

Frank Kolodziej Castro, M.D.
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Floral Park
Hato Rey, PR 00918

US NRC RI
475 Allendale Road
King of Prussia, PA 19406-1415

*M56
L-4*

January 28, 2009

Dear Sir or Madam:

52-31352-01

RE: Additional information for new license application (letter dated January 12, 2009)
Docket No. 03037882
Control No. 143067

1. Accelerator license to produce radioactive materials.

The Accelerator license is attached.

2. Name of the entity on the license.

International Cyclotron

3. a. Authority for the RSO

The Radiation Safety Officer (RSO) has the responsibility to carry out that which ensures that the International Cyclotron complies with the conditions of its Radioactive Materials License and other Federal Regulations designed to eliminate needless exposures to ionizing radiation and needless contamination to the working environment. The RSO derives authority directly from Frank Kolodziej Castro (Owner) and is responsible to implementation of radiation protection measures and control within the facility. The RSO has final authority to stop any unsafe practices at the facility until corrective action has been completed.

3. b Disbursement of funds for the radiation safety program.

The RSO will recommend corrective actions that require funding from Frank Kolodziej Castro. It is the responsibility of Frank Kolodziej Castro to approve the required funds for the radiation safety program.

3. c Other commitments of the RSO

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The RSO consultants at different locations, due to this fact, the senior chemist (Sonia Rodriguez Pagan) will oversee the day-to-day operations of the laboratory. The consultant will visit the facility once per month to review the program. If deficiencies are identified, the consultant will spend as much time as needed to oversee and correct the problem(s).

3. d In-house representative for the RSO

The senior chemist will be appointed as the in-house representative for the RSO.

4. Evidence of training for the RSO (David Rhoe).

Mr. Rhoe received his training at several broad scope licenses. This training covered the used of the TC-99m generators to reconstitute cold-kits that were used in the nuclear medicine department (1991 to 1998). From 1998 to the present, several nuclear medicine laboratories in Puerto Rico were using generators before switching to unit doses. Since then one facility has returned back to using the TC-99m generators (Plaza Nuclear Imaging 52-25340-01). The activities range of all these generators were up to 2.5 Ci.

Mr. Rhoe received additional training when the cyclotron was installed. This training covered the synthesis for the F-18 to FDG and all the QC testing that is required by the FDA under the good manufacturing practice (GMP). A chemist from Argentina provided the initial training to all the staff, which supervised work at the International Cyclotron for several years. Activities handled were up to 2 Ci per bombardment.

5. Authorized Nuclear Pharmacist (ANP)

Based on 37.72 (b) 4 and 5, the pharmacist currently employed meets the requirements of an ANP.

6. Forinal training of Authorized users.

A chemist from Argentina provided the initial training to the staff members of the International Cyclotron. This training/supervision lasted for two years (in the format) as on the job training. The RSO has supplemented this training if additional information is requested or if additional questions arise during the day-to-day operations. It is the senior chemist that continues to use the "on the job" training practice for new chemist.

The following is covered during the day-to-day operations:

- Radiation protection using time distance and shielding.
- Radiation detection using the survey meter and MCA instruments.
- Characteristics of F-18
- Radiation dose limits

- NRC regulations
- Biological effects
- Supervised hands-on use during production, dispensing, and QC test of the final product. The supervised hands-on training last until the individual can show competence in handling the radioactive materials and completing the QC test in an appropriate time frame.

7. Description of facility and equipment

Radiation safety equipment currently in the facility:

- 2 – 2 inch L-blocks
- 2 inch shielded fume hood
- 2 inch shielded remote handling equipment
- 2 inch shielded storage container

Dispensing process:

- O-18 water is bombarded inside the cyclotron to make F-18
- The F-18 is automatically transferred to the synthesis box located inside a hot cell.
- Inside the synthesis box the F-18 is bound to the FDG
- From the synthesis box, the F-18 FDG to automatically transferred to a shielded vial inside a second hot cell.
- After all the F-18 FDG is transferred to the shielded vial, the vial and shield is removed from the hot cell and manual carried to the dispensing cell.
- Inside the dispensing cell, the unit doses are drawn and the syringes are placed inside the bottom half of the unit dose pig.
- The syringe and bottom half of the unit dose pig is automatically lowered from the dispensing cell and the upper half of the unit dose pig is manually screwed on. The assembled unit dose pig containing the unit dose is then placed inside the shipping container.

