

**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

Beta Gamma Nuclear Radiology, Inc.
Fajardo, PR

2008001
Docket No. 03035572
License No. 52-25542-01

REPLY TO A NOTICE OF VIOLATION

On a letter dated April 8, 2008 Beta Gamma Nuclear Radiology Inc. (hereinafter referred to as Beta Gamma) was served notice of violation¹. This notice of violation states that During an NRC inspection conducted on March 11, 2008, one violation of NRC requirements was identified. The Notice of Violation alleges that 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. Beta Gamma hereby contests such allegation because a written directive was dated and signed by an authorized user before the administration of I-131 sodium iodide². These directives were for follow-up WB I-131 scan doses (approx. 4mCi doses) on these instances the written directives for this cases are placed in one of the two labels sent by the radiopharmacy. For the I-131 therapy doses for hyperthyroidism and thyroid cancer the written directives are placed in a color coded sheet.

After NRC inspection, I was very surprised that the 3 records stated did not have the written directives prior to dose administration; since the office procedure is that I am present in all the I-131 doses above 30uCi and that the written directives are written before dose administration, and to confirm that the right

¹ Docket Number 03035572

² See attachments "A", "B" and "C". (Please do not place in the Public Document Room nor in the internet due to HIPAA concerns.)

patient is identified by more than one method of identification, that the pregnancy test results are negative, in the appropriate cases, insuring that the full checklist³ is completed before administering the doses. Therefore, after NRC visit I checked in several places including the patient's record and the daily archive of the radiopharmacy doses for those particular days, to see if the corresponding written directives could have been misplaced there. After checking the daily archives I found the 3 written directives of the mentioned cases⁴. Therefore for these 3 cases there were written directives before I-131 administration; however, the 2 slips enclosed by the radiopharmacy, the one supposed to be archived ended in the record and the one with the written directive on it⁵, ended in the daily archive.

To prevent from this happening again, the written directives for all dosages greater than 30uCi of I-131 sodium iodide will be placed in a color coded form as it has been Beta Gamma standard operation for I-131 therapy doses for hyperthyroidism and thyroid cancer. This corrective step will ensure that the I-131 written directives are not misplaced and more readily accessible during inspection of records. This policy has been informed and discussed with the nuclear medicine technologist and secretary and implemented since April 22, 2008⁶.

In view of the above Beta Gamma respectfully requests the dismissal of the above mentioned notice of violation.

³ In attachment "D".

⁴ See attachments "A", "B" and "C". (Please do not place in the Public Document Room nor in the internet due to HIPAA concerns.)

⁵ That was supposed to be placed in the record.

⁶ See attachment "E".

Under oath I, Juan E. Pérez-Monté declare that I have personal knowledge of all the facts stated on the present reply to the notice of violation and that those facts are true.

In San Juan, Puerto Rico, today May 5, 2008.

Juan E. Perez-Monte

JUAN E. PEREZ-MONTE, M.D.

Affidavit Number: 2818

Suscribed and Sworn before me by Juan E. Pérez-Monté, of legal age, Medical Director of Beta Gamma Nuclear Radiology, Inc. married, resident of Guaynabo, Puerto Rico whom I personally know.

In San Juan, Puerto Rico, today May 5, 2008.

[Signature]

NOTARY PUBLIC



I HERE BY CERTIFY that on this same day, I notified via certified mail the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, U.S. Nuclear Regulatory Commission Region I 475 Allendale Road King of Prussia, Pennsylvania 19406-1415 and to Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

PLEASE DO NOT PLACE IN THE PUBLIC DOCUMENT ROOM NOR IN THE INTERNET ATTACHMENTS "A", "B" AND "C" DUE TO HIPAA CONCERNS.

PIEDRAS BY

| | |
|--|-----------------------------------|
| I-131 NA IODIDE THERAPY CAPSULE | |
| Use: THYROID THERAPY | |
| Activity: 5.00 mCi | Expiry: @ 09:00 14 Sep 2005 (Wed) |
| Volume: 1.00 CAP | Expiry: 09:00 21 Sep 2005 (Wed) |
| Conc: 5.00 mCi/CAP | PLAN 1 PAGE 1 |
| BETA GAMMA NUCLEAR | |
| OSVALDO MOLINA STE. 101 FAJARDO, PR 00970 | Physician: PEREZ MONTE |
| R Ph: EDUARDO DIAZ (EDM) | |
| Current: 55-09/14/05 | |

Handwritten: 5.17 mCi, 9-14-05, 8-11

BMS RADIOPHARMACEUTICALS, INC.
7877651571
1500 MARG. BO. ANTON SAN JUAN
RIO PIEDRAS, PR 00927

NUCLEAR PHARMACEUTICALS

Attachment - A

| | |
|--|-----------------------------------|
| I-131 NAI THERAPY CAP 4 MCI | |
| Use: THYROID THERAPY | |
| Activity: 4.00 mCi | Expiry: @ 12:00 19 Feb 2008 (Tue) |
| Volume: 1.00 CAP | Expiry: 12:00 26 Feb 2008 (Tue) |
| Conc: 4.00 mCi/CAP | PLAN 9 PAGE 1 |
| BETA GAMMA NUCLEAR | |
| OSVALDO MOLINA STE. 101 FAJARDO, PR 00738 | Physician: PEREZ MONTE |
| R Ph: EDUARDO DIAZ (EDM) | |
| Current: 58-02/19/08 | |

