

Holy Name Hospital

Member
New York-Presbyterian Healthcare System
Affiliate Columbia University College of Physicians & Surgeons

718 Teaneck Road | Teaneck, New Jersey 07666
Tel: 201-833-3000 | www.holyname.org

March 10, 2009

K-8

Licensing Materials Section
Nuclear Materials Branch
U. S. Nuclear Regulatory Commission, Region 1
475 Allendale Avenue
King of Prussia, PA 19406-1415

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2009 MAR 16 PM 12:26

Dear License Reviewer:

030 02472

With regard to mail control number 142665 for our Radioactive Materials License No. 29-03382-01, we are submitting to you the qualification letter from Sirtex Medical Inc. (Addendum A). This letter states that we have fulfilled the manufacturer requirements of three (3) proctored cases for the use of Y90 Sir-Spheres®, as per our previous amendment request.

If you have any questions regarding this application, please contact Allan Caggiano, Chief Medical Physicist at (201) 541-6369 or by email at caggiano@holyname.org.

Sincerely,



Jacqueline C. Brunetti, MD
Radiation Safety Officer

JCB:md
cc: Michael Maron, President & CEO
Enclosure

143544

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Sirtex Medical Inc.

16 Upton Drive, #2-4
Wilmington, MA 01887

Telephone: (888) 474-7839

Fax: (978) 229-9585

Web: www.sirtex.com

Allan J. Caggiano, M.S., D.A.B.R.
Senior Medical Physicist
Radiation Oncology
Holy Name Hospital
718 Teaneck, NJ 07666

March 3, 2009

Mr. Caggiano:

This is to inform you that doctors:

John Rundback, MD- Interventional Radiologist
Benjamin Rosenbluth, MD- Radiation Oncologist/ AU

have completed the Sirtex Training, Evaluation, and Certification Program.
Both doctors have been proctored by a Sirtex proctor for three (3) cases and are now qualified to receive, handle and use SIR-Spheres for treating patients with unresectable liver tumors.

If you have any questions or require additional details about SIR-Spheres, please feel free to contact me.

Best Regards,

Craig Lawrence
Sirtex Medical
Regional Sales Manager
Mobile- 516-695-0455
clawrence@thsirtex.com

This is to acknowledge the receipt of your letter/application dated

3/10/2009, and to inform you that the initial processing which includes an administrative review has been performed.

AMC 29-03382-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 143544
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.