UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

November 9, 2012

Docket No. 03020510 License No. 52-21325-01
Control No. 578127

José Carballo Collazo
Executive Director
Centro Médico del Turabo, Inc.
d/b/a Hospital HIMA - San Pablo Bayamón
P.O. Box 236
Bayamón, PR 00960-6036

SUBJECT: CENTRO MÉDICO DEL TURABO, INC., VOIDANCE OF APPLICATION FOR LICENSE AMENDMENT, CONTROL NO. 578127

Dear Mr. Collazo:

This concerns the license amendment request to authorize use of yttrium-90 SIR-Spheres. Additional information as documented in our e-mail dated October 17, 2012, is required to demonstrate that your proposed program meets NRC requirements. In order to allow you sufficient time to gather this information, we have voided your request. When all of the required information is available, please submit it to my attention at the Region I Office, referencing the Control Number listed above. The required additional information includes:

1. Please provide complete and signed documentation for Dr. Nazario; signed by an Authorized User (AU) approved for Sir-Sphere use. You may utilize NRC Form 313A (AUD) and preceptor attestation forms to document Dr. Nazario's SIR-Sphere training and experience or you may prepare a letter similar to your previous letter from MD Anderson Cancer Center dated December 9, 2011. Please include all of the following information in the document signed by the preceptor AU:

    a. Three years supervised clinical experience in diagnostic radiology and one additional year of supervised clinical experience in interventional radiology; and

    b. Eighty hours of classroom and laboratory training for byproduct material, including yttrium-90 microspheres, in:

        i. radiation physics and instrumentation;

        ii. radiation protection;

        iii. mathematics pertaining to the use and measurement of radioactivity;

        iv. radiation biology; and

c. Work experience under the supervision of an AU for SIR-Spheres or training provided by a Sirtex representative that involved:

   i. ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

   ii. performing quality control procedures on instruments used to determine the activity of yttrium-90 microspheres and performing checks for proper operation of survey meters;

   iii. evaluation of each patient or human research subject for the dose/activity of yttrium-90 microspheres to be administered to each treatment site;

   iv. calculating and measuring the activity and safely preparing the yttrium-90 microspheres to be delivered to the patient;

   v. using administrative controls to prevent a medical event;

   vi. using procedures to control and to contain spilled byproduct material, including yttrium-90 microspheres, safely and using proper decontamination procedures;

   vii. follow up and review of each patient's case history for yttrium-90 microspheres

d. Clinical use experience (i.e., casework) with Sir-Spheres that included three supervised hands-on cases.

2. Please note that the microsphere guidance was revised in June 2012, and as such, additional requirements regarding written directives and procedure modification during emergent patient conditions were included. Therefore, please confirm that if the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g. artery spasm or sudden change in blood pressure), the AU will document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive must include the reason for not administering the intended dose/activity, the date, and the signature of an AU for Y-90 microspheres.

3. Please confirm that you will provide whole body and extremity dosimeters to individuals involved in preparation and administration of SIR-Sphere doses.

For your convenience, a copy of the Licensing Guidance for SIR-Spheres Yttrium-90 Microspheres is located at http://pbadupws.nrc.gov/docs/ML1217/ML12179A353.pdf.

In addition, please note that the NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your

organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Please direct any questions on this matter to Maryann Abogunde at (610) 337-5090. Thank you for your cooperation.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
María M. Palacios, M.S., Radiation Safety Officer

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SUNSI Review Complete: MAbogunde

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