

May 31st, 2016

Licensing Assistance Team
 U.S. NRC Region I DNMS
 Nuclear Materials Section B
 475 Allendale Road
 King of Prussia, Pennsylvania 19406-1415

Br. 1
03003370

**RE: License Amendment Request for NRC Radioactive Materials License # 47-00404-02
 Cabell Huntington Hospital, Huntington, WV 25701-0195**

To Whom It May Concern:

We wish amend our radioactive materials license to add authorization for Y-90 TheraSphere® for permanent implant brachytherapy using the BTG/TheraSphere delivery system. The use of TheraSpheres will augment our SIR-Spheres brachytherapy program. Therefore, we request a maximum possession limit of 4 Ci (148 GBq) Y-90 for our combined use of SIR-Spheres and TheraSpheres. For the use of TheraSpheres, we will use the same facilities for receiving, preparation, administration, and storage that we use for or SIR-Spheres program.

Radionuclide:	Yttrium-90 TheraSphere ®
Chemical/Physical Form:	Glass microsphere manufactured by Nordion Inc. as listed in SADR NR-0220-D-131-S, TheraSphere®
Maximum Possession Limits:	540 mCi (20 GBq) per vial and a maximum possession limit of 4 Ci (148 GBq) Y-90 for our combined use of SIR-Spheres and TheraSpheres
Authorized Use:	TheraSphere® for permanent brachytherapy using delivery system as listed in SADR NR-0220-D-131-S

Dr.'s James Reynolds, Michael Korona, and Lee C. Haikal have completed three in-vitro cases using the TheraSphere delivery system simulating patient infusion of Y-90 TheraSpheres supervised by Michael Pappas, a BTG/TheraSphere representative. Supporting documentation is attached. Note that Dr.'s James M. Reynolds and Michael V. Korona are currently authorized users for Y-90 SIR-Spheres and that Dr. Lee C. Haikal is currently listed as an authorized user for 10 CFR 35.300 on our radioactive materials license. Additionally, we commit to the following:

1. Dr.'s Reynolds, Korona, and Haikal will receive training at a TheraSphere Center of Excellence in preparing, measuring, performing dosimetry calculations, and administering Y-90 TheraSphere microspheres.
2. Dr.'s Reynolds, Korona, and Haikal will complete at least the first 3 hands-on patient cases supervised by and in the physical presence of a BTG/TheraSphere representative. We will provide documentation to the appropriate US NRC Regional Office within 30 days of when the 3 supervised patient cases have been completed.
3. We shall follow TheraSpheres recommended procedures for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration, determining the shunting to non-treatment sites; and performing pre- and post-vial dose measurements.

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NMSS/RGNI MATERIALS-002

4. As part of SIR-Spheres implant program, we currently have policy and procedures for written directives, inventory, patient release, labeling, and medical event reporting as specified in the NRC Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance. February 12, 2016, Revision 9. We shall appropriately modify these policy and procedures as needed to include the use of TheraSpheres.
5. We shall provide training in our TheraSphere procedures to all individuals involved in the preparation, measuring, performing dosimetry calculations, or administering Y-90 microspheres. The training will be commensurate with the duties performed by the individual.
6. As with our SIR-Spheres amendment request, we request authorization to make future changes to our Y-90 microsphere radiation safety program when the following conditions are met:
 - a. The revision is in compliance with the regulations; and
 - b. The revision is based upon the NRC's current guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC Medical Uses Licensee Toolkit web site;
 - c. The revision has been reviewed and approved by our Radiation Safety Officer and senior management; and
 - d. The affected individuals are instructed on the revised program before the change is implemented; and
 - e. A record of each change is retained for five years that will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the management representative that reviewed and approved the change.

We also wish to remove Monica Morris, MD, as an authorized user and Joseph Britt Colenda, MS, DABR, as an authorized medical physicist from our radioactive materials license as they no longer practice at our facility.

This request has been reviewed and approved by our Radiation Safety Committee. If there are any questions regarding this request, or should you need any further information, please do not hesitate to contact us. Questions may be directed to our Radiation Safety Officer, James Norweck, MS, DABR. Thank you for your consideration.

