Beta Gamma Nuclear Radiology, Inc.

March 18, 2011

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 on January 21, 2010 enclosed you will find Beta Gamma Nuclear Radiology, Inc. fourth audit report dated March 18, 2011 and prepared by the auditor, Mr. José C. Pacheco.

The audit report mentioned that the dose calibrator is out of order. At present, the dose calibrator has been repaired and the quality control has been performed, and it has been operational since January 28, 2011.

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: Fourth Audit Report

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Medical Licensee Audit

Radiation Protection Medical Licensee Audit

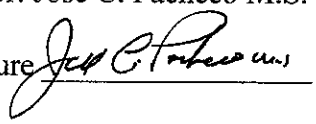
Date Commence the Audit: January 26, 2011

Date of Last Audit Report: September 20, 2010

Audit Period: October 1, to December 31, 2010

Summary Audit Period: January 1, to December 31, 2010

Auditor: José C. Pacheco M.S.

Signature 

Date: March 18, 2011

Persons Contacted:

Juan E. Pérez-Monté, M.D.

Alejandro Pérez-Monté Esq. / Manager

Jossian Javier Pagán-Lisboa, R.S.O.

Dializza Vega, Nuclear Medicine Technologyst

Management Review:

Signature 

Date: 3/18/2011

This is a comprehensive fourth and final summary audit of the license No. 52-25542-01 conducted as per authorization by the Nuclear Regulatory Commission (NRC) letter dated February 25, 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. A renewal request application of the license was submitted on December 2010 for the same facility and location.

I- Audit History:

This is the fourth audit and summary report for the period January 1 to December 31, 2010

II- Organization and Scope of the Facility:

A. Radiation Safety Officer:

On February 16, 2010 the request for amendment for a new Radiation Safety Officer was submitted and accepted. The Radiation Safety Officer change was confirmed on March 19, 2010. The new RSO is Mr. Jossian J. Pagán-Lisboa. He meet all NRC training requirements and fulfill radiation safety issues, and emergency procedures for program expansions.

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The staff is composed 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 materials are authorized and used at the facility located at Caribe Medical Plaza, suite 101, #151 Avenida Osvaldo Molina, Fajardo, Puerto Rico.

E- Byproduct Materials

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.

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H- Reference Sources:

1. Ba-133
   Activity (9243 KBq (249.8 uCi, Feb.1, 2001
   S/N 743-16-22
   Descrition, 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.

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

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

c- Retraining, and Instructions to Workers.

The workers instructions and retraining have been provided. The last refresh training was on February 20, 2010. The faculty staff Dr. Juan E. Pérez-Monté, authorized User, Alejandro Pérez-Monté, manager and Dializza Vega, Nuclear Medicine Technologist received the instructions. The document was submitted and is on NRC files

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

d- Facilities.

BGNR is a Nuclear Medicne facility located at Caribe Medical Plaza, Suite 101 #151, Avenida Osvaldo Molina, Fajardo, Puerto Rico as described in license renewal application documents dated December 2010. Radioactive Materials are secured in appropriate safe lead containers at the hot room with a coded keyed lock door. Radioactive waste is also secured at the same place. License Radioactive Material not in storage (in use) are monitored 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 and 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. To date the dose calibrator is out of order.

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.

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Reference Sealed Sources are Leak Tested as per 35.67(B)(1), and records are kept on files. Last Source Inventory was performed on September 26, 2010 and sealed reference and calibration sources was performed on December 1, 2010 Records are maintained on file.

3. Radiation Survey Instruments.

A survey instrument (GM) is available to show compliance with 10 CFR part 20 and 30.33(a)(2). The instrument is calibrated annually. Last calibration was performed on February 18,2010. 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). 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.

i- Patient release

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

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

As per the (BGNR) Radiation Protection Program, safety precautions has been implemented to include patients instructions, patients safety guidance and 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 containers, properly labeled, numbered, dated and identified and stored at the hot room and leaved to decay in-storage. When waste is stored ad or disposed a radiation safety survey and packages accountability is performed. After decay all radiation signs and labels are defaced. Unused unit doses are disposed through the radiopharmacy. There is no radioactive material released to the sanitary sewer.

Material is secure from external ambient elements. 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 (Radiophamacy employee). Radiopharmacy Unit Doses not used are returned through the Radiopharmacy carrier. Shipping responsibility is assumed by the Radiopharmacy. Radiopharmacy utilizes DOT authorized packages.

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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-aproved 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 September 01, 2010 to December 31, 2010. The maximum TEDE audited was 183 mrems. 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 was explained in writing by Beta Gamma Nuclear Radiology, Inc. (See First Audit Report dated June 21 2010 and Beta Gamma Nuclear Radiology, Inc letter dated June 21, 2010 signed by Mr. Alejandro Pérez-Monté).
2. Keep Staff credentials at facility. The recommendation was implemented.
3. The I-131 record form to separate dose order date from dose administration date was implemented.

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