

**Ning, Yongli**

**From:** Mark Busch [Mark.Busch@btgplc.com]  
**Sent:** Friday, July 26, 2013 10:33 AM  
**To:** Ning, Yongli  
**Subject:** RE: YT-90 THERA SPHERE AMENDMENT REQUEST - REQUEST FOR ADDITIONAL INFORMATION

**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 4080  
**Email:** info@btgplc.com  
[www.btgplc.com](http://www.btgplc.com)



**Subject/Reference: YT-90 Therasphere Amendment Request Providence Alaska – Request for Additional Information**

Dear Mr. Ning:

Per the requirements for amending your license for Therasphere, please see below our commitment to complete the following training and tasks:

- 1) A minimum of three simulated *in-vitro* cases or mock infusions supervised by BTG/Therasphere for our Y-90 microspheres with Dr. John Halligan and Dr. Chakri Inampudi. This will be completed within the next 30 days and prior to attending Therasphere Center of Excellence training in September.
- 2) BTG also commits to providing proctoring/training to all individuals involved in Y-90 microsphere use, commensurate with the individual’s duties to be performed: preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.
- 3) Dr. John Halligan, Dr. Chakri Inampudi, and staff will also be proctored/trained on their first 3 hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which authorization is sought.

Please let me know if you have any questions on the training and if there are any additional requirements you need.

Best Regards,



**Mark Busch** | Account Manager  
BTG International  
Five Tower Bridge, Suite 800, 300 Barr Harbor Drive, West Conshohocken, PA 19428-2998 USA  
**Main:** +1 610 278 1660 | **Mobile:** +1 952 221 3614  
**Email:** [mark.busch@btgplc.com](mailto:mark.busch@btgplc.com) | **Web:** [www.btgplc.com](http://www.btgplc.com)

**PUBLIC**  
 Immediate Release  
 Normal Release

Please consider the environment before printing this email

**From:** Ning, Yongli [mailto:Yongli.Ning@providence.org]  
**Sent:** Thursday, July 25, 2013 6:53 PM  
**To:** Mark Busch  
**Cc:** Winslow, Mark  
**Subject:** FW: YT-90 THERA SPHERE AMENDMENT REQUEST - REQUEST FOR ADDITIONAL INFORMATION  
**Importance:** High

**NON-PUBLIC**  
 A.3 Sensitive-Security Related  
 A.7 Sensitive Internal  
 Other:  
**Reviewer:** **Date:** 8/16/13

**Centre of Excellence (CoE) Invitation**  
**Providence Alaska Medical Center**  
**Chakri Inampudi, MD**

**September, 2013 (official date yet to be determined)**

**Airline Reservations**

Arrival: Tuesday, in Chicago, Illinois  
Departure: Wednesday, after 5:00 PM CST

[Please book your airline reservations and keep receipts](#)

**Transportation**

Arrival: Taxis to the hotel are available outside the Baggage Claim area.  
Departure: Taxis to the airport are available at the Hyatt Chicago Hotel.

[Please obtain receipts](#)

**Hotel:**

Your hotel accommodation will be made for you. The room rate and taxes will be paid by BTG International Canada Inc.

**Hyatt Chicago Magnificent Mile (formerly Wyndham Hotel)**  
**633 North St. Clair**  
**Chicago, IL 60611**  
**312-787-1234**

**Tuesday:** You are invited to join us for dinner at 7:00 PM CST at the Capital Grille.

**Wednesday:**

Hotel meeting room will be posted by Hyatt.  
6:45 AM Light continental breakfast will be available in the meeting room.  
7:00 AM Session begins:  
– Didactic Session with Dr. Salem and staff.  
– Case Studies (please prepare one or two potential TheraSphere® cases for review).  
– Observation of TheraSphere® Treatments.  
Lunch Served during meeting.  
3:00 PM Session ends.

