



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

April 27, 2011

Docket No. 03035572  
Control No. 574132

License No. 52-25542-01

Juan Perez-Monte, M.D.  
Beta Gamma Nuclear Radiology, Inc.  
P.M.B. 372  
P.O. Box 7891  
Guaynabo, PR 00970-7891

**SUBJECT: BETA GAMMA NUCLEAR RADIOLOGY, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 574132**

Dear Dr. Perez-Monte:

This is in reference to your application dated December 17, 2010 requesting to renew Nuclear Regulatory Commission License No. 52-25542-01. In order to continue our review, we need the following additional information:

1. Conflicting information regarding the use of 10 CFR 35.300 materials is provided in Item 5 of your application dated December 17, 2010. Please specify whether you will be using iodine-131 exclusively or will you be using other 35.300 materials for therapies permitted by 10 CFR 35.300. In addition, please confirm that administration of iodine-131 will be limited to patients who may be released in accordance with the requirements in 10 CFR 35.75.
2. Your application did not indicate any use of PET materials, which are now regulated by the NRC. Please indicate whether there is or 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 your PET facilities, including shielding calculations.
3. Item 5 of your application lists cobalt-57, cesium-137, and barium-133 sealed sources for the instrument calibration. These sources are authorized under 10 CFR 35.65 and therefore, will not be listed individually on your license.
4. The facility diagram provided did not contain the level of detail that we require. Therefore, please provide a facility diagram drawn to scale 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.), and

- d. Administration of dosages of iodine-131.

Also provide a detailed description of:

- e. Shielding for the dose storage, dose preparation, waste storage, and iodine-131 administration areas, and
  - f. Areas surrounding your areas of use, including on the same level and above and below. This should include designation of exterior walls.
5. Please describe the instrument (manufacturer and model number) that will be used to evaluate the results of your removable contamination surveys.
  6. In the dose calibrator section of Item 9, you checked a box that addresses the use of alpha-emitting unsealed byproduct material in other than unit doses. Please confirm that you do not intend to use alpha-emitting unsealed byproduct material.
  7. Please provide the current contact telephone number, e-mail, and fax for yourself and the Radiation Safety Officer.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Med, Ind, & Academic Uses**; 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. 574132. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5272.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

***Original signed by Tara L. Weidner***

Tara L. Weidner  
Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety

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**SUNSI Review Complete: TWeidner**

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