

# Beta Gamma Nuclear Radiology, Inc.

September 20, 2010

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

RECEIVED  
REGION I  
2010 SEP 22 PM 2:49

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

Dear Mr. Marc Ferdas:

According to the Confirmatory Order Modifying License issued by the U.S. Nuclear Regulatory Commission on January 21, 2010 enclosed you will find Beta Gamma Nuclear Radiology (BGNR) second audit report dated September 20, 2010 and prepared by the auditor, Mr. José C. Pacheco.

The audit report mentioned that the dose calibrator is out of order. BGNR is in the process of returning the dose calibrator to the manufacturer for repairs, following the protocol provided for this purpose.

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: Second Audit Report

Medical Licensee Audit

Radiation Protection Medical Licensee Audit

Date Commence the Audit: August 16, 2010

Date of Last Audit Report: June 21 , 2010

Audit Period: April 1, to June 30, 2010

Next Audit Period Date: July 1, to September 30, 2010

Auditor: José C. Pacheco M.S.

Signature José C. Pacheco

Date: September 20, 2010

Persons Contacted:

Alejandro Pérez-Monté Esq./Manager

Jossian Javier Pagán-Lisboa, R.S.O.

Dializza Vega, Nuclear Medicine Technologist

Management Review:

Signature Alejandro Pérez

Date: 9/20/2010

## History

This is the second 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:

A previous audit was conducted for the period January 1 to March 31, 2010.

### II- Organization and Scope of Program:

#### A. Radiation Safety Officer:

The Radiation Safety Officer continue to be Mr. Jossian Pagán-Lisboa. The staff continue to be off sufficient personnel to cover the number of patients procedures and administrative duties.

#### B- Professional Staff:

- 1 Juan E. Pérez-Monté, M.D. AU (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 byproduct materials authorized and used at the facility located at Caribe Medical Plaza, suite 101, #151 Avenida Osvaldo Molina, Fajardo, Puerto Rico continue to be as needed as per previous audit.

#### 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.

APM  
JAP

#### 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:

The revised Radiation Safety Program is on hand an kept on file.

##### 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.

Audit

pp-3

b- Amendments since Last Audit.  
No amendments since last audit.

c- Training, Retraining, and Instructions to Workers.  
No other training since last audit.

#### IV- Facilities:

There are no changes to the facilities since last audit

#### V- Measuring Equipment.

The equipments at the facility are the same as per last audit. The dose calibrator is out of order at this moment. Determination of Dosages of unsealed Byproduct Materials, for (Instance) the doses are determined by decay correction.

#### VI- Radiation Control and Control of Radioactive Material

##### 1. Use of Radiopharmaceuticals

The staff continues using protective clothing (uniforms). A security coded entrance key has been installed at hot room door.

Each radiation worker wear a proper dosimeter (Film Badge for whole body or ring TLD Badges.

##### 2. Leak Tests and inventories.

Reference Sealed Sources and calibration sources were leak tested. Last leak test was performed on June 18, 2010. Records are kept on files.

##### 3. Radiation Survey Instruments.

a. The radiation survey instrument (GM) was calibrated on February 18, 2010

##### 4. Radiation Safety Surveys

a. Daily surveys and weekly wipe tests and surveys were performed in all areas as scheduled and documented.

#### VII - Patient release

All I-131 Therapy patients records were reviewed during the audit period. Records were found to be in order. Information (hand-outs) were provided to patients.

VIII - Unsealed Byproduct material for which a written directive is required.

Records were reviewed and found to be in order.

IX - Radiation Waste

Records were reviewed and found to be in order. .

X - Receipt and transfer of radioactive materials

All in-coming radioactive materials (Unit Doses) were received by the Nuclear Medicine Technologist. Procedures established were followed.

XI - Transportation

Radioactive Materials continues to be transported via common carrier contracted by the radiopharmacy (Radiopharmacy employee). .

XII - Personnel Radiation protection

The personnel monitoring audited was from January 01, 2010 to April 30, 2010. The maximum TEDE audited was 28 mrems

XIII - Medical Events

No medical events has been reported.

XIV - Posting and Labeling

Posting and Labeling are properly affixed.

XV - Nuclear Regulatory Commission Inspection (NRC)

An NRC Inspection was conducted on July 13-14 2010. Based on the inspection findings, no violations were identified.

XVI- Recommendations:

Recommendations has been implemented or are in process.