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52-31166-01
03037226

Carlos Jimenez Marcha, M.D.
San Patricio MRI & CT Center
1508 Roosevelt Avenue, Suite 103
San Juan, PR 00920

ADDITIONAL INFORMATION CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 138956

Enclose the additional information requested for the review of this application. This information was corrected and completed using the appropriate guidance document for the purposes requested NUREG-1556, Vol. 7" Program- Specific Guidance About Academic Research and Development, and other Licenses or Limited Scope".

Please contact us for any additional information at phone number (787) 620-5757.

138956

NMSS/RGNI MATERIALS-002

Attachment 1

Information for the Application for Material License items 5 through 11 of NRC Form 313

ITEM 5. Radioactive Material:

a. Element and mass number b. Chemical and /or physical form c. Maximum amount possessed at any one time.

A. Equipment Calibration Use (Dose Calibrator):

• Tc 99M	Sodium Pertecnetate	150 mCi
• Cs 137	Cesium 137 – Sealed Vial Reference Source Manufacturer: Isotope Product Laboratories Catalog No. RV-137-200U	Act. 250 uCi
• Ba 133	Barium 133 – Sealed Vial Manufacturer: Isotope Product Laboratories	Act. 250 uCi

ITEM 6. Purpose(s) for which licensed material will be used:

A. The following isotopes will be use for the equipment calibration (Dose Calibrator):

- Tc 99M Sodium Pertecnetate will be use for the equipment calibration (Dose Calibrator)
- Cs 137 Cesium 137 – Sealed Vial Reference Source will be use for the equipment calibration (Dose Calibrator
- Ba 133 Barium 133 – Sealed Vial Reference Source will be use for the equipment calibration (Dose Calibrator).

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ITEM 7. Individual(s) responsible for Radiation Safety Program and their training experience:

- ***Radiation Safety Officer (RSO) and an Authorized User:*** Mr. Jossian J. Pagán Lisboa

  On 2003 he received a 40 hrs Radiation Safety Training at Radiation Safety Academy Washington DC Radiation Safety Officer. He also received a certification of the Department Of Transportation and Nuclear Regulatory Commission Requirements for Shipping and Receiving Radioactive Materials at the Radiation Safety Academy Washington DC Radiation Safety Officer. In 1989 – 1990 obtained a bachelor degree at the University of Puerto Rico Medical Science Campus in Nuclear Medicine Technology Program. Since 1991 to 2004 he worked as a Nuclear Medicine Technologist and as the RSO at the Ashford Presbyterian Community Hospital. Since 2004 up to present have worked as a Radiation Safety Officer at the University of PR, Medical Sciences Campus and since 2005 up to present at the San Patricio MRI & CT Center.

- Authorized User: Dr. Carlos Jimenez Marchan: Nuclear Medicine Physician and the Radiation Control Program Director for this facility:

  Two years experience (July 1994-1996) sub specialty (Fellowship graduate in Nuclear Medicine at William Beaumont Army Medical Center, Texas. This program included rotations at Water Reed Army Medical Center, Bethesda Naval Hospital and National Institute of Health (NIH). Since 1994 he use and manage different radioisotopes such as: Gallium-67, Tecnecium-99M, Indium-111, Thallium-201, Cobalt-57, Iodine-131, Iodine-123, Xenon-133, Samarium-153, Strontium-89, Fluoro-18 y Rubidium-82. The experience working with these isotopes have been for the use of diagnostic and therapeutic procedures (Iodine-131, Samarium-153 and Strotium-89). Since 1999 up to present Dr. Jimenez have worked as a Medical Director for Centro Cardiovascular de PR y el Caribe and the Ashford Presbyterian Community Hospital.

- Authorized User: Emily Alicea: Certified Nuclear Medicine Technologist. She will be working with the license material listed above for instrument calibration.

  Graduated on 2004 at the University of Puerto Rico Medical Science Campus from the Nuclear Medicine Technology Program and a Certified Nuclear Medicine Technologist from the Nuclear Medicine Certified Technologist Board. Some courses taken in the Nuclear Medicine Technology Program at the University of PR, Medical Sciences Campus are: Radiation Physics and Instrumentation, Radiation Protection, Mathematics Pertaining to the Use and Measurement of Radioactivity, Radiation Biology, Radiopharmacy and Radionuclide Chemestry of Byproduct Material for Medical Use, Radioassay, Clinical Practice in Nuclear Medicine Technology in different Hospitals at the Medical Sciences Campus, University of Puerto Rico. In 2004 worked as a Nuclear Medicine Technologist at the University of Puerto Rico, Hospital Universitario. Since 2004 to present works as a Nuclear Medicine Technologist at San Patricio MRI & CT Center. These years of experience have given her the experience in the safety use, management and disposal of radioactive materials. She also have the experience in working with different radioisotopes for the use of diagnostic and therapeutic procedures. Also receives an Annual Radiation Safety Refresher Course as part of the Radiation Safety Program.

