

January 25, 2018

Division of Nuclear Materials Safety  
United States Nuclear Regulatory Commission  
Region I  
2100 Renaissance Blvd.  
King of Prussia, PA 19406-1415  
Attn: Medical Licensing

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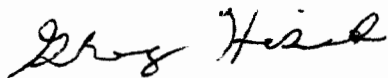
RE: Notification of Training Completion (Lic. No. 06-00854-03)

To whom it may concern,

A condition of a recent amendment to the radioactive materials license of St Francis Hospital to add Y-90 microsphere therapy is to send documentation of the completion of three proctored cases for Authorized Users to the NRC. Dr. Swapnil Bagade has completed this training. A training record from the vendor is attached.

If you have any questions, please do not hesitate to contact me.

Sincerely,



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REC'D IN LAT 2-13-18

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NMSS/RGN1 MATERIALS-002

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**TheraSphere® Training Record – Dr. Swapnil Bagade, MD**  
Saint Francis Hospital and Medical Center, Hartford, CT

October 28, 2016 - Attended BTG Center of Excellence Training program  
November 21, 2016 - TheraSphere® Kit set-up training completed  
November 21, 2016 - Mock infusion training, 3 in-vitro administrations  
November 21, 2016 - Completed NRC required Safe Handling Practices training (A-G)  
June 1, 2017 - Proctor Supervision of TheraSphere® Patient #1 completed  
June 21, 2017 - Proctor Supervision of TheraSphere® Patient #2 completed  
January 11, 2018 - Proctor Supervision of TheraSphere® Patient #3 completed

This is to confirm that BTG, Inc. provided training on the recommended use of TheraSphere® in accordance with the TheraSphere® Package Insert to Saint Francis Hospital and Medical Center. Dr. Swapnil Bagade has successfully completed the BTG Authorized User training program for TheraSphere®.

The training included:

1. Presentation (November 21, 2016) with the following elements:

- 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 or human research subject 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 or human research subject;
- 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 or human research subject's case history for Y-90 microspheres

2. Interactive Practice (November 21, 2016) of TheraSphere® infusions performed during three simulated (MOCK) infusions 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

3. Successful administration of TheraSphere® during three proctor supervised patient cases

- Dates of successful supervised administrations are provided above

Sincerely,

Sean McCabe  
Medical Science Liaison  
BTG International

Date: 1/11/2018

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