



September 25, 2014

Frank Tran  
Materials Licensing Branch  
US Nuclear Regulatory Agency – Region III  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

Dear Mr. Tran,

Re: Control Number 584493

Here is the information you requested for the amendment to Materials License 21-08317-01.

We will be using Y-90 TheraSpheres as permitted by 10 CFR 1000.

The physical form is glass microspheres.

TheraSpheres are manufactured by: Nordion (Canada), Inc. for Biocompatibles UK Ltd. a BTG International group company.

The delivery system/model is Mark III Administration Set and Administration Accessory kit. No single vial will exceed 540 milliCuries (20 GBq); total possession not to exceed 3240 milliCuries (120 GBq).

Manufacturer representative will provide documentation of AU training to the licensee that will be forwarded to NRC Region 3 within 30 days after satisfactory completion of first three patient cases treating with Y-90 TheraSpheres.

Sincerely,

Dennis Aurand, MS, DABR<sup>®</sup>  
Diagnostic Medical Physicist  
Radiation Safety Officer  
daurand@mhc.net  
phone: 231.392.8612  
fax: 231.935.3204

**Tran, Frank**

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**From:** Aurand, Dennis <daurand@mhc.net>  
**Sent:** Thursday, September 25, 2014 10:58 AM  
**To:** Tran, Frank  
**Subject:** RE: re NRC License No. 21-08317-01/CN 584493  
**Attachments:** NRC amendment Commitment and other Sept 25 2014.pdf

I hope I addressed the Name of the delivery system and Sealed sources name and model adequately.

See attached.

Dennis Aurand  
Ext 28612

**From:** Tran, Frank [mailto:Frank.Tran@nrc.gov]  
**Sent:** Thursday, September 25, 2014 10:31 AM  
**To:** Aurand, Dennis  
**Subject:** RE: re NRC License No. 21-08317-01/CN 584493

Hi Dennis,

Could you please provide the total possession limit for each system using microspheres (i.e. Sir-Spheres: 500 mCi, TheraSphere: 2 Ci).

Thank you,

Frank Tran

**From:** Tran, Frank  
**Sent:** Thursday, September 25, 2014 9:12 AM  
**To:** 'Aurand, Dennis'  
**Subject:** re NRC License No. 21-08317-01/CN 584493

Dear Mr. Aurand:

For Y-90 permitted by 10 CFR 35.1000, our current policy is to list the sealed source manufacturer and model, the name of the delivery system, and the total quantity of Y-90 on the license. Could you please provide us the following information.

1)

|             | Name of delivery system | Sealed source's name and model |
|-------------|-------------------------|--------------------------------|
| Sir-Sphere  |                         |                                |
| TheraSphere |                         |                                |

2) the total possession limit for Y-90 permitted by 10 CFR 35.1000.

In addition, based on your response to question #1 of our request dated September 24, 2014, please confirm that the licensee will provide documentation from the manufacturer to the NRC Region 3 within 30 days of when the first three patient cases treating with Y-90 permitted by 10 CFR 35.1000 have been satisfactorily completed.

Please provide a response to the above in writing with an authorized signature by October 11, 2014. In addition, please refer Control Number 584493 in your response to facilitate proper mail handling in our office.

If you have any question, please contact me at 630-829-9623 or reply to this email. Your response could be sent to [frank.tran@nrc.gov](mailto:frank.tran@nrc.gov) or faxed to 630-515-1078 (if you prefer one of these delivery methods, please retain the original copy for your record).

Thank you,

Frank Tran