Mrs. Ritchlin:

Good morning. I have reviewed your request dated April 5, 2023, for the addition of three Authorized Users with authorization for 10 CFR §35.1000 (limited to yttrium-90 as SIR-Spheres). Upon review of your request, I identified the following areas in which additional or clarifying information is needed:

- Section 5.1, "Authorized Users," of the <u>Y-90 Microsphere Brachytherapy Sources and Devices</u> <u>TheraSphere and SIR-Spheres Licensing Guidance, Rev. 10.2</u>, identifies that the proposed Authorized Users must have attained 80 hours of classroom and laboratory training for byproduct material requiring a written directive, applicable to Y-90 microspheres, including the following subjects:
 - Radiation physics and instrumentation;
 - Radiation protection;
 - Mathematics pertaining to the use and measurement of radioactivity; and
 - Radiation biology.

Submit documentation demonstrating that Shivang Patel, D.O., Jeffrey Savin, M.D., and Dominic Scola, M.D., have completed 80 hours of classroom and laboratory training as described above.

 Your request identified that Jeffrey Savin, M.D., and Dominic Scola, M.D., have work experience under the supervision of an Authorized User for Y-90 microspheres or training by a Y-90 microsphere authorized user proctor and preceptor.

Submit documentation demonstrating that the proposed Authorized Users have attained work experience under the supervision of an Authorized User for Y-90 microsphere brachytherapy or training provided by a Y-90 microsphere manufacturer representative, including:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the active of Y-90 microspheres and performing checks for proper operation of survey meters;
- Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject;
- 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;

- 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;
- Using administrative controls to prevent a medical event involving the use of byproduct material; and
- 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.

Please respond to this request for additional information in writing within 15 calendar days. Please reference your license number and Control Number 635214 in your signed response letter.

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