



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

May 29, 2013

Docket No. 03038633  
Control No. 580336

License No. 52-35057-01

Joel Ramos, M.D.  
Director  
Centro Cardiovascular Las Piedras  
P.O. Box 2017  
PMB 50086  
Las Piedras, PR 00771

SUBJECT: CENTRO CARDIOVASCULAR LAS PIEDRAS, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 580336

Dear Dr. Ramos:

This is in reference to your application dated February 26, 2013, applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. Please indicate the Owner and/or President of Centro Cardiovascular Las Piedras. In addition, provide a copy of a business license or registration issued by the Commonwealth of Puerto Rico.
2. Item 7 of your application regarding the proposed Radiation Safety Officer (RSO) and authorized user (AU) references an NRC license (Medicina Nuclear del Este, 52-25333-01) that lists your name as Joel Ramos Ayala, M.D. Please clarify your full name and how you would like it listed on the license.
3. Please confirm that the proposed location of use is not a location of use for any other active NRC license.
4. Please provide directions to your location of use (Centro Cardiovascular Las Piedras, Carr 198 km 23.6, Bo Collores Las Piedras, PR 00771) from San Juan/PR-30.

In addition, clarify the correct listing of the address that can be identified on a map. Please note that an internet search did not identify this address in Las Piedras, PR. It appears that the location may be on Calle Jose Celso Barbosa (HWY 198) and Bo Collores is the neighborhood.

5. Your application and facility diagram did not indicate any use of PET materials, which are now regulated by the NRC. Please indicate if there will be any use of PET isotopes (e.g., C-11, N-13, O-15, F-18, Rb-82), and if so, provide a detailed description of PET

- facilities, including shielding calculations.
6. Please list the manufacturer and model number for any sealed sources that do not fall under 10 CFR 35.65.
  7. You have requested to be named RSO on your license. You also indicated that you serve as RSO on other active NRC licenses. Please address the following:
    - a. Describe the control over the radiation safety program that will be delegated so that you will be able to exercise authority when confronted with radiation safety problems that require implementation of corrective actions.
    - b. Describe the relationship that will exist between you and institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.
    - c. Identify your other commitments for other NRC or Agreement State licensed facilities, along with a description of how you will allocate time to permit the performance of the duties of the RSO as described in the regulations. In addition, state the minimum amount of on-site time (hours per week or month).
    - d. Appoint an in-house representative who will serve as the point of contact during your absence. This person may be allowed to assist you with limited authority.
    - e. Describe your overall availability as RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take for you to arrive at the facility in the event of an emergency that requires your presence.
  8. Regarding your facilities and equipment, please clarify the information listed below. Please be aware that information (including diagrams) that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "security-related information – withhold under 2.390":
    - a. Please indicate room numbers (if any) for all areas of byproduct material use or preparation for use (e.g. hot lab).
    - b. You stated that the facility is a one-floor area. Please provide a description of all areas surrounding the areas of use, including the area(s) below if any.
    - c. Please provide a detailed diagram of your hot-lab room and indicate the position of each of the areas described below:
      - i. Storage of radiopharmaceuticals;
      - ii. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste; and
      - iii. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, etc.).

- d. In addition, please provide a detailed description of:
  - i. any radioactive waste storage areas outside of the hot lab room; and
  - ii. Shielding for the dose storage, dose preparation, waste storage, and radiopharmaceutical administration areas.
9. Item 9 of your application regarding the dose calibrator and other equipment used to measure dosages of unsealed byproduct material includes a commitment related to administering dosages of alpha-emitting unsealed byproduct material. Please clarify whether this type of material will be used at your facility.
10. The statement you provided regarding the safe use of unsealed licensed material did not indicate that the procedures will be written. Please revise this commitment by stating: "We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."
11. In order to facilitate future communications, please provide a current contact e-mail address, telephone, and fax number for your RSO and President/Senior Management.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material; Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 580336. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5090.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

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.

J. Ramos

4

Thank you for your cooperation.

Sincerely,

***Original signed by Maryann Abogunde***

Maryann Abogunde  
Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety

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**SUNSI Review Complete: MAbogunde**

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