



85 East US Highway 6
Valparaiso, IN 46383
219-983-8300
www.porterhealth.com

May 16, 2013

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Branch
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532

Re: Amendment to 13-17073-01

Dear madam or Sir:

We wish to amend our Materials License 13-17073-01 as follows:

AUTHORIZED USER

We wish to expand the approved authorized privileges granted to:

- Vivek Mishra, M.D. Add Y-90 SIR Spheres as per 35.1000

In support of this request we have enclosed a confirmation letter from SIRTEX dated May 14, 2013, which notes completion of three (3) manufacturer proctored in vitro cases as required. We confirm that we will notify NRC of the completion of three(3) live manufacturer proctored cases as additionally required.

If you have any questions, please contact our Medical Nuclear Physicist, Thomas M. Kumpuris, M.S. of Medical Physics Consultants at tkumpuris@mpcphysics.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'B. Sinotte'.

Brian Sinotte
Chief Operating Officer

RECEIVED MAY 24 2013



SIRTEX MEDICAL INC.

300 Unicorn Park Drive

Woburn, MA 01801

Tel: +1 (781) 721 3800

Fax: +1 (781) 721 3880

Ref: 104US07

May 14, 2013

Vivek Mishra, MD
Interventional Radiologist
Porter Health Care System
85 East US Hwy 6
Valparaiso, IN 46383

Dear Dr. Mishra,

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

This letter certifies that on May 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 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 Webster", followed by a long horizontal line extending to the right.

Derek Webster
Regional Sales Manager

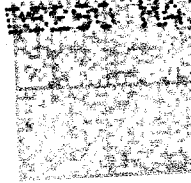
cc:Brad Boring
Area Sales Manager



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Valparaiso, IN 46383

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