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ITEM 8. Training for Individuals working in or Frequenting Restricted Areas:

All employees (Radiological Technologist, Nuclear Medicine Technologist, nurses, secretaries, receptionist, janitors, etc.) in this facility receive a Radiation Safety Training and also receive a refresher course each year from the Radiation Safety Officer Mr. Jossain J. Pagán Lisboa.

Emily Alicea, Nuclear Medicine Technologist, obtained a bachelour degree on 2004 at the University of Puerto Rico Medical Science Campus from the Nuclear Medicine Technology Program. Some courses taken in the Nuclear Medicine Technology Program at the University of PR, Medical Sciences Campus are: Radiation Physics and Instrumentation, Radiation Protection, Mathematics Pertaining to the Use and Measurement of Radioactivity, Radiation Biology, Radiopharmacy and Radionuclide Chemestry of Byproduct Material for Medical Use, Radioassay, Clinical Practice in Nuclear Medicine Technology. In 2004 worked as a Nuclear Medicine Technologist at the University of Puerto Rico Hospital Universitario. Since 2004 to present works as a Nuclear Medicine Technologist at San Patricio MRI & CT Center. These years of experience have given her the experience in the safety use, management and disposal of radioactive materials. She also have the experience in working with different radioisotopes for the use of diagnostic and therapeutic procedures. Also receives an Annual Radiation Safety Refresher Course as part of the Radiation Safety Program.

ITEM 9. Facilities and Equipment:

<u>**Facility Diagram:**</u>

The master or central permittee files and all other docketed and required files and records will be maintained in the San Patricio MRI & CT Center.

A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:

- Drawings of the San Patricio MRI & CT facility is included :
- Location of each room or area where radioactive material will be used or stored (Camera Room, Control Room, Hall Ways, Hot Room, Injection Site, Rest Room, etc.)
  - **Zone 1: PET/CT CAMERA:** restricted area and posted with a Radioactive Area Sign
  - **Zone 2: CONTROL ROOM:** Area where the PET/CT control panel is located. Identified as an unrestricted area
  - **Zone 3: HALL WAY FLOOR I** Identified as an unrestricted area
  - **Zone 4: HALL WAY FLOOR II** Identified as an unrestricted area
  - **Zone 5: HOT LAB (ROOM):** Is a restricted area and a Radioactive Material Sign is posted on the door. Here is where the radioactive material (unit dose) from the International Cyclotron Inc. is received and stored for daily use in their respectively lead shields. This area is prepared for the safety use, management , storage and measurement of radioactive material:
    - **Lead nest:** Sealed vial reference sources are stored.

- **L block:** it is to protect the Nuclear Medicine Technologist from radioactive exposure while measuring the unit doses for each patient and while performing the calibration procedure for the dose calibrator.
- **Dose Calibrator:** to measure and confirm the activity received from each unit dose before administrating it to a patient.
- **Decay storage area:** radioactive waste will be stored for decay and then treated as regular trash.
- **Counter Top:** use for reviewing patient records and documents.

- **Zone 6:** **INJECTION SITE:** *It is a restricted area and it is use for the administration of radioisotope to the patient's.* Also it is use for the patient waiting time before the image acquisition.
- **Zone 7:** **READING ROOM:** A non radioactive area. However it is not considered a restricted area.
- **Zone 8:** **REST ROOM:** Area designated for the use of Nuclear Medicine patients.

- Location of adjacent rooms (e.g., office, file, toilet, closet, hallway), indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and
- *The shielding calculations where performed* by Siemens Company and were approved by the company engineers.

