

Beta Gamma Nuclear Radiology, Inc.

June 21, 2010

Mr. Marc Ferdas
Chief Medical Branch
NRC Region I
475 Allendale Road
King of Prussia, PA19406

RE: Beta Gamma Nuclear Radiology, Inc.
Docket No. 030-35572
License No. 52-25542-01

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2010 JUN 23 PM 12: 21

Dear Mr. Marc Ferdas:

According to the Confirmatory Order Modifying License issued by the U.S. Nuclear Regulatory Commission (NRC) on January 21, 2010 enclosed you will find Beta Gamma Nuclear Radiology (BGNR) first audit report dated June 21, 2010 and prepared by the auditor, Mr. José C. Pacheco.

The audit report contains the following recommendations made by the auditor and they are being address as follows:

1. *Amend License to include another authorized user to cover Dr. Juan E. Pérez Monté vacations and/or sick leave.*

It is a BGNR policy not to provide I-131 therapies (> 30 *mci*) or any other procedure that requires the presence of an authorized user (AU) without the presence of the AU. Therefore, while Dr. Juan E. Pérez Monté is in vacation or sick leave BGNR will not provide I-131 therapies (> 30 *mci*) or any other procedure that requires the presence of an AU. BGNR will implement the auditor's recommendation when an increase in patient volume justify the addition of a second AU to the license.

2. *Keep Staff credentials at facility.*

Its BGNR management policy to require staff members to keep their credentials in its facility. After reviewing the auditor's recommendation BGNR reminded staff on the need to keep credentials on site and instructed one staff member to bring the credentials that the audit detected missing. This policy will be added to BGNR written policy.

3. *Rearrange the I-131 record form to add a separate dose order date from dose administration date.*

It is already part of BGNR written policy to provide all the information required by the NRC in the written directives, to do so, it has produced color coded forms that properly fulfills those policies. Staff will be refreshed on the proper procedure regarding written directives and reminded to

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properly fill the order date in the color coded form. To reinforce this instruction staff will be required to add "(ordered)" next to the order date in the color coded form.

The report mentioned that this is a nuclear medicine facility located at the Caribe Medical Plaza, but that was the prior name of the building, actually the building is known as Caribbean Medical Center¹.

If you have any question or comments, please let us know.

Sincerely,


Alejandro Pérez Monté

cc: Mr. José C. Pacheco, Auditor
Mr. Jossian Javier Pagán Lisboa, Radiation Safety Officer

Enclosure: First Audit Report

¹ As it was mentioned in the license modification submitted on February 2010.

Medical Licensee Audit

Radiation Protection Medical Licensee Audit

Date Commence the Audit: March 26, 2010

Date of Last Audit: N/A

Audit Period: Jan 1, to March 31, 2010

Next Audit Period Date: April 1, to June 30, 2010

Auditor: José C. Pacheco M.S.

Signature 

Date: June 21, 2010

Persons Contacted:

Juan E. Pérez-Monté, M.D.

Alejandro Pérez-Monté Esq./Manager

Jossian Javier Pagán-Lisboa, R.S.O.

Dializza Vega, Nuclear Medicine Technologist

Management Review:

Signature 

Date: 6/21/2010

History

Beta Gamma Nuclear Radiology (BGNR) is a small (approximately 1,000 annual patients), Nuclear Medicine Facility servicing the Eastern part of the island of Puerto Rico. The laboratory was licensed by the Nuclear Regulatory Commission (NRC) on December 21, 2000 as per application dated September 10, 2000.

This is a comprehensive audit of the license No. 52-25542-01 conducted as per authorization by the Nuclear Regulatory Commission (NRC) letter dated February 25, 2010

I- Audit History:

Were not previous audits conducted

II- Organization and Scope of Program:

A. Radiation Safety Officer:

On February 16, 2010 a request for amendment for a new Radiation Safety Officer was submitted. The Radiation Safety Officer change was confirmed on March 19, 2010. The new RSO meet all NRC training requirements and fulfill radiation safety issues, and emergency procedures for program expansions.

The staff consist of sufficient personnel to cover the number of patients procedures and administrative duties.

B- Professional Staff:

- 1 Juan E. Pérez-Monté, M.D. Authorized User
2. Jossian Javier Pagan-Lisboa (RSO), CNMT Certified Nuclear Medicine Technologist
3. Dializza Vega, CNMT. Certified Nuclear Medicine Technologist.

C- Other Administrative Staff (eg. secretaries etc).

