

From: [Miguel Rios](#)
To: [Gallagher, Robert](#); [Javier, MD Nazario](#); [CGuzman1@himapr.com](#)
Subject: [External_Sender] Re: Request for Additional Information - Control No. 590794
Date: Monday, July 11, 2016 7:11:03 AM

License No. 52-21325-01
Docket No. 03020510
Control No. 590794

1. We confirm that our Radiation Safety Officer will attend the training in our procedures. The training is to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed and that this training would be provided to all individuals preparing, measuring, performing dosimetry calculations, administering Y-90 microspheres or part of the radiation safety personnel.
2. The Atomlab 500 dose has been purchase and we are waiting delivery of it. The calibrator will be used in our current Hot Lab in addition to measure the Y-90 SIR-Spheres.
3. We will be using the SIRTEX Medical Limited SIR Spheres microspheres.
4. We confirm that we will follow the manufacturer's procedures for determining shunting to non-treatment sites prior to treatments.

Regards,

Miguel A. Ríos, MS, DABR
Medical Physicist

On Jun 22, 2016, at 2:20 PM, Gallagher, Robert <Robert.Gallagher@nrc.gov> wrote:

License No. 52-21325-01
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PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

Mr. Rios Gerena,

This letter is in regards to the application dated April 4, 2016 requesting the addition of Javier Nazario, M.D. as an authorized user for Yttrium-90 (Y-90) microspheres, specifically SIR-Spheres®, to NRC License No. 52-21325-01 issued to Centro Medico del Turabo, Inc. d/b/a Hospital HIMA – San Pablo Bayamon. This will also add authorization for your facility to use Y-90 for manual brachytherapy use in the Sirtex Medical Limited

SIR-Spheres. In order to continue our review more information is necessary.

1. You committed to providing training in your procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed and that this training would be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres. Please confirm that your Radiation Safety Officer will attend this training.
2. The application dated April 4, 2016 states that you intend on purchasing an Atomlab 500 dose calibrator to measure the Y-90 SIR-Spheres. Do you intend on using this new dose calibrator in your current Hot Lab and do you currently possess it?
3. Provide the manufacturer's name for the microspheres that you are requesting.
4. You committed to follow the manufacturer's procedures. Please confirm that you will follow the manufacturer's procedures for determining shunting to non-treatment sites prior to treatments.

We will continue our review upon receipt of the above requested information. Please contact Robert Gallagher at (610) 337-5182 with any questions.

Regards,

Robert L. Gallagher
Health Physicist
U.S. NRC, Region I
2100 Renaissance Blvd.
King of Prussia, PA 19406
(610) 337-5182 office
(610) 337-5269 fax

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