



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 16, 2009

Docket No. 03037872  
Control No. 143031

License No. 52-31347-01

Rigoberto Ramos, M.D.  
Centro Cardiovascular & Medicina Nuclear La Montaña  
Muñoz Rivera Street #35  
Adjuntas, PR 00631

**SUBJECT: CENTRO CARDIOVASCULAR & MEDICINA NUCLEAR LA MONTAÑA,  
REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION  
FOR NEW LICENSE, CONTROL NO. 143031**

Dear Dr. Ramos:

This is in reference to your application dated November 12, 2008, applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. Your application should have been signed by a management representative. Please provide either a letter signed by a management representative indicating that management has reviewed the application and concurs in the statements and representations contained therein or send a letter confirming Dr. Ramos's title and management status. Note also that a management representative should sign all future correspondence that requests a change in your license.
2. On a detailed version of your facility diagram, please indicate the position of each of the areas described below (a-e) and describe the type, dimensions, and thickness of shielding that you will use. Please also include room numbers on your facility diagram.
  - a. Use and storage of Tc-99m generators or confirm that only unit dosages will be used.
  - b. Storage of radiopharmaceuticals (refrigerated and nonrefrigerated).
  - c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. If this area is not located within your main department, describe how you will secure the material.
  - d. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, etc.).
  - e. PET storage and use areas or confirm that PET isotopes are not currently being used.

In addition, identify adjacent areas across the walls including areas above and below use and storage locations and show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301.

3. Please provide a description of the radiation monitoring instruments (e.g. gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, liquid scintillation counter, proportional counter, etc.) that will be used to perform radiation level detection, measurement, and contamination surveys, as well as package receipt wipe tests.
4. Please confirm that the equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.
5. Please confirm that you will develop, implement and maintain written procedures for the safe use of unsealed byproduct materials that meet the requirements of 10 CFR 20.1101 and 20.1301.
6. Please confirm that you will develop, implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 Part 20.1101.
7. Please confirm that your proposed location of use, listed in Item 3 of your application, is not a location of use for any other active NRC license.
8. Please note that Gallium-67 Citrate, Indium-111 Chloride, and Thallium-201 Chloride will be included under 10 CFR 35.200. Therefore, they will not be listed as line items on your license.
9. You requested a maximum possession limit of 100 millicuries of Cobalt-57 sealed sources. Please note that these sources may be covered by 10 CFR 35.65, and therefore will not be listed separately on your license. Please review the requirements in 10 CFR 35.65. For sources that do not meet the requirements in 10 CFR 35.65 (e.g., greater than 30 millicuries), please provide the manufacturer and model number for each source requested.
10. Please indicate the purpose for which the licensed material will be used.
11. Please provide a business license to show that you have been registered as a legitimate business entity in the Commonwealth of Puerto Rico.
12. On your application, you did not indicate an accurate certifying officer, please submit this information along with a Curriculum Vitae detailing this individual's previous employment and training history.

R. Ramos

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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; then 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. 143031. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5169.

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.

Sincerely,

***Original signed by Penny Lanzisera***

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

cc:  
Ricardo E. Santiago, M.D., Radiation Safety Officer

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**SUNSI Review Complete: PLanzisera**

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