



September 24, 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.

1) Training – TheraSpheres

Attached to the e-mail is the manufacturer representative's training commitment. Training will be provided during the first three (minimum) cases.

2) Authorization

Dr. Mir does not have sufficient training with Sir-Spheres. His authorized use will be limited to TheraSpheres until sufficient training is acquired.

3) Training – TheraSpheres

All individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres will be trained in the licensee's procedures, commensurate with the individual's duties to be performed.

Sincerely,

Dennis Aurand, MS, DABR[®]
Diagnostic Medical Physicist
Radiation Safety Officer
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phone: 231.392.8612
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a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

This is standard operating procedure for all Nuclear Medicine departments. We will address this in relationship to Y-90 TheraSphere as needed.

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;

As part of our training, BTG issues Calibration Data Sheets for all doses received and we will use these to determine a unique calibration setting for Y-90 TheraSphere on your dose calibrator. This will insure NIST traceability. We will also demonstrate the operation of the survey meter used for dose, background, and patient measurements

c) Evaluation of each patient or human research subject for the dose/activity of Y-90 microspheres to be administered to each treatment site;

We will be reviewing the planned treatment of a minimum of 3 patients and based on the perfused volume, LSF, and desired dose, we will determine that the dose of Y-90 TheraSphere is correct prior to ordering and administration

d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject;

As mentioned above, we will calculate and measure the Y-90 TheraSphere. TheraSphere is a sealed dose intended for a single patient treatment and does not require any intervention by the staff. We will assure that the microspheres are at the bottom of the V-vial as per protocol prior to administration and of course use proper radiation safety techniques while handling the dose.

e) Using administrative controls to prevent a medical event involving the use of byproduct material;

The dose will be checked for activity against the written directive prior to treatment and assure compliance with the pre-written directive. Should we experience departmental or patient issues beyond our control, we will make appropriate adjustments prior to the procedure to minimize any reportable medical event from occurring.

f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures;

As part of our in-house training, we will demonstrate procedures to assure control and containment of any possible spillage of Y-90 TheraSphere. The staff will be instructed on proper techniques when handling and removing any contaminated items.

g) Follow up and review of each patient's or human research subject's case history for Y-90 microspheres;

The staff will be debriefed following each of the 3 proctored events. Suggestions will be noted to improve the program moving forward and Nordion will remain available for patient discussions and follow-up.

Tran, Frank

From: Aurand, Dennis <daurand@mhc.net>
Sent: Wednesday, September 24, 2014 11:56 AM
To: Tran, Frank
Subject: RE: Request for additional information re NRC License No. 21-08317-01/CN 584493
Attachments: NRC a-g training requirements template 1 (Mike).pdf; NRC amendment Commitment and other Sept 24 2014.pdf

Mr. Tran,

Please see attached documents. The numbered paragraphs in the letter refer to the numbers in your correspondence below.

Mike Pappas is the manufacturer representative who will be providing the training.

Dennis Aurand, MS, DABR[®]
RSO, Diagnostic Medical Physicist
Munson Medical Center
Traverse City, MI
Ph 231-392-8612
daurand@mhc.net

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From: Tran, Frank [<mailto:Frank.Tran@nrc.gov>]
Sent: Wednesday, September 24, 2014 9:21 AM
To: Aurand, Dennis
Subject: Request for additional information re NRC License No. 21-08317-01/CN 584493

Dear Mr. Aurand:

We have reviewed the provided information dated September 17, 2014. In order to complete our review, we will need the following.

1) Based on the 8-hours training course objective, we found that some required training areas in the Microsphere Brachytherapy Sources and Devices guidance may have been omitted. Please provide additional information regarding the training for Dr. Mir and Walsh for the followings:

- 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) Using administrative controls to prevent a medical event involving the use of byproduct material (Appendix S to NUREG-1556, Volume 9 provides additional guidance on this subject); and
- d) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures (Appendix N to NUREG- 1556, Volume 9 provides additional

guidance on this subject). The procedures should address any special circumstances that may be encountered, such as electrostatic charge of microspheres and proper survey instrument and survey technique for beta emitters.

The training above must be provided by an authorized user for Y-90 microspheres or by a Y-90 microsphere manufacturer representative.

2) The licensee requests authorization for Dr. Mir for the use of Y-90 microsphere, including Theraspheres and Sir-Spheres, permitted by 10 CFR 35.1000; however, his training record did not show any cases using Sir-Spheres. Please provide training record for Dr. Mir with regard to Sir-Spheres use (at least three cases) in accordance with the Microsphere Brachytherapy Sources and Devices guidance.

3) Please provide a commitment to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

Please provide a response to the above in writing with an authorized signature by October 8, 2014. In addition, please refer Control Number 584493 in your response to facilitate proper mail handling in our office. The current Microsphere Brachytherapy Sources and Devices guidance is published on the NRC's website at <http://pbadupws.nrc.gov/docs/ML1217/ML12179A353.pdf>.

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 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

From: Aurand, Dennis [<mailto:daurand@mhc.net>]
Sent: Tuesday, September 23, 2014 10:58 AM
To: Tran, Frank
Subject: License amendment 21-08317-01

Mr. Tran,

See attached.

Thank you.

Dennis Aurand, MS, DABR[®]
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daurand@mhc.net

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