

Note to File:
April 6, 2011

Request for Additional Information
Hospital Oncológico Dr. I Gonzales Martínez
New License No. 52-13471-03
Docket No. 03038415
Control No. 574356

David Rhoe,

Please provide the following additional information in support of the application for the new license for Hospital Oncológico, San Juan, Puerto Rico.

1. Please clearly specify the radioactive materials you are requesting and their authorized uses. In items 5 and 6 of the license application, you requested 35.100 and 35.200 materials. In Item 6, you specified 35.200 radiopharmaceuticals for use in uptake, dilution, and excretion studies. 35.200 radiopharmaceuticals are permitted for use in imaging and localization studies. Further, there is a note below Items 5 and 6 in the application that states that only F-18 FDG will be used. F-18 FDG is included under 35.200 materials.
2. You have requested that David Rhoe be named Radiation Safety Officer (RSO) on your license. It appears that this individual may be an outside consultant\contractor. If this is so, in support of this request, 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).
 - 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.
3. Your application dated February 8, 2011 requested the addition of F-18 FDG. In your shielding calculations you submitted, you indicated that the shielding you have specified is "existing or to be added". Prior to issuance of this license we will need you to specify the final shielding design including materials and thickness. Please submit the following in support of your request:
 - a. On a detailed version of your facility diagram, please indicate the position of each area described below and describe the type, dimensions, and thickness of shielding that you will use
 - i. Storage of NARM radiopharmaceuticals (e.g., stored in transport shielding from the radiopharmacy).

- ii. Preparation and dispensing of NARM radiopharmaceuticals (e.g. 2 inch lead glass block, tungsten syringe shields, flush counter mounts for dose calibrator, well counter, etc.).
- iii. Patient quiet room rooms for patient awaiting scanning (e.g. ¼ to ½ inch lead shielding in walls, floor, and ceiling).
- iv. Dedicated patient bathrooms.
- v. Scan rooms (e.g. ¼ to ½ inch lead shielding in walls, floor and ceiling), and remote monitoring of patients with video cameras and/or lead shields for use by technician.
- vi. Storage of radioactive wastes, including decay-in-storage prior to disposal as non-radioactive waste. If this area is not located within your main department, describe how it will be secured
- vii. Storage of sealed sources.

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

b. If your well counter is located near NARM activities, describe additional shielding of the detector.

4. Please confirm that Frieda Silva is the same individual as Frieda Silva de Roldan.

Lester Tripp
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