

From: Abogunde, Maryann
Sent: Wednesday, October 17, 2012 2:33 PM
To: mariosdabr@me.com
Subject: NRC request for additional information - License amendment for Centro Médico del Turabo, Inc.
Attachments: nrc313a(aut).pdf

Licensee: Centro Médico del Turabo, Inc.
d/b/a Hospital HIMA – San Pablo Bayamon
License No.: 52-21325-01
Docket No.: 030-20510
Control No.: 578127

Dear Mr. Collazo:

In order to continue our review of your amendment request dated August 9, 2012, we need the following additional information:

1. Please provide a complete and signed NRC Form 313A (AUD) and preceptor attestation that documents Dr. Nazario's SIR-Spheres training and experience included all of the following:
 - a. 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
 - b. work experience under the supervision of an AU for SIR-Spheres or a Sirtex representative that involves:
 - 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; and
 - vii. follow up and review of each patient's case history for yttrium-90 microspheres.

2. Please provide a copy of the permit or license that lists supervising individual, Dr. Armeen Marvash as an AU for SIR-Spheres uses.
3. Please confirm that you will provide whole body and extremity dosimeters to individuals involved in preparation and administration of SIR-Spheres doses.

For your convenience, I have attached a copy of NRC Form 313A (AUT), which can be used to document Dr. Nazario's experience, clinical case work, and preceptor statement. It can also be located at: [http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(aut\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aut).pdf).

You may fax your reply to my attention to 610-337-5269. Please reference Mail Control Nos. 578127 in your response.

Please send a return e-mail to confirm that you received this message.

Please note that the office of the Region I Division of Nuclear Materials Safety has moved effective May 9, 2012. Our new address is:

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

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.

Thank you for your assistance,

/RA/

Maryann Abogunde
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