



May 24, 2022

US Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

NRC License #: 13-06009-01
Community Health Network

To Whom It May Concern:

Please accept this letter as a request to modify the Nuclear Regulatory Commission license for Community Health Network in Indianapolis, Indiana.

Please add Dr. Alexandria Jo as a conditional Authorized User for 10CFR35.1000, limited to yttrium-90 as TheraSpheres and SIR-Spheres. Attached, please find documentation for her training from the manufacturer of each product. Once she has completed her three patients for each manufacturer, we will submit for full approval.

If you require additional clarification or documentation, please contact our Radiation Safety Officer, Erin Bell, at 317.355.5528 or via email at ebell2@ecomunity.com.

Sincerely,

A handwritten signature in black ink that reads "Nichole Goddard". The signature is written in a cursive, flowing style.

Nichole Goddard, CNMT, MBA
Vice President of Operations
Community Health Network
Indianapolis, Indiana

TheraSphere® Training Record – Alexandria Jo, MD
Community Health Network
Indianapolis, IN

January 20, 2022 - Mock infusion training, 3 in-vitro administrations
October 21, 2021 - Completed NRC required Safe Handling Practices training

This is to confirm that Boston Scientific provided training on the recommended use of TheraSphere in accordance with TheraSphere Package Insert at Community Health Network. Dr. Jo has successfully completed the Authorized User training program. The full scope of training included the following.

1. Has completed three in-vitro administrations with focus on:

Safe handling practices
TheraSphere Administration Set and TheraSphere Administration Accessory Kit overview
Dose Calibrator verification using Calibration Data Sheet for Y-90
Preparation of TheraSphere dose vial
Assembly of the Administration Set
System priming
TheraSphere administration
Disassembly

2. Has training provided by a Y-90 microsphere manufacturer representative involving:

- a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; and
- b. Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters; and
- c. Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject; and
- d. Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures. The procedures should address any special circumstances that may be encountered, such as the electrostatic charge of Y-90 microspheres and the proper survey instrument and survey technique for beta emitters; and
- e. Preparing and administering patient dosage. The individual does not have to be the physician who places the micro-catheter or administers patient dosage, but it is necessary that the individual have training in the administration process, including selection of activity of Y-90 microspheres to be administered to each treatment site and catheter positioning to ensure administration of the Y-90 microspheres is in accordance with the written directive; and
- f. Using administrative controls to prevent a medical event involving the use of byproduct materials; and
- g. Evaluation of patient or research subject's treatments to determine whether the administered dosage was in accordance with the written directive or if a medical event has occurred.

Cynthia Ann Hollenbeck

Cynthia Ann Hollenbeck, PhD
Medical Science Liaison

April 7, 2022

The American Board of Radiology

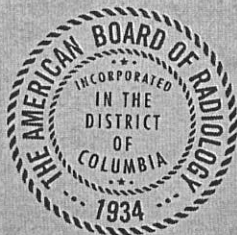
hereby certifies that

Alexandria Jo, 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

AU Eligible



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

Therent P. Mathew, MD
President

[Signature]
Secretary-Treasurer

[Signature]
Executive Director

DABR



Certificate No. 73888

Effective: May 14, 2021



Verification of Certification and Maintenance of Certification (MOC)

June 1, 2021

Name: Dr. Alexandria Jo

Practice Locations: No U.S or Canadian practice locations listed.

Participating in MOC

| Certificate | Status | Valid Through | Maintenance | MOC Requirements |
|---|--------|---------------|-------------|------------------|
| Interventional Radiology/Diagnostic Radiology | Valid | 03/01/2023* | 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. Alexandria Jo by entering the required information in the 'Verify board certification status' search on the ABR website at 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.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Wagner".

Brent Wagner, MD, MBA
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: 104US07

July 22, 2020

Alexandria Jo, MD
Community Hospital South
1402 E County Line Rd
Indianapolis, IN 46227

Dear Dr. Jo,

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

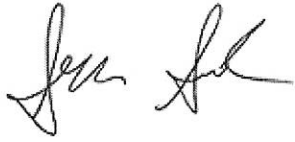
This letter certifies that on July 21st, 2020, you successfully completed training in the operation of the delivery system, safety procedures and clinical use of SIR-Spheres yttrium-90 microspheres that are to be injected via the hepatic artery to treat patients with unresectable liver tumors in accordance with the June 2012 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures as well as encompassing the following:

- a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; ✓
- b) Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters; ✓
- c) Evaluation of each patient for the dose/activity of Y-90 microspheres to be administered to each treatment site;
- d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient; ✓
- e) Using administrative controls to prevent a medical event involving the use of byproduct material;
- f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures; and ✓
- g) Follow up and review of each patient's case history for Y-90 microspheres

Once your licence has been appropriately amended, Sirtex will arrange with you to have a proctor oversee your first three (3) patient treatments at a minimum, including being on site for each case.

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

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Steve Schilt', written over a thin horizontal line.

Steve Schilt

Regional Sales Manager

cc: Derek Webster
Area Sales Director



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

Ref: 105US03

June 11, 2021

Dr. Alexandria Jo
Community Health South
1402 E. County Line Road
Indianapolis, IN, 462227

Dear Dr. Jo;

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

I am writing to confirm that on April 12, 2021, Dr. Guillermo Gonzalez 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.⁷

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: March 1, 2021 (mapping); April 1 (dose administration); April 12, 2021 (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,

Paula Habib, MD
Chief Medical Officer - Americas

cc: Mike McFereson, Regional Sales Manager
TEC@sirtex.com

From: [Tomczak, Tammy](#)
To: [Pavon, Sandy](#); [Pavon, Martha](#)
Subject: FW: Amendment request 13-06009-01
Date: Tuesday, May 24, 2022 1:04:30 PM
Attachments: [E-RAD20@ecommunity.com_20220524_123100.pdf](#)

Good afternoon, Sandy and Martha,

Can you please add the attached to ADAMS?

Thank you!!

Tammy

-----Original Message-----

From: Bell, Erin <EBell2@ecommunity.com>
Sent: Tuesday, May 24, 2022 12:45 PM
To: Tomczak, Tammy <Tammy.Tomczak@nrc.gov>
Subject: [External_Sender] Amendment request 13-06009-01

Good afternoon,

Please accept the following amendment request for NRC License number 13-06009-01, Community Health Network, Indianapolis, Indiana.

Thank you,

Erin Bell

Erin Bell, MHP, DABSNM
Radiation Safety Officer/Medical Physicist Community Health Network
(o) 317.355.5528
(c) 317.313.0406
Ebell2@ecommunity.com

CONFIDENTIALITY NOTE: This e-mail contains information that may be privileged, confidential and subject to legal restrictions and penalties regarding its unauthorized disclosure or other use. You are prohibited from copying, distributing or otherwise using this information if you are not the intended recipient or the employee or agent to deliver to the intended recipient. If you have received this e-mail in error, please notify us immediately by return e-mail and delete this e-mail and all attachments from your system. Thank you.