

December 21, 2020

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Amendment to License No. 21-12829-01, Metro Health - University of Michigan Health

Dear Madam or Sir:


Please amend our license to add 35.1000 Y90 Therasphere and Y90 SIR-Spheres as an authorized use for Christina Bakalis, MD. Documentation of her training is enclosed.

Y90 Therasphere: Dr. Bakalis has completed three (3) hands-on patient cases under the supervision of Dr. Tiede.

Y90 SIR-Spheres: Dr. Bakalis has completed three (3) supervised simulated cases. We will submit documentation of three (3) hands-on patient cases when she has completed them.

If you have any questions, please contact, Dawn Edwards, at 734-662-3197 or dedwards@mpcphysics.com or Suzanne Kasper, at 616-252-7355 or Suzanne.kasper@metrogr.org.

Sincerely,



Ronald G. Grifka, MD, FAAP, FACC, FSCAI
Chief Medical Officer
Metro Health-University of Michigan Health
Professor of Pediatrics
University of Michigan Medical School
Attending Cardiologist
C. S. Mott Children's Hospital



December 21, 2020

Re: Confirmation of Y-90 Therasphere Work Experience for Christina Bakalis, MD

To whom it may concern:

Dr. Christina Bakalis, MD has work experience under my supervision for Y-90 microsphere brachytherapy involving:

- a) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys; and
- 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; and
- c) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject; and
- d) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures. The procedures addressed any special circumstances that may be encountered such as the electrostatic charge of Y-90 microspheres and the proper survey instrument and survey technique for beta emitters;

In addition, Dr. Bakalis, MD has work experience under my supervision for Y-90 Therasphere brachytherapy including:

- a) Preparing and administering patient dosage: including selection of activity of Y-90 Therasphere to be administered to each treatment site and catheter positioning to ensure administration of the Y-90 Therasphere is in accordance with the written directive; and
- b) Using administrative controls to prevent a medical event involving the use of byproduct material, and
- c) Evaluation of patient or research subject's treatments to determine whether the administered dosage was in accordance with the written directive or if a medical event has occurred

Under my supervision Dr. Bakalis has completed training in the operation of the Therasphere delivery system, safety procedures and clinical use for Y-90 Therasphere. Attached is documentation of three hands-on patient cases for Y-90 Therasphere conducted in my presence.

The dates of the work experience and training were from January 2019 – September 2020.

Regards,

Matthew A. Tiede, MD
Authorized User
Metro Health-University of Michigan Health
NRC License number 21-12829-01



Therasphere AU supervised hands-on patient training for Dr. Bakalis

Date: 9/25/2020 Patient Initials: CD

Date: 10/02/20 Patient Initials: VH

Date: 10/09/20 Patient Initials: TD

Proctor signature:

Matthew A. Tiede, MD
Authorized User
Metro Health-University of Michigan Health
NRC License number 21-12829-01

