

Beta Gamma Nuclear Radiology, Inc.

December 17, 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**

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) third audit report dated December 17, 2010 and prepared by the auditor, Mr. José C. Pacheco.

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: Third Audit Report

2010 DEC 20 AM 11:21
RECEIVED
REGION I

Medical Licensee Audit

Radiation Protection Medical Licensee Audit

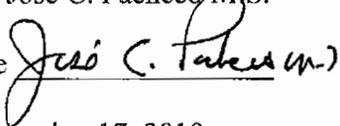
Date Commence the Audit: November 9, 2010

Date of Last Audit Report: September 20 , 2010

Audit Period: July 1, to September 30, 2010

Next Audit Period Date: October 1, to December 31, 2010

Auditor: José C. Pacheco M.S.

Signature 

Date: December 17, 2010

Persons Contacted:

Alejandro Pérez-Monté Esq. / Manager

Jossian Javier Pagán-Lisboa, R.S.O.

Dializza Vega, Nuclear Medicine Technologist

Management Review:

Signature 

Date: 12/17/2010

History

This is the third 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 April 1 to June 30, 2010.

II- Organization and Scope of Program:

A. Radiation Safety Officer:

The Radiation Safety Officer is 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:

There are no changes to the amounts and byproduct materials authorized and used at the facility located at Caribe Medical Plaza, suite 101, #151 Avenida Osvaldo Molina, Fajardo, Puerto Rico. The amounts continue to be as needed as per previous audit.

G- Financial Assurance:

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

APM
JAL

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
JP

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.

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

c- Training, Retraining, and Instructions to Workers.
No other new 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 and under repair at factory. 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). The security coded entrance key is working properly at the hot room door.

Each radiation worker wear a proper dosimeter (Film Badge) for whole body and ring TLD Badges for hands exposure.

2. Leak Tests and inventories.

Reference Sealed Sources and calibration sources were leak tested. Last leak test was performed on September 26, 2010. Records are kept on files.

3. Radiation Survey Instruments.

a. The radiation survey instrument (GM) last calibration was 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. Radiation Safety

APM
JGP

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.

APM
JGP

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 March 01, 2010 to August 31, 2010. The maximum TEDE audited was 58 mrems year to date.

XIII - Medical Events.

No medical events has been reported.

XIV - Posting and Labeling.

Posting and Labeling are properly affixed.

XV- License renewal is in process.

V- Recommendations:

Recommendations has been implemented .