

# Research Medical Center™

Your HCA Midwest Hospital

11 May 2012

U. S. Nuclear Regulatory Commission  
Region III  
Materials Licensing Section  
2443 Warrensville Road, Suite 210  
Lisle, Illinois 60532-4352

Attn.: Colleen Carol Casey

Re: Additional information to control number 576359

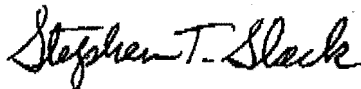
David Shaeffer, M. D. was approved for Y-90 microspheres as SIR-Spheres under license 24-18625-01, held by Research Medical Center, subject to the condition of completion of three cases in the physical presence of a manufacturer's representative.

On May 1, 2 and 3, Dr. Shaeffer served as authorized user in the delivery of SIR-Spheres Y-90 microspheres in the presence of a SIR-TeX company representative. He received additional training as part of each case.

A copy of a letter from Tom Fromm of SIR-TeX is enclosed. In addition, I was present at each of these cases and can attest to Dr. Shaeffer's further training and experience.

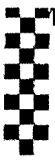
Should you need any further information, please feel free to contact us at (816) 276-4449.

Sincerely,



Stephen T. Slack, Ph. D.  
Radiation Safety Officer

Enclosure



# SIRTeX

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

Ref: 104US05

May 7th, 2012

David Shaeffer, MD  
Radiation Oncologist  
Research Medical Center  
2316 East Meyer Blvd.  
Kansas City, MO 64132

Dear Dr Shaeffer,

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

This letter certifies that on May 1<sup>st</sup>, May 2<sup>nd</sup>, and May 3<sup>rd</sup> 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 October 2011 NRC guidance. This training included three (3) supervised hands-on *in-vitro* 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,

Tom Fromm  
Regional Sales Manager

Cc: Linda Teigland

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Received Time May. 9. 1:33PM

Midwest Gamma Knife Center

Research Medical Center

FAX Cover Sheet

TO: *USNRC Materials Licensing*

From: Stephen T. Slack,

Return FAX number: (816) 276-3478

Date: *5/11/12*

*Attn: Colleen Carol Casey*

*Additional Information re control # 576359*