



October 26, 2018

U.S. Nuclear Regulatory Commission, Region I
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

03001242

RE: NRC License# 06-00649-03, Amendment Request change in Radiation Safety Officer –
Additional Information, as Requested

In response to your email dated October 4, 2018, please find enclosed documented training for
Jason Marsden, MS, CHP, DABR for Nucletron High Dose Rate Remote Afterloader and
Yttrium-90 TheraSpheres.

If you require further information, please feel free to contact myself or Mr. Marsden.

Sincerely,

David Giuffrida, P.E.

Vice President, Operations

10/26/2018

- Enclosures:
1. Letter from AMP George Pavlounis for HDR training dated October 11, 2018
 2. Letter from Brain Erasmus from BTG International for TheraSphere dated October 25, 2018.

A Member of the Middlesex Health System


610121
NUCLEAR MATERIALS-001

October 11, 2018

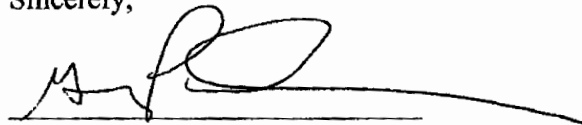
Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406-2719

I am writing this letter in support of Jason Marsden application to become the Radiation Safety Officer for Middlesex Hospital (License No. 06-00649-03).

I have provided him with a copy of all of the pertinent regulatory and clinical policies and procedures as they relate to the High Dose Rate Brachytherapy Program. After his review of the documents we discuss in detail specific questions that he had regarding the program. A detailed review of the emergency procedures was performed. In addition, current radiation safety practices and pertinent regulatory requirements from 10 CFR Part 35 were discussed.

Should you have any questions please feel free to contact me at the email address listed below or by phone at 

Sincerely,



George Pavlonnis, AMP
Chief Medical Physicist
george.pavlonnis@midhosp.org

BTG International Canada Inc.
Roy Errington Building
3rd Floor
447 March Road
Ottawa, Ontario
Canada
K2K 1X8

Tel: +1 613 801 1880
Fax: +1 613 701 4086
Email: info@btgplc.com

www.btgplc.com



To: Jason Marsden, RSO
MSL: Brian A Erasmus
Training Date: October 25, 2018
Subject: TheraSphere® Training
Training Location: Middlesex Hospital, Middletown, CT

I am pleased to confirm that Jason has successfully completed the U.S.NRC required Authorized User (AU) manufacturer provided training for TheraSphere® Y-90 Glass Microspheres System through the path outlined below:

- Jason has completed training provided by a BTG representative involving:
 - 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; and
- The user has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for TheraSphere provided by BTG, including three supervised hands-on *in-vitro* simulated cases.

Sincerely

A handwritten signature in black ink, appearing to read "B. Erasmus", is written over the word "Sincerely".

Brian A Erasmus
Executive Medical Science Liaison
BTG