



June 27, 2022

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Office of Materials Licensing
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: License Amendment Request
Additional Information
Elkhart General Hospital
License Number: 13-18879-01
Docket Number: 030-17305
Mail Control Number: 631243

Dear Mr. Tran:

We have attached a letter from Sirtex documenting the required training that Dr. Ezuddin received listed under 5.1.A.3iii(a-d) and 5.1.A.3.iv(a-c). This training was provided by a Sirtex representative, Justin Watkins, and physician proctors Drs. Michael Doherty and Brandon Martinez. In addition, the training listed under 5.1.A.3iv(a-c) was provided by Dr. Justin Lightburn who is listed as an authorized user on our NRC license No. 13-18879-01.

If you have any questions or require additional information, please contact our Radiation Safety Officer, Daniel Archambeault at 574-647-7956 or by e-mail at DArchambeault@beaconhealthsystem.org.

Sincerely,

Cindi McPhie
Vice President of Operations
Elkhart General Hospital



SIRTEX MEDICAL INC.
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Woburn, MA 01801
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6/23/22

Dr. Mohammed Ezuddin
Elkhart General Hospital
600 East Blvd
Elkhart, In 46514

Re: SIR-Spheres® Y-90 Resin Microspheres Authorized User Training and Certification

This letter certifies that on 01/26/2022, you successfully completed training in the operation of the Box Delivery System, safety procedures and clinical use of SIR-Spheres Y-90 resin microspheres in accordance with the March 2020 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures, and encompassed 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) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient;
- d) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures, The procedures address 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;
- e) Preparing and administering patient dosage, including selection of activity of Y-90 microspheres to be administered to each treatment site and, if applicable and AU proctor present, catheter positioning to ensure administration of the Y-90 microspheres is in accordance with the written directive;
- f) Using administrative controls to prevent a medical event involving the use of byproduct material; and
- g) Evaluation of patient treatments to determine whether the administered dosage was in accordance with the written directive or if a medical event has occurred.

If required, Sirtex will arrange to have a manufacturer representative oversee your first three (3) patient treatments. Sirtex would like to thank you for your support in this process.

Trainer Signature:



Regional Sales Manager:
Justin Watkins

cc: AU@Sirtex.com

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