1. Alejandro Pérez-Monté Esq./Manager
2. Socorro Díaz, Secretary

D- Authorized Licensed Material and Use:

The following byproduct material are authorized and used at the facility located at Caribe Medical Plaza, suite 101, #151 Avenida Osvaldo Molina, Fajardo, Puerto Rico.

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E- Byproduct Material

1. Any byproduct material permitted by 10 CFR 35.100, any chemical form, amount as needed
2. Any byproduct material permitted by 10 CFR 35.200, any chemical form, amount as needed.
3. Any byproduct material permitted by 10 CFR 35.300, any chemical form, amount as needed.

The unsealed materials used under 10 CFR 35.100, 35.200, 35.300 are obtained from a manufacturer or preparer licensed under 10 CFR 32.72

F- Authorized Use:

1. Any uptake, dilution and excretion study permitted by 10 CFR 35.100
2. Any imaging and location study permitted by 10 CFR 35.200
3. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300, for which the patient can be released under the provisions of 10 CFR 35.75

G- Financial Assurance:

The total amount of radioactive material possessed does not require financial Assurance.

H- Reference Sources:

1. Ba-133
Activity (9243 KBq (249.8 uCi, Feb.1, 2001
S/N 743-16-22
Description, Plastic Vial
2. Co-57
Activity (200.2 MBq (5.42 mCi, Jan. 1 ,2008
S/N 1296-18-22
Description Plastic Vial
3. Cs-137
Activity (8717 KBq (235.6 uCi Feb.1 2001)
S/N 743-6-19
Description Plastic Vial
4. Cs-137
Activity (370 KBq (10 uCi, Nov. 1. 2002
S/N Unknown/ Survey Meter check source
Description, Plastic tape adhered to survey meter

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I- Calibration Sources:

1. Cs-137
Activity (379.1 KBq (10.24 uCi, Jan 1 2003)
S/N 32176
Description , round plastic disk.
2. Cs-137
Activity (18.5 KBq,(500 nCi Nov. 1, 2009
S/N 1377-81-44
Description, plastic rod.

III- Radiation Safety Program:

A revised Radiation Safety Program was submitted on February 24, 2010. The content and implementation are reviewed by licensee annually. Records of reviews are maintained available for any agency inspection.

a- Use by Authorized Individuals:

Dr. Juan E. Pérez-Monté is the only authorized user. Dr. Pérez-Monté is listed on facility license and is Board Certified by The American Board of Radiology and The American Board of Nuclear Medicine. Credentials are on hand at the NRC archives.

b- Amendments Since Last Audit.

This is the first audit as per designation of Mr. José C. Pacheco M.S. as the Auditor. The Radiation Safety officer position was amended to change Mr. Jossian Pagán Lisboa instead of Dr. Juan E. Pérez-Monté as the Radiation Safety Officer.

c- Training, Retraining, and Instructions to Workers.

The workers instructions and retraining have been provided. The faculty staff Dr., Juan E. Pérez-Monté, authorized User, Alejandro Pérez-Monté, manager and Dializza Vega, Nuclear Medicine Technologist received the instructions. See the enclosed main topics document (Annex A-1)

The (BGNR) workers are cognizant of the General Radiation Safety Program (eg. annual dose limits, dose to embryo-fetus and declared pregnant workers) Procedures for opening packages are clearly posted. Individuals are supervised by the AU and the RSO in accordance with 10 CFR 35.27

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d- Facilities.

This is a Nuclear Medicine facility located at Caribe Medical Plaza, Suite 101 #151 Avenida Osvaldo Molina, Fajardo, Puerto Rico as described in license application dated September 10, 2000. Radioactive Material are secured in appropriate safe lead containers at the hot room within keyed door. Radioactive waste is also secured at the same place. License Radioactive Material not in storage (in use) are surveyed by the Nuclear Medicine Technologist and or the AU.

e- Dose or Dosage Measuring Equipment.

The facility posses an Atom Lab 100 Pluss Dose Calibrator (Calibration Instrument) to measure the Unit Doses obtained from preparer (Radiopharmacy) in order to assure the (Unit Dose calibration accuracy for patient administration). The unsealed radionuclides are obtained from a preparer (Radiopharmacy) in Unit Doses and activities are assured by measuring the Unit Dose activity in the Atom Lab 100 Pluss Dose Calibrator. The procedures are followed utilizing the instrument manual by the nuclear medicine technologist. Constancy, Accuracy, Linearity, and Geometry dependence test are part of the Institution Protocols an are conducted by the Nuclear Medicine Technologist in accordance with nationally recognized standards an manufacturers instruction manuals. In case tests do not meet the performance objectives of the Institution Protocols, instrument is repaired or replaced or dosages are mathematically corrected. Records are maintained as required. Every repair or dosage mathematically corrected records are maintained with required information.

