Cabell Huntington Hospital

1340 Hal Greer Boulevard
Huntington, WV 25701

August 15th, 2016

Penny Lanzisera, Senior Health Physicist
U.S. NRC Region I DNMS
2100 Renaissance Blvd., Suite 100
King of Prussia, Pennsylvania 19406-2713

RE: **License Amendment Request for Additional Information and/or Confirmations**
NRC Radioactive Materials License # 47-00404-02
Cabell Huntington Hospital, Huntington, WV 25701-0195
Mail Control Number: 591053

Dear Penny:

The letter is in response to your request for additional information and confirmations related to the recent request to add authorization for Y-90 TheraSphere® to our radioactive materials license.

Attached you will find supporting documentation for the three in-vitro simulated administrations supervised by a BTG/TheraSphere® representative for Dr.'s James Reynolds, Michael Korona, and Lee C. Haikal. Additionally, we commit that our procedures developed for Therasphere will include the following:

Procedures for Administration
Administration of Y-90 microspheres will be performed in accordance with the written directive. We shall record the dose or activity delivered to the treatment site. The record will be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity and the date.

Written Directives
For the purpose of written directive and medical event reporting requirements in the Y-90 microsphere guidance, "prescribed dose" means the total dose (rad or Gy). Alternatively, prescribed activity (mCi or GBq) may be used in lieu of prescribed dose. If prescribed activity is used in lieu of prescribed dose, activity will be used for all documentation and evaluations.

The written directive shall include the patient or human research subject's name; the date; the signature of an authorized user for Y-90 microspheres; the treatment site; the radionuclide and manufacturer name and physical form (TheraSphere® Y-90 microspheres); the prescribed dose or activity; and, if appropriate for the type of microsphere used, the statement "or dose or activity delivered at stasis."

Termination of Treatment Due to Stasis
If the administration was terminated because of stasis, then the total dose or activity to the treatment site will be the value of the total dose or activity administered when stasis occurred and the administration was terminated. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual

who determined the administered dose or activity, the date, and the signature of an authorized user for Y-90 microspheres.

Emergent Patient Conditions
If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g., artery spasm or sudden change in blood pressure), the authorized user should document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive should include the reason for not administering the intended dose or activity, the date, and the signature of an authorized user for Y-90 microspheres.

Medical Event Reporting
We shall report any event, except for an event that results from intervention of a patient or human research subject, in which:

- The administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from the use of the wrong radionuclide; or
- The administration of byproduct material: to the wrong individual or human research subject; via the wrong route; or by the wrong mode of treatment; or
- The total dose or activity administered differs from the prescribed dose or activity, as documented in the written directive, by 20 percent or more, except when stasis or emergent patient conditions are documented and resulted in a total dose or activity administered that was less than that prescribed; or
- The administration of byproduct material results in dose or activity to an organ or tissue other than the treatment site, as documented in the written directive, except for shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.

Additionally, we shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

Inventory
The semi-annual physical inventory of microsphere aggregates (e.g., vials) should include:

- The radionuclide and physical form; and
- Unique identification of each vial in which the microspheres are contained; and
- The total activity contained in each of the vial(s); and
- The location(s) of the vial(s).

We shall retain each semi-annual physical inventory record for three years.

Labeling
We commit to the following when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

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- Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).
- Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).

Patient Release

We commit to developing procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his or her release in accordance with 10 CFR 35.75.

Waste Disposal Issues

We shall consider the potential presence of radioactive contaminants when disposing TheraSphere® Y-90 microspheres. Depending on the contaminants, we shall:

- Hold the remaining microspheres longer in decay-in-storage in accordance with 10 CFR 35.92; or
- Return the microspheres to the manufacturer, if the manufacturer is authorized to receive Y-90 microspheres; or
- Transfer the microspheres to an authorized recipient.

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

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Date: August 17, 2016

James Norweck, MS, DABR
Radiology Inc.
5221 US 60 East
Huntington, WV 25705

Subject/Reference: Additional information requested by NRC

Hi Jim,

Please find enclosed the letters for Drs. Haikal, Korona and Reynolds which state 3 in-vitro cases were completed by each doctor. I have signed the letters on behalf of Michael Pappas, the Interventional Oncology Proctor who trained the doctors; Michael is out of the office until Monday, August 29th.

Sincerely,

Brian Erasmus
Director, Interventional Oncology Proctors

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Date: August 17, 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 3 in-vitro, hands-on, simulated cases that demonstrate issues that are encountered during TheraSphere administration procedures.

Sincerely,

Brian Erasmus
Director, Interventional Oncology Proctors
On behalf of Michael Pappas, BSRT, CNMT
Interventional Oncology Proctor

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Date: August 17, 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 3 in-vitro, hands-on, simulated cases that demonstrate issues that are encountered during TheraSphere administration procedures.

Sincerely,

Brian Erasmus
Director, Interventional Oncology Proctors
On behalf of Michael Pappas, BSRT, CNMT
Interventional Oncology Proctor

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Date: August 17, 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 3 in-vitro, hands-on, simulated cases that demonstrate issues that are encountered during TheraSphere administration procedures.

Sincerely,

Brian Erasmus
Director, Interventional Oncology Proctors
On behalf of Michael Pappas, BSRT, CNMT
Interventional Oncology Proctor