

 **MIDDLESEX**  
HOSPITAL

October 11, 2016

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U.S. Nuclear Regulatory Commission, Region I  
Division of Nuclear Materials Safety  
2100 Renaissance Boulevard, Suite 100  
King of Prussia, PA. 19406-2713  
Via email: [Penny.Lanzisera@nrc.gov](mailto:Penny.Lanzisera@nrc.gov)

REC'D 10/18/16 AM 08:53

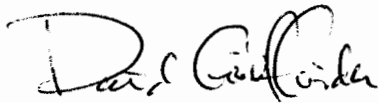
Ref: NRC License# 06-00649-03 *103001242*

Dear Ms. Lanzisera:

This letter is in response to your letter of March 31, 2016, attached to NRC license 06-00649-03 amendment 67, requesting notification of the successful completion of three (3) Y-90 Therasphere cases for Dr. Kovalenko. Attached please find documentation from BTG that Dr. Kovalenko performed three (3) Y-90 Therasphere cases, under supervised proctoring, on August 25, 2016, September 1, 2016 and October 7, 2016. These cases were successfully completed.

Please notify The Middlesex Hospital RSO, Dr. Joan Merton if any further information is required. (860-358-6470)

Sincerely,



David Giuffrida, P.E.  
Vice President, Operations

*592208*

**NNSS/RGNI MATERIALS-001**

Middlesex Hospital  
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Middletown, CT 06457  
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**TheraSphere® Training Record – Dr. Bruce Kovalenko**  
Middlesex Hospital – Middletown, Connecticut 06457

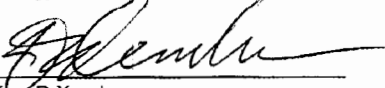
July 28, 2016 - Proctoring presentation/training and NRC A-G completed  
September 12, 2014 & July 28, 2016 - Kit set-up training completed  
September 12, 2014 - 3 in-vitro Mock infusion training  
July 28, 2016 - Final review of therapy and mock kit set up  
August 25, 2016 - Proctoring Supervision of TheraSphere patient treatment #1 completed.  
September 1, 2016 - Proctoring Supervision of TheraSphere patient treatment #2 completed.  
October 7, 2016 - Proctoring Supervision of TheraSphere patient 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. Bruce Kovalenko has successfully completed the BTG Authorized User training program. The full scope training included:

1. PowerPoint Presentation (July 28, 2016) 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 (September 12, 2014 & July 28, 2016) 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. Kovalenko completed the required 3 patient supervised proctoring events with Jeff Xander, Interventional Oncology Proctor, TheraSphere as the BTG representative.

  
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Jeffrey D Xander  
Interventional Oncology, BTG- TheraSphere

10-7-2016  
Date



**ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE**

**Name and Address of Applicant and/or Licensee**

Middlesex Hospital  
ATTN: Garrett Havican, Vice President  
28 Crescent Street  
Middletown, CT 06457-3650

**Date**

October 28, 2016

**License Number(s)**

06-00649-03

**Mail Control Number(s)**

592208

**Licensing and/or Technical Reviewer or Branch**

Medical Branch (Branch 1)

*Notification*

This is to acknowledge receipt of your: ☐ Letter and/or ☐ Application Dated: October 11, 2016

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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**U. S. Nuclear Regulatory Commission**  
**Division of Nuclear Materials Safety**  
**2100 Renaissance Boulevard, Suite 100**  
**King of Prussia, PA 19406-2713**  
**(610) 337-5260, (610) 337-5313,**  
**(610) 337-5398, or (610) 337-5239**