Sincerely,



Tim Martin, MBA, RT(R), ARRT, ASRT, ACHE
Vice President of Ancillary and Support Services
Office Phone: (304) 526-2205
Office FAX: (304) 526-2008
Email: tim.martin@chhi.org

cc: James T. Norweck, M.S., DABR, Radiation Safety Officer
Office Phone: 304-522-1550 x 234
Office FAX: 304-522-0704
Email: jnorweck@radiology-inc.com

BTG International Inc.
Five Tower Bridge
Suite 800
300 Barr Harbor Drive
West Conshohocken
Pennsylvania 19428-2998
USA

Tel: +1 610 278 1660
Fax: +1 610 278 1605
Email: info@btgplc.com

www.btgplc.com



Date: May 4, 2016

James Reynolds, MD
Radiologist
Cabell Huntington Hospital
1400 Hal Greer Blvd.
Huntington, WV. 25701

Subject/Reference: **Statement of Vendor Training in the use of
TheraSphere Yttrium-90 Glass Microspheres**

James Reynolds, MD, Radiologist, Cabell Huntington Hospital, 1400 Hal Greer Blvd.,
Huntington, West Virginia 25701, USA, has received vendor training in simulated
administrations on May 4, 2016 at Cabell Huntington Hospital.

Dr. Reynolds therefore complies with US Nuclear Regulatory Commission vendor
training requirements for the following:

- a) Operation of the improved TheraSphere administration system, safety
procedures, and clinical use, and
- b) Supervised in vitro, hands-on, simulated cases that demonstrate issues that
are encountered during TheraSphere administration procedures.

Sincerely,

Michael W. Pappas, BSRT, CNMT
Interventional Oncology Proctor

BTG International Inc.
Five Tower Bridge
Suite 800
300 Barr Harbor Drive
West Conshohocken
Pennsylvania 19428-2998
USA

Tel: +1 610 278 1660
Fax: +1 610 278 1605
Email: info@btgplc.com

www.btgplc.com



Date: May 4, 2016

Michael Korona, MD
Radiologist
Cabell Huntington Hospital
1400 Hal Greer Blvd.
Huntington, WV. 25701

**Subject/Reference: Statement of Vendor Training in the use of
TheraSphere Yttrium-90 Glass Microspheres**

Michael Korona, MD, Radiologist, Cabell Huntington Hospital, 1400 Hal Greer Blvd.,
Huntington, West Virginia 25701, USA, has received vendor training in simulated
administrations on May 4, 2016 at Cabell Huntington Hospital.

Dr. Korona therefore complies with US Nuclear Regulatory Commission vendor
training requirements for the following:

- a) Operation of the improved TheraSphere administration system, safety
procedures, and clinical use, and
- b) Supervised in vitro, hands-on, simulated cases that demonstrate issues that
are encountered during TheraSphere administration procedures.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael W. Pappas", written over a white background.

Michael W. Pappas, BSRT, CNMT
Interventional Oncology Proctor

BTG International Inc.
Five Tower Bridge
Suite 800
300 Barr Harbor Drive
West Conshohocken
Pennsylvania 19428-2998
USA

Tel: +1 610 278 1660
Fax: +1 610 278 1605
Email: info@btgplc.com

www.btgplc.com



Date: May 4, 2016

Lee Haikal, MD
Radiologist
Cabell Huntington Hospital
1400 Hal Greer Blvd.
Huntington, WV. 25701

**Subject/Reference: Statement of Vendor Training in the use of
TheraSphere Yttrium-90 Glass Microspheres**

Lee Haikal, MD, Radiologist, Cabell Huntington Hospital, 1400 Hal Greer Blvd.,
Huntington, West Virginia 25701, USA, has received vendor training in simulated
administrations on May 4, 2016 at Cabell Huntington Hospital.

Dr. Haikal therefore complies with US Nuclear Regulatory Commission vendor training
requirements for the following:

- a) Operation of the improved TheraSphere administration system, safety
procedures, and clinical use, and
- b) Supervised in vitro, hands-on, simulated cases that demonstrate issues that
are encountered during TheraSphere administration procedures.

Sincerely,

Michael W. Pappas, BSRT, CNMT
Interventional Oncology Proctor



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee Cabell Huntington Hospital ATTN: Tim Martin, Vice President of Ancillary and Support Services 1340 Hal Greer Boulevard Huntington, WV 25701-0195	Date June 7, 2016
	License Number(s) 47-00404-02
	Mail Control Number(s) 591053
	Licensing and/or Technical Reviewer or Branch Branch 1

This is to acknowledge receipt of your: Letter and/or Application Dated: 05/31/2016

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:
 [Empty box for listing omissions]

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:

Region I
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