

January 21, 2010

EA-09-147

Alejandro Pérez Monté
Manager
Beta Gamma Nuclear Radiology, Inc.
P.O. Box 7891, PMB 372
Guaynabo, PR 00970-7891

SUBJECT: CONFIRMATORY ORDER (EFFECTIVE IMMEDIATELY)
[OFFICE OF INVESTIGATIONS REPORT NO. 1-2008-052]

Dear Dr. Pérez:

On July 2, 2009, the U.S. Nuclear Regulatory Commission (NRC) issued a letter to Beta Gamma Nuclear Radiology (BGNR), enclosing a summary of an investigation conducted by the NRC Office of Investigations (OI) (Reference OI Investigation Report No. 1-2008-052). OI opened the investigation to determine whether BGNR had submitted falsified written directives in a May 5, 2008 response to an April 8, 2008 Severity Level (SL) IV Notice of Violation (NOV).

The SLIV NOV had been issued for BGNR's failure to prepare written directives prior to administering diagnostic doses of radioactive iodine on the dates of September 14, 2005, and February 19 and 26, 2008. In its May 5, 2008 response, BGNR disputed the SLIV NOV in a sworn and notarized letter stating that the BGNR Director, as the Authorized User, had in fact prepared written directives for the I-131 sodium iodide administrations prior to conducting them on September 14, 2005, and February 19 and 26, 2008, and that although the written directives had been misplaced, since the inspection, the written directives had been located. The letter enclosed copies of these written directives. During review of the letter, the NRC identified that the written directive for the administrations performed on September 14, 2005, was dated September 14, 2008, calling into question the validity of the date on which this directive, and the others, had been written.

Based on evidence developed during the investigation, the NRC identified an apparent violation, including that the BGNR Director, on behalf of BGNR, submitted falsified written directives to support BGNR's dispute of the SLIV NOV; and that as a result, BGNR maintained incomplete and inaccurate written directives in violation of 10 CFR 30.9.

The July 2, 2009 NRC letter informed BGNR that the NRC was considering escalated enforcement for the apparent violation. On July 6, 2009, BGNR requested the use of Alternative Dispute Resolution (ADR) to resolve this matter. An ADR session was held on October 27, 2009, and an agreement was reached.

The enclosed Confirmatory Order contains commitments that were made by BGNR as a result of the settlement agreement reached during the ADR session. As evidenced by the signed "Consent and Hearing Waiver Form (copy enclosed) dated January 12, 2010, BGNR agreed to issuance of this letter and Confirmatory Order.

As part of the settlement agreement, BGNR agreed to take a number of actions, such as performing quarterly comprehensive radiation safety audits and authorizing a new Radiation Safety Officer for a two year period, to ensure licensee compliance with NRC regulations, including the requirement to provide complete and accurate information to the NRC. The actions are detailed in the enclosed Confirmatory Order. As indicated in the Confirmatory Order, actions involving the submittal of written material are to be sent to the NRC for review as they are completed; instructions are provided below. In recognition of these actions, the NRC agreed to not issue the civil penalty amount of \$13,000, as suggested by the NRC Enforcement Policy, but rather to issue a civil penalty of \$5,000, and to issue BGNR an NOV containing a SLIII violation (Enclosure 3). The NRC will evaluate the implementation of the Confirmatory Order commitments in future inspections.

Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate, any provision of this Confirmatory Order shall be subject to criminal prosecution as set forth in that section. Violation of this Confirmatory Order may also subject the person to civil monetary penalties.

BGNR is not required to respond to this letter. However, if you choose to provide a response, please submit it within 30 days to: Office of the Regional Administrator, NRC Region I, 475 Allendale Rd., King of Prussia, PA 19406. If you have any questions or comments concerning this letter, please contact Mr. Karl Farrar of my staff at 610-337-5301. Regarding the actions detailed in the Confirmatory Order that involve the submittal of written material, please forward all documents to Mr. Marc Ferdas, Chief, Medical Branch, at the above address. Mr. Ferdas can be reached at 610-337-5022.

A copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC will also include this letter, and its attached Confirmatory Order, on its website at www.nrc.gov; select What We Do, Enforcement, Significant Enforcement Actions. BGNR's response, if it chooses to provide one, will also be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS).

Sincerely,

/RA/

Marc L. Dapas,
Deputy Regional Administrator

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

Enclosures:

1. Confirmatory Order
2. Consent and Hearing Waiver Form
3. Notice of Violation

cc: Commonwealth of Puerto Rico

A. Perez Monte

As part of the settlement agreement, BGNR agreed to take a number of actions, such as performing quarterly comprehensive radiation safety audits and authorizing a new Radiation Safety Officer for a two year period, to ensure licensee compliance with NRC regulations, including the requirement to provide complete and accurate information to the NRC. The actions are detailed in the enclosed Confirmatory Order. As indicated in the Confirmatory Order, actions involving the submittal of written material are to be sent to the NRC for review as they are completed; instructions are provided below. In recognition of these actions, the NRC agreed to not issue the civil penalty amount of \$13,000, as suggested by the NRC Enforcement Policy, but rather to issue a civil penalty of \$5,000, and to issue BGNR an NOV containing a SLIII violation (Enclosure 3). The NRC will evaluate the implementation of the Confirmatory Order commitments in future inspections.