Equipment available at the location where radioactive material will be used:

A description of the equipment available at the location where radioactive material will be used:

- **Survey Meter:** The external pancake probe is used to check hands, clothing, floors, furniture, equipment, and package surfaces for contamination. Survey Meter with Pancake GM Probe (Model 14C), monitors alpha, beta and gamma rays. It has five counting scales(x0.1, x1, x10, x100, x1000).
- **Dose Calibrator:** This instrument will be used to measure the patient's unit dose that will be received by the Radiopharmacy. The Atomlab 300 Dose Calibrator's ultra-fast response time, extended measurement range and computer compatibility provide state-of-the-art performance for PET pharmacies, chemistry laboratories or clinics. The Atomlab 300 provides fast, accurate radionuclide activity measurements that easily surpass the most stringent regulatory requirements. There are 13 isotope selection keys, 10 are pre-programmed for the most commonly used PET and constancy radionuclides and 3 are user defined. There are 88 isotope-specific dial values listed in the manual, including Y-90 and Sr-89. Any key can be reprogrammed by the user for a desired isotope. Activity is displayed on a LED readout in either Curie or Becquerel units. Background correction and zero adjustment are performed at the touch of a button. Range selection is automatic. This instrument will be covered by dose calibrator shielding rings of 2" lead thick.
- **Wipe Counter:** Will be used to measure surface contamination levels in areas where radiopharaceuticals are used.
- **Fimbadegs:** The Landauer company will supply the filmbadges (whole body and ring) for the personnel of the San Patricio MRI & CT Center.

- **L-Block Shield:** Used for receiving and preparing unit doses of high-energy radionuclides. It contains a 1.5 inch thick lead shielding in front, and 1 inch thick lead in the base. A lead brick cave is added to provide lateral shielding around the full perimeter of the L-block's base.
- **Sharps Container Shield:** It is use for disposal of syringes that have been contaminated with high energy radionuclides. The shield is constructed of steel and lined with 1" thick (2.5cm) lead.

ITEM 10. Radiation Safety Program

Radiation Monitoring Instruments:

"We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG-1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary."

- *A description of the instrumentation:*
  - **Survey Meter:** The external pancake probe is used to check hands, clothing, floors, furniture, equipment, and package surfaces for contamination. Survey Meter with Pancake GM Probe (Model 14C), monitors alpha, beta and gamma rays. It has five counting scales (x0.1, x1, x10, x100, x1000).

Material Receipt and Accountability:

"Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license."

Licensed materials will be tracked to ensure accountability, identify when licensed material could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded. An inventory is maintained by the Nuclear Medicine Technology in which is documented the receipt, use and disposal of radioactive materials. This information is maintained in a log book located in the Hot Lab of the San Patricio MRI & CT Center. The log should contain records of amounts used, who used them and dates of use for each shipment received. Physical inventories are conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.

It is requirement to maintain accurate, timely records of the receipt, use, and disposal of radioactive material in its possession. These records must be maintained by the Authorized User for at least three (3) years and will be available for periodic review by Radiation Safety Officer and/or regulatory personnel.

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Occupational Dose:

"we will perform a prospective evaluation and determine 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." In order to do this we will have a whole body film badge in the receptionist area (near the principal hallway) and another one located in the lunch area to monitor any exposure to the non radioactive working personnel (ancillary personnel).

These two devices will be sent to Landauer Company for monthly exposure reports for a period of six month. If this prospective evaluation shows that the individual's dose is not likely to exceed 10% of the allowable limits than it is not necessary to monitor the ancillary personnel.

"we will monitor individuals that manage radioactive material in accordance with the criteria in the section entitled 'Radiation Safety Program - Occupational Dose' in NUREG-1556, Vol. 7, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope,'" dated December 1999."

Safe Use of Radionuclides and Emergency Procedures:

"We have developed and maintain procedures for safe use of radionuclides and emergencies". Radioactive materials will remain locked in safety area, Hot Laboratory. Only the authorized personnel, will have the key to access the Hot Laboratory.

Surveys:

"We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG-1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999.

Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. We will implement the model leak test program published in Appendix R to NUREG-1556, Vol. 7, "Consolidated Guidance about Materials Licenses: 'Program-Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope,' dated December 1999."

For each source to be tested, list identifying information such as manufacturer, model number, serial number, radionuclides, and activity.

- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area (but not directly from the surface of a source) where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 becquerels (0.005 microcurie) of the Radionucides and ensure that its calibration is current.

- Using the selected instrument, count and record background count rate.
- Calculate efficiency.

For example: $\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in uCi}}$ = efficiency in cpm/uCi

where: cpm = counts per minute
std = standard
bkg = background
uCi = Micro curie

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries).

