



August 12, 2014

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Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. NUCLEAR Regulatory Commission, Region 1
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Br. 1

03001242

Re: NRC License No. 06-00649-03 (Three Hands On Y-90 Therasphere cases)

To whom it may concern,

On March 18, 2013, the NRC issued Middlesex Hospital an amendment (no. 61) which permits the use of Y-90 microspheres. As part of the application process Middlesex Hospital committed to notify the NRC within 30 days of the completion of three hands-on Therasphere Y-90 cases in accordance with procedures in our request letter dated June 7, 2012. The three cases were performed in the presence of the BTG representative Mr. Jeffery Xander.

Enclosed please find a letter from Jeffery Xander of BTG International which is dated August 8, 2014 and which states that the first three Y-90 cases were performed at Middlesex under the supervision and proctoring of Mr. Xander. The first three cases were performed at Middlesex Hospital on:

June 9, 2014

July 21, 2014

August 7, 2014

Please let us know if any further information is required.

Sincerely,

A handwritten signature in black ink, appearing to read 'Garrett Havican'.

Garrett Havican
Vice President of Operations
Middlesex Hospital

A handwritten signature in black ink, appearing to read 'Joan Merton'.

Joan Merton DrPH
RSO
Middlesex Hospital

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NMSS/RGN1 MATERIALS-002

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TheraSphere® Training Record – Dr. Jeffrey Takahashi

Middlesex Hospital – Middletown, Connecticut 06457

October 5, 2011	-Attended Center of Excellence Program, Northwestern Memorial Hospital
April 16, 2014	- Proctoring presentation/training completed
April 16, 2014	- Kit set-up training completed
April 16, 2014	- Mock infusion training
June 4, 2014	-Final review of therapy and mock kit set up
June 9, 2014	- Proctoring Supervision of Treatment #1 completed.
July 21, 2014	- Proctoring Supervision of Treatment #2 completed.
August 7, 2014	- Proctoring Supervision of Treatment #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 Middlesex Hospital, Middletown, Conn. Dr. Takahashi has successfully completed the BTG Authorized User training program. The full scope training included:

1. PowerPoint Presentation (April 16, 2014) with the following elements:

- Product overview
- Patient selection
- Dose calculations
- Site Dose Measurement
- TheraSphere infusion
- % Delivery Determination
- 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 (April 16, 2014) of TheraSphere infusions, including 3 In-vitro 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

Multiple patient infusions were observed by a TheraSphere representative on three separate dates. Dr. Takahashi completed the required 3 patient supervised proctoring events with Jeff Xander, Interventional Oncology Proctor, TheraSphere as the BTG representative.

A handwritten signature in black ink, appearing to read "J. Xander", written over a horizontal line.

Jeffrey D Xander
Interventional Oncology, BTG- TheraSphere

8-8-2014

Date