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JUN 25 2018

DNMS

United States Nuclear Regulatory Commission
Region IV
1600 E. Lamar Blvd.
Arlington, Texas 76077-4511

Re: Completion of required training for Dr. Lenter, license 40-18000-01 item 6.G in reference to Amendment Number 37

Dear Michelle R. Simmons, Health Physicist Nuclear Medicine Materials Safety Branch B,

Please find enclosed documentation from the manufacture of Dr. Les Lenter's required hands-on patient cases. The cases were supervised by a certified proctor provided by Sirtex. This should complete the requirements for Dr. Lenter as an authorized user for Y-90 SIR Spheres .

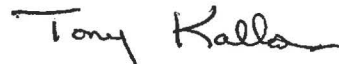
If there are any questions or further information regarding this, please contact our Lead Nuclear Medicine Technologist David Martin at 605-622-5072 or Tony Kallas, Radiology Department Manager at 60-622-5071.

Thank You

Regards



David Martin RT(R) CNMT



Tony Kallas, Director Radiology

Avera St. Luke's Hospital

PUBLIC

- Immediate Release
 Normal Release

NON-PUBLIC

- A.3 Sensitive-Security Related
 A.7 Sensitive Internal
 Other: _____

Reviewer: AKC

Date: 7-1-18



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

Ref: 105US03

June 13, 2018

Dr. Leslie Lenter
Avera St. Luke's Hospital
305 South State Street
Aberdeen, SD 57401

Dear Dr. Lenter;

Re: SIR-Spheres® Yttrium-90 Resin Microspheres Training, Evaluation, Certification (TEC) Program

I am writing to confirm that on May 30, 2018, Dr. Randall Smith presented and discussed the preparation of and procedures associated with SIR-Spheres yttrium-90 (Y-90) resin microspheres that are injected via the hepatic artery to treat patients with unresectable liver tumors. I am pleased to inform you that Sirtex considers that you and your staff are trained in the preparation and clinical aspects of treating patients with SIR-Spheres Y-90 resin microspheres.

This letter also certifies that you were proctored by a Sirtex certified proctor in the use of SIR-Spheres Y-90 resin microspheres on the following dates: April 11, 2018 (mapping); April 20, 2018 (dose administration); May 9, 2018 (dose administration); and May 30, 2018 (dose administration).

I would like to thank you and your team for your support and commitment to the Sirtex **Training, Evaluation, Certification (TEC) Program**.

Yours sincerely,

Shyam Srinivas, M.D., Ph.D.
Chief Medical Officer
Sirtex Medical, Inc.

cc: Barrett Olk, Regional Sales Manager
TEC@sirtex.com



305 South State Street
Aberdeen, SD 57401

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JUN 21 2013
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Michelle Simmons
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1600 E. Lamar Blvd.
Arlington, Texas 76077-4511

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