For example: $\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/ uCi}}$ = uCi on wipe sample

- Sign and date the list of sources, data and calculations. Retain records for 3 years (10 CFR 20.2103(a)).
- If the wipe test activity is 185 Bq (0.005 µCi) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly.
- Also notify NRC

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ITEM 11. Waste Management:

"We will use the *Decay-In-Storage* model waste procedures that are published in Appendix T to NUREG-1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999."

Model Waste Management Procedures

General Guidelines

- A reference source used for equipment calibration will be shipped back to the company for proper disposal procedures when ever a new one is purchase.
- All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste.
- Remind employees that non-radioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.
- Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.
- Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.

Procedure for disposal by Decay-In-Storage (DIS):

- The syringe used for the administration of FDG is stored in the radioactive waste area inside the Hot Lab to be return to the radiopharmacy for proper disposal procedures. It can also be kept in the radioactive storage area for decay and disposed as regular biohazard trash.
- Short-lived waste should be segregated from long-lived waste (half-life greater than 120 days).
- Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.
- Liquid and solid wastes must be stored separately.
- When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.
- The identification label should include the date when the container was sealed, the longest lived radioisotope in the container, date when ten half-lives of the longest-lived radioisotope will have transpired, and the initials of the individual who sealed the container. The container should be transferred to the DIS area.
- The contents of the container should be allowed to decay for at least 10 half-lives of the longest-lived radioisotope in the container.

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Prior to disposal as ordinary trash, each container should be monitored as follows:

- Check the radiation detection survey meter for proper operation.
- Survey the contents of each container in a low background area (less than 0.05 millirems per hour).
- Remove any shielding from around the container.
- Monitor all surfaces of the container.
- Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity, i.e., surface readings are indistinguishable from background.
- If the surveys indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.
- If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste.

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ITEM 10. Radiation Safety Program

Material Receipt and Accountability:

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SAN PATRICIO MRI & CT CENTER

SEALED SOURCE INVENTORY

	Ge/Ga-68 S/N 2700 Reference date: 06/06/06 Activity: 55 MBq (1.48 mCi)			Ge/Ga-68 S/N: 5536 Reference date: 06/06/06 Activity: 45 MBq (1.22 mCi)			Ge/Ga-68 S/N: 5535 Reference date: 06/06/06 Activity: 45 MBq (1.22 mCi)			Co-57 S/N 111-79-16 Reference date: May/01/06 Act: 5.651 mCi (209.1 MBq)			Cs-137 S/N: 1111-60-14 Reference date: May/01/05 Act: 210.6 uCi (7792KBq)			
te:	Inventory	L.Test	mR/hr 1 m	Inventory	L.Test	mR/hr 1 m	Inventory	L.Test	mR/hr 1 m	Inventory	L.Test	mR/hr 1 m	Inventory	L.Test	mR/hr 1 m	Initial

151

ITEM 11. Waste Management:

Radioactive Waste Disposal Record

(Form Disposal by Decay-in-Storage)

San Patricio MRI & PET-CT CT Center

Radiation Levels Readings (mR/hr)

Before Decay					After decay 10 half life				
ID	Name of Isotope	Storage date	Reading mR/hr	Initials	Disposition date	Reading mR/hr	Bkg	Outgoing tag	Initials

Survey Instrument GM:		Model: 14C	S/N: 214776
GM Probe:		Model: 44-9	S/N: PR-225220

Note: Radioactive waste material must be retained for at least 10 half lives of the longest half lived isotope. Prior to disposal of waste material in the non radioactive trash if the radiation survey shows a radiation level indistinguishable from background.

(19)

ITEM 10. Radiation Safety Program

<u>Material Receipt and Accountability:</u>

Package Receipt and Monitor Rercord
San Patricio MRI & PET-CT Center

Date Received	Activity (mCi)	Iso/Chem	Vendor	Package OK	R/S Wipe Test (dpm)	R/S At 1 Meter (mR/hr)	R/S At Surface (mR/hr)	Empty Bkg	Check Source	R/S Tech's Initials	Coments

ISO.CHEMICAL:
1. F18 (FDG)
2. Rd 68
3. Co57
4. Cs 137
5. Ba 133

VENDOR:
1. International Cyclotron
2. Bristol-Myers Squibb

	Model	S/N
Meter GM	14C	214776
Probe GM	44-9	PR-225220
W.Counter	1051	4215607

Trigger limits for both are 2*

Meter Bkg: ________ mR/hr

Well Counter Bkg: _____ ____dpm

R/S: Receiving the package / Shipping the package back