



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

November 25, 2011

Docket No. 03038493
Control No. 576157

License No. 52-31455-01

Lourdes Garcia, M.D.
Chief of Nuclear Medicine
Carolina Cardiovascular Diagnostic
P.O. Box 11665
Santurce, PR 00910

SUBJECT: CAROLINA CARDIOVASCULAR DIAGNOSTIC, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 576157

Dear Dr. Garcia:

This is in reference to your application dated October 5, 2011 applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. Item 2 of this application listed Lourdes Garcia and Carolina Cardiovascular Diagnostic as the name of the applicant. Please clarify whether you are requesting the license to be issued to Lourdes Garcia or to Carolina Cardiovascular Diagnostic.
2. Please indicate the Owner and/or President of Carolina Cardiovascular Diagnostic. In addition, provide a copy of a business license or registration issued by the Commonwealth of Puerto Rico.
3. Please confirm that the proposed location of use is not a location of use for any other active NRC license.
4. Item 5 of this application requested authorization to use 500 millicuries of any byproduct material permitted by 10 CFR 35.300. Table C.2 of this application requested both 500 millicuries of any byproduct material permitted by 10 CFR 35.300 and 500 millicuries of Iodine-131. Please clarify if the authorization for 10 CFR 35.300 materials should be limited to I-131 only.
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. It appears that your facility may be limited to provide only outpatient services. Please confirm that you will limit treatments to patients who may be released from licensee control under 10 CFR 35.75.
8. You have requested that Mr. Jossian J. Pagan Lisboa be named Radiation Safety Officer (RSO) on your license. It appears that this individual may be an outside consultant/contractor. If this is so, please address the following:
 - a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.
 - b. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.
 - c. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's 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 the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.
 - e. Describe the overall availability of the consultant-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 the RSO to arrive at the facility in the event of an emergency that requires his presence.
9. Please provide a detailed diagram of your hot lab room and indicate the position of each of the areas described below:
 - a. Storage of radiopharmaceuticals;
 - b. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste;
 - c. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, etc.)

Also provide a detailed description of:

- a. Shielding for the dose storage, dose preparation, waste storage, and radiopharmaceutical administration areas.
 - b. The areas above and below your areas of radioactive materials use.
 - c. Any radioactive waste storage areas outside of the hot lab room.
10. Item 9 of this application stated that you have developed and will implement and maintain written survey meter calibration procedures, however you did not request authorization for a survey meter calibration source. Please confirm that you will not do in-house survey meter calibrations or provide a description of the sources to be used, calibration location and geometry, the authorized user for survey meter calibrations, and the user's training to do this task.
11. The occupational dose commitment in Item 10 of this application referenced a superseded document. Please revise this commitment to reference the current version of the NUREG, by stating: "We will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, Rev. 2, dated January 2008."
12. The statement you provided in Item 10 regarding 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."
13. 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; select **Nuclear Materials; Medical, Industrial, & Academic Uses of Nuclear Materials**; then **Licensee Toolkits, See our toolkit index page**. 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. 576157. If you have any technical questions regarding this deficiency letter, please call Ms. Maryann Abogunde at (610) 337-5090.

L. Garcia

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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 Sandra Gabriel

Sandra Gabriel
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
Jossian J. Pagan Lisboa, Radiation Safety Officer

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SUNSI Review Complete: MAbogunde

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