

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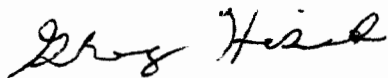
RE: Notification of Training Completion (Lic. No. 06-00854-03)

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,



Greg Hisel, MS, MBA, CHP
Radiation Safety Officer
Saint Francis Hospital and Medical Center
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Hartford, CT 06105
Office: 860-714-5596
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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,

A handwritten signature in black ink, appearing to read 'Sean McCabe', is written over a white background.

Sean McCabe
Medical Science Liaison
BTG International

Date: 1/11/2018

Imagine where we can go.