



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 8, 2008

Docket No. 03035572

License No. 52-25542-01

Juan E. Pérez Monté, M.D.
Director
Beta Gamma Nuclear Radiology, Inc.
P.O. Box 7891, PMB 372
Guaynabo, PR 00970-7891

SUBJECT: INSPECTION 03035572/2008001, BETA GAMMA NUCLEAR RADIOLOGY, INC., FAJARDO, PUERTO RICO LOCATION, AND NOTICE OF VIOLATION

Dear Dr. Pérez Monté:

On March 11, 2008, Héctor Bermúdez of this office conducted a safety inspection of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with you at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications Page**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC; Organization and Functions; Office of Enforcement; About Enforcement**; then **Enforcement Policy**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

J. Pérez Monté, M.D.
Beta Gamma Nuclear Radiology, Inc.

2

Please contact the undersigned at (610) 337-6952 if you have any questions regarding this matter.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Commonwealth of Puerto Rico

J. Pérez Monté, M.D.
Beta Gamma Nuclear Radiology, Inc.

3

Please contact the undersigned at (610) 337-6952 if you have any questions regarding this matter.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Commonwealth of Puerto Rico

Distribution:
D. J. Holody, RI

DOCUMENT NAME: C:\FileNet\ML081010261.wpd
ADAMS Document Accession No. ML081010261

SUNSI Review Complete: HBermúdez

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI				
NAME	Hbermúdez/pjh f/		Phenderson/pjh				
DATE	04/08/08		04/0808				

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Beta Gamma Nuclear Radiology, Inc.
Fajardo, PR

Docket No. 03035572
License No. 52-25542-01

During an NRC inspection conducted on March 11, 2008, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.40(a) requires, in part, that a written directive be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries.

Contrary to the above, on September 14, 2005, and February 19 and 26, 2008, the licensee administered 5.17, 3.64 and 3.57 millicuries of I-131 sodium iodide, respectively, without a written directive.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Beta Gamma Nuclear Radiology, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This 8th day of April 2008