Handwritten: 3.64 mCi, 11:20 AM, 2-19-08

BMS RADIOPHARMACEUTICALS
7877655508
150 FEDERICO COSTAS S.W.
SAN JUAN, PR 00918-1303

NUCLEAR PHARMACEUTICALS

Attachment - B

| | |
|--|-----------------------------------|
| I-131 NAI THERAPY CAP 4 MCI | |
| Use: THYROID THERAPY | |
| Activity: 4.00 mCi | Expiry: @ 12:00 26 Feb 2008 (Tue) |
| Volume: 1.00 CAP | Expiry: 12:00 04 Mar 2008 (Tue) |
| Conc: 4.00 mCi/CAP | PLAN 9 PAGE 1 |
| BETA GAMMA NUCLEAR | |
| OSVALDO MOLINA STE. 101 FAJARDO, PR 00738 | Physician: PEREZ MONTE |
| R Ph: EDUARDO DIAZ (EDM) | |
| Current: 53-02/26/08 | |

Handwritten: 3.57 mCi, 2-26-08, 2:00 PM

BMS RADIOPHARMACEUTICALS
7877655508
150 FEDERICO COSTAS S.W.
SAN JUAN, PR 00918-1303

NUCLEAR PHARMACEUTICALS

Attachment - C

PERSONAL INFORMATION WAS REMOVED
BY NRC, R.T.

BETA GAMMA NUCLEAR RADIOLOGY
CHECK FOR QUALITY ASSURANCE
For use patients receiving more than 30uCi of I-131

Attachment - D

NAME: _____

DATE: _____

LAB# _____

| | | YES | NO | N/A | INICIAL |
|------|---|-------|-------|-------|---------|
| I. | Written order from the referring physician | | | | |
| | A. Date | _____ | _____ | | _____ |
| | B. History and diagnosis | _____ | _____ | | _____ |
| | C. Signature of referring physician | _____ | _____ | | _____ |
| II. | Written directive from authorized user physician | | | | |
| | A. Date of treatment | _____ | _____ | | _____ |
| | B. Type of treatment | _____ | _____ | | _____ |
| | C. Radiopharmaceutical | _____ | _____ | | _____ |
| | D. Dosage | _____ | _____ | | _____ |
| | E. Route of administration | _____ | _____ | | _____ |
| | F. Signature of authorized user-physician | _____ | _____ | | _____ |
| III. | Patient identify | | | | |
| | A. Patient's name asked | _____ | _____ | | _____ |
| | B. Compared with name in ID bracelet | _____ | _____ | _____ | _____ |
| | C. Compared with patient record information | | | | |
| | 1. birth date | _____ | _____ | | _____ |
| | 2. address | _____ | _____ | | _____ |
| | 3. social security number | _____ | _____ | | _____ |
| | 4. signature | _____ | _____ | _____ | _____ |
| IV. | Verify written directive before administering radiopharmaceutical | | | | |
| | A. Radiopharmaceutical | _____ | _____ | | _____ |
| | B. Dosage (measured in dose CAL) | _____ | _____ | | _____ |
| | C. Route of administration | _____ | _____ | | _____ |
| V. | Evidence patient record | | | | |
| | A. Date | _____ | _____ | | _____ |
| | B. Time | _____ | _____ | | _____ |
| | C. Radiopharmaceutical | _____ | _____ | | _____ |
| | D. Volume | _____ | _____ | | _____ |
| | E. Route of administration | _____ | _____ | | _____ |
| | F. Pregnancy test (if applicable) | _____ | _____ | _____ | _____ |
| VI. | Signature of patient in "Permiso para uso de radioisotopo" | _____ | _____ | _____ | |
| VII. | Signature of authorized person who administered the radiopharmaceutical | | | | |

SIGNATURE _____

Beta Gamma Nuclear Radiology, Inc.

PMB 372 PO BOX 7891

Guaynabo PR 00970

Attacment -E

April 22, 2008

To: All Nuclear Medicine Personnel

SDC

From: Juan E. Pérez Monté, M.D.

JPM

RE: Written Directives for doses above 30 uCi of I-131

Effective today, all the written directives for all dosages greater than 30uCi of I-131 sodium iodide will be placed in a color coded form as it has been Beta Gamma standard operation for I-131 therapy doses for hyperthyroidism and thyroid cancer. This will ensure that the I-131 written directives are not misplaced and more readily accessible for any inspection of records.

Please keep this Memorandum posted at all times.

jpm