



US NRC
Materials Licensing Branch
2443 Warrenville Rd, Suite 210
Lisle, IL 60532-4352
ATTN: License Amendment

RE: License Amendment Request to add SIR-Spheres, Yttrium 90 microspheres, produced by SIRTEX Medical Ltd.

Dear License Reviewer:

Please amend our radioactive material license, number 21-01190-05 for St. John Macomb Oakland Hospital, Macomb Center, to include Y-90 as microspheres for use in the Model **SIR-Spheres**, Brachytherapy Device. Authorization is requested for 189 mCi maximum activity per vial and for a 5 vial maximum possession limit of 945 mCi provided by SIRTEX Medical Ltd in accordance with FDA requirements.

The authorized user who has completed his training with the SIRTEX vendor and attached training paperwork. We confirm we will perform the first three actual SIRTEX SIR-Sphere Y-90 procedures with the vendor assist.

The requested activity and multiple activity holdings are required for the anticipated administration into malignant hepatic tumors.

The proposed changes to our radioactive material medical use program have been approved by the Radiation Safety Committee.

Sincerely,

A handwritten signature in black ink, appearing to read 'Laura T. Smith', written over a circular stamp.

Laura T. Smith, MS, DABR
Radiation Safety Officer
lsphysics@att.net
pager 313 609-2038

SIRTeX

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

Ref: 104US05

October 31, 2011

Dr. Philip Adler
Interventional Radiologist
St. John Macomb-Oakland Hospital, Macomb Center
11800 E. 12 Mile Road
Warren, MI 48093

Dear Dr. Adler,

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

This letter certifies that on October 31, 2011, 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 January 2011 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.

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

Yours sincerely,



Terry Hendricks
Regional Sales Manager

cc: Laura T. Smith, MS, DABR
Linda Teigland, Director of Operations

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facsimile transmittal

To: NRC – License Amendment **Fax:** 16308299782

From: Laura T. Smith **Date:** 11/6/2011

Re: License Amendment **Pages:** 3

CC:

Urgent For Review Please Comment Please Reply Please Recycle

Note:
 Please contact me with any questions at all regarding Sir-Spheres.

I prefer email communications but am also available by pager 313 609-2038.
 lsphysics@att.net
 =)
 Laura Smith, MS, DABR

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