

Hill, Carol

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**From:** Chris <chrisfitz65@hotmail.com>  
**Sent:** Tuesday, March 03, 2015 2:59 PM  
**To:** Hill, Carol  
**Subject:** TheraSphere training record for Brian Christenson St. Vincent healthcare Billings Mt  
**Attachments:** Dr. Christenson Training record final 2-2015.docx

Good Afternoon Carol, please accept the attached document confirming Brian Christenson has completed his required 3 cases under a proctor for TheraSpheres at St Vincent Healthcare. I sent notification of his first case in January and the second two cases were completed on 02/06/15.

Thank you

Chris Fitz, RSO  
St Vincent Healthcare  
billings MT.

25-0553-01

**PUBLIC**

- ☐ Immediate Release  
☒ Normal Release

**NON-PUBLIC**

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

Reviewer: RTZ Date: 3-30-2015

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RECEIVED  
MAR 03 2015

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Reviewer: R102 Date: 3.30.2015

**DNMS**

To: Chris Fitz, RSO; Brian Christenson MD  
From: Mark Moe  
Date: 2/6/15  
Subject: TheraSphere® In-vitro/ In-vivo Administration Training for Authorized Users.

I am pleased to confirm that Brian Christenson MD 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:

Vendor radiation safety lecture and three in-vitro set assemblies were conducted on 12/18/14. 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.

Brian Christenson MD completed training with three in-vivo cases on the dates of 12/19/14 and two cases on 2/6/15. Mark Moe, Interventional Oncology Proctor for BTG supervised/trained users at the above cases.

- 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* cases.

This completes the BTG training for TheraSphere®. I look forward to working with you and your staff to develop a successful Y-90 TheraSphere® program at your hospital.

Sincerely,

*Mark Moe*

Interventional Oncology Proctor, TheraSphere  
BTG Inc.

14 5 8 6 3 7 3



DATE

03/27/2015

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE

Christopher K. Fitz  
Radiation Safety Officer  
St. Vincent Healthcare  
P.O. Box 35200  
Billings, Montana 59107-5200

LICENSE NUMBER

25-07553-01

MAIL CONTROL NUMBER

586373

LICENSING AND/OR TECHNICAL REVIEWER

CH

This is to acknowledge the receipt of your:

☒ LETTER and/or ☐ APPLICATION DATED: 03/03/2015

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 fill out NRC Form 531, located at the following link:

<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

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 IV  
U. S. Nuclear Regulatory Commission  
DNMS/NMSB - B  
1600 E. Lamar Boulevard  
Arlington, TX 76011-4511  
(817) 200-1103 or (817) 200-1140

✓ 3/27



BETWEEN:

Accounts Receivable/Payable  
and  
Regional Licensing Branches

[ FOR ARPB USE ]  
INFORMATION FROM WBL

Program Code: 02230  
Status Code: Pending Amendment  
Fee Category: 7C  
Exp. Date: 04/30/2015  
Fee Comments:  
Decom Fin Assur Reqd: N

## License Fee Worksheet - License Fee Transmittal

### A. REGION

#### 1. APPLICATION ATTACHED

Applicant/Licensee: ST. VINCENT HEALTHCARE  
Received Date: 03/03/2015  
Docket Number: 3002396  
Mail Control Number: 586373  
License Number: 25-07553-01  
Action Type: Notifications

#### 2. FEE ATTACHED

Amount: \_\_\_\_\_

Check No.: \_\_\_\_\_

#### 3. COMMENTS

Signed: \_\_\_\_\_

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

### B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / / )

1. Fee Category and Amount: \_\_\_\_\_

#### 2. Correct Fee Paid. Application may be processed for:

Amendment: \_\_\_\_\_

Renewal: \_\_\_\_\_

License: \_\_\_\_\_

3. OTHER \_\_\_\_\_  
\_\_\_\_\_

Signed: \_\_\_\_\_

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