

January 28, 2013

Br. 1

Janice Nguyen  
Health Physicist  
U.S. NRC Region 1 DNMS  
2100 Renaissance Blvd, Suite 100  
King of Prussia, Pa. 19406

REC RG 1 01 31 13 PM 07:17

**Re: NRC Control Number: 577731 (License Amendment Request: Y-90)**

Dear Ms. Nguyen:

03001242

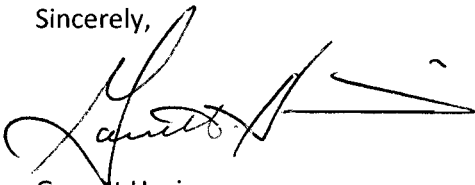
We are requesting the addition of Nordion Y-90 microspheres and the addition of Dr. Jeffrey Takahashi as an authorized user of Y-90 to Middlesex Hospital's NRC license number 06-00649-03.

Per the authorized user training and documentation requested in your September 4, 2014 letter, Nordion provided the required training to Dr. Takahashi on January 8, 2013. Attached, please find the required documentation of the authorized user training from Nordion.

Thank you for your guidance during this process.

Please let us know if any additional information is needed.

Sincerely,



Garrett Havican  
VP Operations  
Middlesex Hospital

cc. J. Merton DrPH  
Radiation Safety Officer

28 Crescent Street  
Middletown, Connecticut 06457-3650

tel 860 358-6000  
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**nordion**  
SCIENCE ADVANCING HEALTH

To: Jeffrey Takahashi, MD  
From: Mike Pappas  
Date: January 8, 2013  
Subject: TheraSphere® Training for Authorized Users

I am pleased to confirm that you have 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:

- As an interventional radiologist, the user has completed training provided by a Nordion representative involving:
  - 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 Nordion, including three supervised hands-on *in-vitro* simulated cases.

This completes the Nordion training required prior to submitting a license amendment to the NRC to be named as an Authorized User for TheraSphere®. I look forward to working with you and your staff to develop a successful Y-90 TheraSphere® program at your hospital.

Sincerely,

Michael W. Pappas, BSRT, CNMT

Clinical Specialist, TheraSphere  
Nordion (Canada) Inc.

This is to acknowledge the receipt of your letter/application dated

1/28/13, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (06-00649-03)  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 579928.

When calling to inquire about this action, please refer to this control number. You may call us on (610) 337-5398, or 337-5260.