



**SIRTEX MEDICAL INC.**

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April 21, 2025

Vivek P. Padha, M.D.  
WVU Berkeley Medical Center  
2500 Hospital Drive  
Martinsburg, WV 25401  
RAML No. 47-15501-01

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

This letter certifies that on April 3, 2025, 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.

The three (3) documented patient cases for the medical use of SIR-Spheres Y-90 resin microspheres were performed with you at WVU Berkeley Medical Center under my supervision on the following dates:

- |                       |                        |
|-----------------------|------------------------|
| 1. Case 1: 01/30/2025 | Y-90 Radioembolization |
| 2. Case 2: 03/06/2025 | Y-90 Radioembolization |
| 3. Case 3: 04/03/2025 | Y-90 Radioembolization |

I believe you have satisfactorily completed the work experience required by U.S. Nuclear Regulatory Commission's Microsphere Brachytherapy Sources and Devices Guidance, Revision 10.2, Sections 5.1. A.3.i.b.iii. (a)-(d) and iv (a)-(c). Additionally, he has completed training in the operation of the delivery system, safety procedures, and clinical use for SIR-Spheres to become an Authorized User for SIR-Spheres Yttrium-90 resin microspheres.

Regards,

A handwritten signature in black ink, appearing to read "Emil Cohen", with a stylized flourish at the end.

Emil Cohen, M.D.  
Authorized User Proctor  
RAML No. 08-30577-01