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f- Determination of Dosages of unsealed Byproduct Materials.

Each dosage is determined at the radiopharmacy and recorded on Patients Record prior to medical use. Measurements of Unit Doses of photon emitting Radionuclides are compared with the Laboratory Dose Calibrator measurements. In case (Instance) the Laboratory instrument (Dose Calibrator) is out of order, the Dose is determined by decay correction. Mo-99 breakthrough is tested at the Radiopharmacy and recorded on the Unit Dose label and affixed to the Patients Record. Records are maintained of Radiopharmaceuticals administered in order to comply with [35.204(a)(1)].

g- Radiation Control and Control of Radioactive Material

1. Use of Radiopharmaceuticals

Staff uses protective clothing (uniforms). After working hours the Nuclear Medicine Technician monitor her hands, records are kept on files. Information working signs are posted to alert personnel of "No eating, No Food, No drinking or Personal Make-up Property are not allowed in the Laboratory Imaging

Area". To each radiation worker a proper dosimeter (Film Badge for whole body or ring TLD Badges are assigned and worn during working hours. Small amounts of radioactive waste materials are kept at the hot room and keyed after working hours. There are enough protective shielding equipment (Syringe shields, remote handling forceps) to reduce radiation exposure.

2. Leak Tests and inventories.

Reference Sealed Sources are Leak Tested as per 35.67(B)(1), and records are kept on files. Inventory of sealed reference and calibration sources are performed semiannually as per [35.67(g)], and records are maintained

3. Radiation Survey Instruments.

a. A survey instrument (GM) is available to show compliance with 10 CFR part 20 and 30.33(a)(2). The instrument is calibrated annually and calibration and or repairs records are kept on file.

4. Radiation Safety Surveys

- a. Daily surveys are performed in all areas where radiopharmaceuticals are prepared and administered.
- b. Weekly wipe tests and surveys are performed in areas where radiopharmaceuticals are prepared and administered.
- c. Trigger Levels has been established for all different areas and documented in an official Laboratory form.
- d. Instrument is effective to detect low radiation levels of (0.1mR/Hr) and 2000 DPM. The radiation Safety Surveys are designed to assure that the maximum radiation level and average radiation levels from radioactive materials do not exceed the Radiation Safety Levels.

h- Public Dose

Licensed materials are used in a manner to keep doses below 1 mSv (100 mR) in a year. Surveys are performed in order to assure compliance with regulations. The surveys demonstrate that radiation levels does not exceed 0.02 mSv (2 mrem in any one hour. This Nuclear medicine facility has not been changed since the application date. The licensed material is used and stored in a manner that would prevent unauthorized access or removal from authorized premises. Records are maintained of all radiation Safety Surveys.

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i- Patient release

All I-131 Therapy patients are instructed an written Information (hand-outs) are provided to individuals, including breast-feeding womens . Patients are released when TEDE is less than 0.5 rems. Complete patients records are maintained.

j- Unsealed Byproduct material for wich a written directive is required.

As per the (BGNR) Radiation Protection Program, safety precautions has been implemented to include patients instructions, patients safety guidance an contamination controls. In case of an injected radioactive patient emergency the RSO and the AU are promptly notified.

k- Radiation Waste

Minimum amounts of radioactive waste are collected in safety cans and leaved to decay in-storage. After decay all radiation signs and labels are defaced. Unused unit doses are disposed through the radiopharmacy. Records are maintained. There is no radioactive material released to the sanitary sewer. The small amounts of radioactive contaminated materials are stored in radioactive waste containers, properly labeled, numbered, dated and identified at the hot room. Material is secure from external ambient elements and fire. Records of disposal are maintained. Packages integrity are adequately maintained. There is no radioactive waste disposal other than the radiopharmacy. When waste is disposed a radiation safety survey and packages accountability is performed. Records are maintained.

l- Receipt and transfer of radioactive materials

All in-coming radioactive materials (Unit Doses) are received by the Nuclear Medicine Technologist. Package-Opening procedures are established and followed in The Radiation Safety Program. Copy of the Radiation Safety Program is on NRC archives. Incoming packages are surveyed and results are recorded and maintained on file.

