dr. Williams:

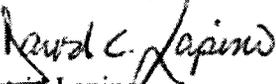
**Re: SIR-Spheres<sup>®</sup> Microspheres Authorized User Training and Certification**

This letter certifies that on June 9, 2009 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 September 2008 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures that demonstrate possible issues encountered during the yttrium-90 microsphere administration.

Following the license amendment that names you as an AU for SIR-Spheres yttrium-90 microspheres use, Sirtex will arrange for the first three (3) *in-vivo* patient cases to be performed in the physical presence of a Sirtex proctor.

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

Yours sincerely,

  
David Lapine  
Regional Sales Manager

cc: Kenneth Zinn, M.D. – Chief of Interventional Radiology/AU