Facility diagram is attached.

Ventilation diagram for the hot cells is attached.

8. Tc-99m generators

Facility diagram is attached.

- Use and storage – Located inside the fume hood in the dispensing area.
- Storage of radiopharmaceuticals (refrigerated and non- refrigerated) – inside the QC area.
- Radioactive waste
- Preparation and dispensing of radiopharmaceuticals – Dispensing area.
- Adjacent areas

9. Procedures for safe handling of radioactive materials

All procedures are in place and the procedures will become an item of inspection.

10. Dose measurement systems

Capintec Dose Calibrator

We have developed, and will implement and maintain a written procedure for the performance of dose measurement system checks and tests that meets 10 CFR 32.72(c).

11. Transportation

We confirm that the transportation of licensed materials will be in accordance with 10 CFR Part 71.

12. Leak test (sources that required leak testing > 100 uCi) as listed in 10 CFR 35.65

Radioactive material	quantity	use
Cs-137	250 uCi	reference source
Ba-133	250 uCi	reference source
CO-57	6 mCi	reference source

13. Example of labels

Actual labels were provided to the NRC during their visit on January 15, 2009. We agree to affix the required labels to all "transport radiation shields" and to each container used to hold the radioactive drugs.

14. Drug shielding and distribution.

Radionuclide	Maximum activity	Container type
F-18 FDG	250 mCi	Syringe
Tc-99 compounds	100 mCi	Syringe
Tl-201 compounds	100 mCi	Syringe
Ga-67 compounds	100 mCi	Syringe

Transport shield

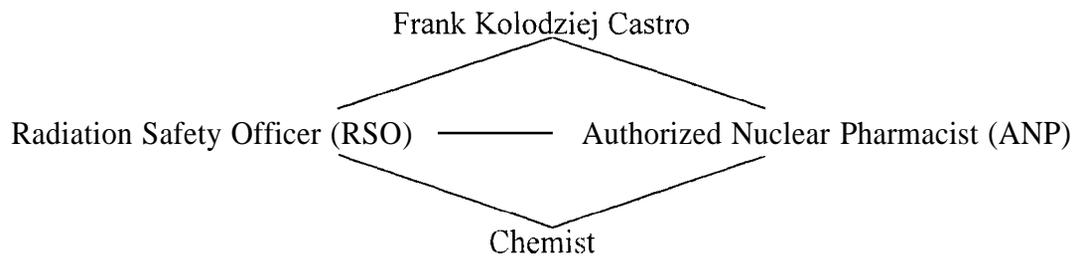
Item	Lead shielding	Max activity	Radiation Level
PET shipping system	None	535 mCi	YII
PET unit dose pig	0.5 inches	235, 160, 140 mCi	
Shipping bag*	None	440 mCi	YII
Unit dose pig*	0.25 inches	40 mCi	YJI

* Will be used for Tc-99m, Tl-201, In-111, and Ga-67

15. Relationship between Frank Kolodziej Castro, MD, Somascan, and International Cyclotron

Frank Kolodziej Castro is the owner/president of both Somascan and International Cyclotron.

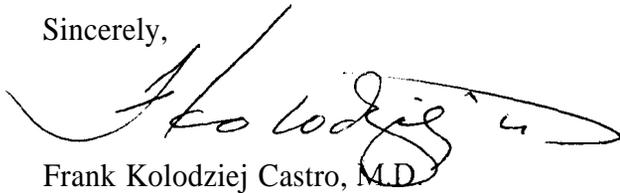
16. Organization chain of command



The RSO supersedes the ANP in regards to radiation safety. The ANP has the final decision in regards to FDA compliance. The RSO and ANP will work jointly to comply will all NRC and FDA regulations.

If your need any further information, please contact David Rhoe at (787) 245-7248.

Sincerely,



Frank Kolodziej Castro, M.D.