

**From:** Mas, Pedro  
**To:** [Lanzisera, Penny](#)  
**Cc:** [Janda, Donna](#)  
**Subject:** [External\_Sender] RE: Request for Additional Information  
**Date:** Thursday, July 26, 2018 8:10:43 AM  
**Attachments:** [IR-DR certification.pdf](#)  
[Lazzara Bryan -SIRTeX approval.pdf](#)

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RE: Additional information to License amendment request; Stamford Hospital, License No. 06-06697-02, Docket No. 03001265, Mail Control No. 609204

Per your request to continue with your review;

1. Subspecialty documentation on Dr. Lazzara and Dr. Noga is attached.
2. Each individual will complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative. Please refer to the third attachment "Lazzara Bryan –SIRTeX approval.pdf" which documents Dr. Lazzara's completed training, prepared by David Cade, MD, Chief Medical Officer at SIRTeX. Documentation from the manufacturer, confirming three patient cases by Dr. Noga, will be submitted to NRC Region 1 within 30 days of completion.
3. We regret that Ms. Sarah Bull is not presently practicing as an Authorized Medical Physicist at Stamford Hospital due to personal circumstances. Her name may be removed from the list of AMPs.

Lastly, I have requested the hospital management clarify the nature of the affiliation(s) with external institutions, such as the New York - Presbyterian Healthcare System. That information will be presented to the NRC with an assessment of the "control" of our licensed materials program.

Peter J. Mas, MS, DABMP, RSO  
Stamford Hospital - Medical Physics Services  
Phone: (203) 276-4036 | Fax: (203) 276-7858

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**From:** Lanzisera, Penny [mailto:Penny.Lanzisera@nrc.gov]  
**Sent:** Friday, July 20, 2018 7:39 AM  
**To:** Mas, Pedro  
**Cc:** Janda, Donna  
**Subject:** Request for Additional Information

**This email did not originate at Stamford Health. Use caution when accessing attachments or links and never enter your Stamford Health password into a website or attachment associated with this email.**

Licensee: Stamford Hospital  
License No. 06-06697-02  
Docket No. 03001265  
Mail Control No. 609204

In order to continue our review of the request for microsphere use by Drs. Lazzara and Noga, please submit the following for each physician:

1. subspecialty certification in interventional radiology by either the American Board of Radiology or the American Osteopathic Board of Radiology or one additional year of supervised clinical experience in interventional radiology
2. commitment that each individual will complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which authorization is sought. Additionally, confirm that you will submit documentation from the manufacturer to NRC Region 1 within 30 days of when these three patient cases have been satisfactorily completed.

In addition, please confirm that Ms. Sarah Bull is continuing to practice as an Authorized Medical Physicist at Stamford Hospital.

Finally, it appears that your license may have undergone a change of control at some point over the last 2-3 decades to include an affiliation with New York – Presbyterian Healthcare System and/or Stamford Health. We have reviewed our records and have not found a notification from your facility of this change. In a separate amendment request, please describe the change of control or affiliation for both entities. Please include the information described in Appendix E to NUREG-1556, Volume 15 found at <https://www.nrc.gov/docs/ML1618/ML16181A003.pdf>.

Thank you for your assistance,

Penny Lanzisera  
Senior Health Physicist  
U.S. NRC, Region I

# The American Board of Radiology

*Organized through the cooperation of the  
American College of Radiology, the American Roentgen Ray Society,  
the American Radium Society, the Radiological Society of North America,  
the Section on Radiology of the American Medical Association,  
the American Society for Radiation Oncology, the Association of University Radiologists,  
the American Association of Physicists in Medicine, and the Society of Interventional Radiology,  
the American Board of Radiology hereby certifies that*

**Josef R. S. Noga, MD**

*Has pursued an accepted course of graduate study and clinical work; has met certain standards  
and qualifications, including passing the examinations conducted under the authority of  
the American Board of Radiology, demonstrating to the satisfaction of the Board qualification  
to practice; and is therefore awarded the Board's certification in*

**Interventional Radiology/Diagnostic Radiology**

*Ongoing validity of this certificate is contingent upon  
meeting the requirements of Maintenance of Certification.*

*This diplomate of the American Board of Radiology  
is permitted to use the **DABR** mark to signify this certification.*



Certificate No. 61297

*Milton J. Diliberto, MD*  
President

*[Signature]*  
Secretary-Treasurer

*[Signature]*  
Executive Director

**DABR**



Effective: October 16, 2017



AMERICAN  
BOARD OF  
RADIOLOGY

## Verification of Certification and Maintenance of Certification (MOC)

July 23, 2018

**Name:** Dr. Bryan Matthew Lazzara  
**Practice Locations:** New York, NY  
**Participating in MOC**

Certificate	Status	Valid Through	Maintenance	MOC Requirements
Interventional Radiology/Diagnostic Radiology	Valid	03/02/2020*	Maintained	Meeting

The information provided in this letter is considered the primary source verification. The most current certificate and MOC public reporting status information can be accessed at any time for Dr. Bryan Matthew Lazzara by entering the required information in the 'Verify board certification status' search on the ABR website at [www.theabr.org](http://www.theabr.org).

For questions regarding the ABR MOC Program or its participation requirements, please contact the board office at (520) 519-2152 or [information@theabr.org](mailto:information@theabr.org).

Sincerely,

Valerie Jackson, MD  
Executive Director  
American Board of Radiology

\*Validity of certification is contingent upon participation in Maintenance of Certification. The ABR recommends verification of certification be repeated annually, three business days after the ABR's March 2nd annual review.



**SIRTEX MEDICAL INC.**

300 Unicorn Park Drive

Woburn, MA 01801

Tel: +1 (781) 721 3800

Fax: +1 (781) 721 3880

Ref: 105US03

September 8, 2017

Bryan Lazzara, M.D.  
Stamford Hospital  
1 Hospital Plaza  
Stamford, CT 06902

Dear Dr. Lazzara,

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

I am writing to confirm that on August 17, 2017, Dr. Suvranu Ganguli 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. Dr. Ganguli also proctored you for the administration of SIR-Spheres Y-90 resin microspheres.

Given your prior experience administering SIR-Spheres Y-90 resin microspheres at New York Presbyterian – Columbia (2013 – 2017), 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.

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

Yours sincerely,

A handwritten signature in blue ink, appearing to read "David N. Cade".

David N. Cade, M.D.  
Chief Medical Officer  
Sirtex Medical, Inc.

cc: George Cross  
Ashley Cockerham  
TEC@sirtex.com