m- Transportation

Radioative Materials are transported via common carrier contracted by the radiopharmacy (Radiopharmacy employee). Radiopharmacy Unit Doses not used are returned through the

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Radiopharmacy carrier. Shipping responsibility is assumed by the Radiopharmacy. Radiopharmacy utilizes DOT authorized packages.

n- Personnel Radiation protection

Radiation workers are monitored for external exposures, including administrative and clerical personnel. The supplier of personnel Radiation Monitors (film Badge & TLD ring badges are supplied by-monthly by Mirion Technologies (GDS) Inc, former ICN. Mirion Technologies (GDS) is an NCLAP-approved supplier. Dosimeters are exchanged at regular intervals. The ALARA Program has been implemented. Dosimetry (Exposure Records) are reviewed by the RSO and Or the AU by-monthly. The personnel monitoring was audited from June 01, 2009 to December 31, 2009. The maximum TEDE audited was 154 mrems NRC equivalent forms were completed for the last annual review. audited period 2009. Records of radiation exposure monitoring, surveys, and radioactive contamination and evaluation are maintained on files

o- Medical Events

No medical events has been reported.

p- Posting and Labeling

“Notice to Workers” (Form NRC-3 is posted, copies of parts 19, 20, 21, section 206 of Energy Recognition Act, procedures has been adopted pursuant to 10 CFR 21. A notice indicating where documents can be obtained is posted at the facility. All other posting and Labeling are properly affixed.

IV- Recommendations:

1. Amend License to include another authorized user to cover Dr. Juan E. Pérez-Monté vacations and/or sick leave.
2. Keep Staff credentials at facility.
3. Rearrange the I-131 record form to add a separate dose order date from dose administration date.

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Certificate of Training in Radiation Protection Program

I hereby certify that the BETA GAMMA NUCLEAR RADIOLOGY personnel:

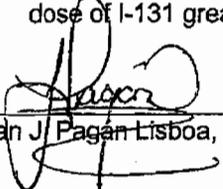
1. Juan E. Pérez Monté, Nuclear Physician
2. Alejandro Pérez Monté, Manager
3. Dializza Vega Vélez, Certified Nuclear Medicine Technologist

received a training in the Radiation Protection Program that includes the following:

- Notice of Employee document
- Basic radiation protection to include concepts of time, distance, and shielding;
- Concept of maintaining exposure ALARA;
- Risk estimates, including comparison with other health risks;
- Posting requirements
- Proper use of personnel dosimetry (when applicable);
- Access control procedures
- Proper use of radiation shielding, if used;
- Patient release procedures
- Instruction in procedures for notification of the RSO and AU, to ensure that radiation protection issues are identified and addressed in a timely manner.
- Occupational dose limits and their significance
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy
- Worker's right to be informed of occupational radiation exposure
- Each individual's obligation to report unsafe conditions to the RSO
- Applicable regulations, license conditions, information notices, bulletins, etc.
- Where copies of the applicable regulations, the NRC license, and its application are posted or made available for examination
- Proper recordkeeping required by NRC regulations
- Appropriate surveys to be conducted
- Proper calibration of required survey instruments
- Emergency procedures;
- Decontamination and release of facilities and equipment
- Dose to individual members of the public
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed-source leak testing).
- Review of providing complete and accurate information to the NRC.
- Compliance with NRC regulations.
- Freedom to raise safety concerns with the institutions management, with out fear of retaliation.

In addition to the topics identified above, the following topics were included in instruction for staff involved in the therapy treatment of patients.

- Licensee's WD Procedures, to ensure that each administration of by product materials (I-131) wear administered in accordance with the WD, patient identity is verified, and that will receive a dose of I-131 greater of 30 microcuries.



Jossian J. Pagan Lisboa, RSO

Feb/20/2010
Date

BETA GAMMA NUCLEAR RADIOLOGY
TRAINING IN RADIATION PROTECTION PROGRAM
ASSITANCE LIST
DATE: FEBRUARY 20, 2010
RESOURCE: Jossian J. Pagan Lisboa, RSO

| Name | Position | Signature |
|-----------------------|---------------------|---------------------|
| Juan E. Pérez Montano | Nuc. Physician | Juan Pérez Montano |
| Dializza Vega Vélez | Tecnóloga Med. Nuc. | Dializza Vega Vélez |
| Alejandro Pérez Monté | Manager | Alejandro Pérez |
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