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September 7, 2017

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

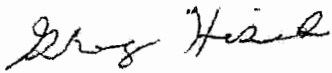
RE: Notification of Training Completion (Lic. No. 06-00854-03) 103001246

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. Anthony Posteraro 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
Cell: 518-755-7465
Email: ghisel@stfranciscare.org

REC'D IN LT 11/30/2017

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NUCLEAR MATERIALS-002

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TheraSphere® Training Record – Dr. Anthony Posteraro
Saint Francis Hospital and Medical Center – Hartford, Conn.

September, 2016 - Attended TheraSphere Y90 Center of Excellence Program
November 21, 2016 - TheraSphere Administration Kit set-up training completed
November 21, 2016 - Mock infusion training, 3 in-vitro administrations completed
November 21, 2016 - NRC required Safe Handling Practices training (A-G) completed
April 6, 2017 - Proctor Supervision of TheraSphere Patient Number 1 Completed
April 6, 2017 - Proctor Supervision of TheraSphere Patient Number 2 Completed
August 11, 2017 - Proctor Supervision of TheraSphere Patient Number 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. Anthony Posteraro has successfully completed the initial BTG Authorized User training program. The full scope 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

This completes the BTG Authorized User Training for Dr. Anthony Posteraro


Jeffrey D Xander

Interventional Oncology Medical Science Liaison

8-11-2017
Date



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Saint Francis Hospital and Medical Center
ATTN: Robert J. Falaguerra, VP, Facilities,
Support Services, and Construction
114 Woodland Street
Hartford, CT 06105-1299

Date

December 6, 2017

License Number(s)

06-00854-03

Mail Control Number(s)

601835

Licensing and/or Technical Reviewer or Branch

Robin Elliott

Notification

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 09/07/2017

The initial processing, which included an administrative review, has been performed.

☐ Amendment ☐ Termination ☐ New License ☐ Renewal

☒ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

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