**Depart for Airport:** Approximately 3:00 PM CST.

**PUBLIC**

- Immediate Release  
 Normal Release

**NON-PUBLIC**

- A.3 Sensitive-Security Related  
 A.7 Sensitive Internal  
 Other: \_\_\_\_\_

Reviewer: gpc Date: 9/7/13



**Cook, Jackie**

**From:** Ning, Yongli [Yongli.Ning@providence.org]  
**Sent:** Friday, July 26, 2013 3:03 PM  
**To:** Cook, Jackie  
**Subject:** RE: YT-90 THERA SPHERE AMENDMENT REQUEST - REQUEST FOR ADDITIONAL INFORMATION  
**Attachments:** BTG training.pdf; CoE Training Invitation Dr. Inampudi Sep 2013.docx

Jackie,

Nice talking to you. Please see the attached for the training by BTG that was postponed from June to September 2013 due to time conflicts. Also please see the company's commitment for *in-vitro* simulated cases and the commitments for other requirements. It is also the commitments from Providence Alaska Medical Center to the three items pointed by you.

Please notice that TheraSphere® is manufactured by Nordion (Canada) Inc. for BTG International Canada Inc. TheraSphere® is a trademark of Theragenics Corporation used under license by BTG International Canada Inc. BTG and the BTG roundel logo are registered trademarks of BTG International Ltd.

As the RSO I will be responsible to have our institute in compliance with all regulations of NRC.

Please point out to me if there is any more I need to do.

Thank you.

Yongli Ning, MS  
Chief Medical Physicist - Radiation Oncology  
Radiation Safety Officer  
Providence Alaska Medical Center

Phone: 907 212-3186, 907 212-5691  
Cell: 907-230-2072; Fax: 907 212-3665  
Email: [yning@provak.org](mailto:yning@provak.org)

**PUBLIC**  
 Immediate Release  
 Normal Release

**NON-PUBLIC**  
 A.3 Sensitive-Security Related  
 A.7 Sensitive Internal  
 Other: \_\_\_\_\_

Reviewer: JAC Date: 8/1/13

**From:** Cook, Jackie [<mailto:Jackie.Cook@nrc.gov>]  
**Sent:** Tuesday, July 16, 2013 1:30 PM  
**To:** Ning, Yongli  
**Subject:** YT-90 THERA SPHERE AMENDMENT REQUEST - REQUEST FOR ADDITIONAL INFORMATION  
**Importance:** High

License: 50-17838-01  
Docket: 030-13426  
Control: 580869

Mr. Ning:

I am processing your above subject amendment request dated May 15, 2013. Please provide the following items in response to my request for additional information.

**PUBLIC**  
 Immediate Release  
 Normal Release

**NON-PUBLIC**  
 A.3 Sensitive-Security Related  
 A.7 Sensitive Internal  
 Other: \_\_\_\_\_

Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

1. Please submit documentation of Dr. John Halligan and Dr. Chakri Inampudi's training and experienced received by the device manufacturer which should have included the *in-vitro* simulated cases and a commitment that each individual will complete at least the 1<sup>st</sup> 3 hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which authorization is sought.
2. In addition, please submit documentation from the manufacturer to the appropriate NRC Regional Office within 30 days of when the 3 patient cases have been satisfactorily completed.
3. Please commit to providing training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. Please note that this training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

**Please respond to this email by Friday, July 26, 2013.** If you are unable to respond by this due date, please don't hesitate to contact me so we can discuss an extension to the date. If you have any questions regarding this fax, please call me at (817) 200-1132. When responding to this fax, please include the license, docket and control numbers located at the top of this page.

Sincerely,

*Jacqueline "Jackie" D. Cook*  
Senior Health Physicist  
Division of Nuclear Materials Safety  
Nuclear Materials Safety Branch B  
1600 E. Lamar Blvd., Arlington, TX 76011  
817-200-1132 (office)/817-200-1263 (fax)  
e-mail address: [Jackie.Cook@nrc.gov](mailto:Jackie.Cook@nrc.gov)

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