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Sincerely,
/RA/
Marc L. Dapas,
Deputy Regional Administrator

Docket No. 03035572
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cc: Commonwealth of Puerto Rico
see next page for Distribution

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Region I OE Files (with concurrences)

Enclosure 1

Consent and Hearing Waiver Form

Beta Gamma Nuclear Radiology (BGNR) hereby agrees with the attached immediately effective Confirmatory Order. I recognize that by signing below, BGNR consents to the issuance of the Confirmatory Order, effective immediately, containing commitments agreed on, as incorporated into the Confirmatory Order, including payment of the civil penalty. The agreement was reached during an Alternative Dispute Resolution mediation session held at the NRC Region 1 475 Altondale Road, King of Prussia, Pennsylvania 19406 office, on October 27, 2009. By agreeing to the attached Confirmatory Order, pursuant to 10 CFR 2.202(e)(3) and (d), BGNR waives the right to request a hearing on all or any part of the Confirmatory Order.



Alejandro Pérez Monté
Manager
Beta Gamma Nuclear Radiology, Inc.

January 12, 2010

Date

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

[7590-01-P]

In the Matter of)

Beta Gamma Nuclear Radiology)

) Docket No. 03035572
) License No. 52-25542-01
) EA-09-147

CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

I

Beta Gamma Nuclear Radiology (BGNR) (Licensee) is the holder of medical License No. 52-25542-01, issued by the U.S. Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30 on December 21, 2000. The license authorizes the operation of BGNR (facility) in accordance with conditions specified therein. The facility is located on the Licensee's site in Fajardo, Puerto Rico.

This Confirmatory Order is the result of an agreement reached during an alternative dispute resolution (ADR) mediation session conducted on October 27, 2009. ADR is a process in which a neutral mediator with no decision-making authority assists the parties in reaching an agreement on resolving any differences regarding the dispute.

II

On July 2, 2009, the NRC issued a letter to BGNR, enclosing a summary of an investigation conducted by the NRC Office of Investigations (OI) (Reference OI Investigation Report No. 1-2008-052). OI opened the investigation to determine whether BGNR had submitted falsified written directives in a May 5, 2008 response to an April 8, 2008 Severity Level (SL) IV Notice of Violation (NOV).

The SLIV NOV had been issued for BGNR's failure to prepare written directives prior to administering diagnostic doses of radioactive iodine on the dates of September 14, 2005, and February 19 and 26, 2008. In its May 5, 2008 response, BGNR disputed the SLIV NOV in a sworn and notarized letter stating that the BGNR Director, as the Authorized User, had in fact prepared written directives for the I-131 sodium iodide administrations prior to conducting them on September 14, 2005, and February 19 and 26, 2008, and that although the written directives had been misplaced, since the inspection, the written directives had been located. The letter enclosed copies of these written directives. During review of the letter, the NRC identified that the written directive for the administrations performed on September 14, 2005, was dated September 14, 2008, calling into question the validity of the date on which this directive, and the others, had been written.

Based on evidence developed during the investigation, the NRC identified an apparent violation, including that the BGNR Director, on behalf of BGNR, submitted falsified written directives to support BGNR's dispute of the SLIV NOV; and that as a result, BGNR maintained incomplete and inaccurate written directives in violation of 10 CFR 30.9.

The July 2, 2009 NRC letter informed BGNR that the NRC was considering escalated enforcement for the apparent violation. On July 6, 2009, BGNR requested the use of an ADR mediation session to resolve this matter. On October 27, 2009, the NRC and BGNR met in an ADR session mediated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution. This Confirmatory Order is issued pursuant to the agreement reached during the ADR process.

III

During the ADR session, a preliminary settlement agreement was reached. The elements of the agreement consisted of the following:

A. BGNR and the NRC agree to the following facts:

1. BGNR provided inaccurate information, in a response contesting the April 8, 2008 SLIV NOV, in that, the BGNR director, acting on behalf of the licensee, stated that three written directives for diagnostic doses of iodine-131 were written prior to the administrations, when in fact, the written directives were signed and dated after the administrations, in violation of 10 CFR 30.9;
2. BGNR maintained incomplete or inaccurate written directives in violation of 10 CFR 30.9; and,
3. The violation of 10 CFR 35.40 contained in the NOV dated April 8, 2008 occurred as stated in the NOV.

B. BGNR will contract with a current or former Radiation Safety Officer (RSO), who has been authorized in that capacity on an NRC or Agreement State medical license, to perform comprehensive audits of BGNR's radiation safety program, including a review of the corrective actions documented in the ADR Confirmatory Order (Order). This will include the following actions:

1. Within 30 days of the issuance date of the Order, BGNR will submit the qualifications of

the selected auditor to the NRC in writing;

2. Within 30 days of NRC approval of the auditor, the auditor will conduct the first audit, and the auditor will complete the first audit report within 90 days of NRC approval of the auditor;
3. Following the first audit, three additional audits will be conducted on a quarterly basis at BGNR (four audits completed within approximately one year); and,
4. Within 30 days of the completion of each audit, BGNR will submit the audit report to the NRC for review.

C. BGNR will request a license amendment from the NRC to designate a new RSO on the BGNR license who will be responsible for implementation and oversight of the radiation safety program, for a period of two years from the date of this Order. The license amendment request, including information regarding the qualifications of the proposed RSO in accordance with the requirements of 10 CFR Part 35, will be submitted to the NRC within 30 days of the date of Order issuance.

D. BGNR will create a written policy, and train employees, regarding expectations for: (1) employees providing complete and accurate information to the NRC; (2) compliance with NRC regulations; and, (3) the freedom to raise safety concerns with BGNR management and/or to the NRC without fear of retaliation; within 30 days of the date of the Order. All new employees will also be trained on this policy.

In recognition of these actions, the NRC agreed to issue a civil penalty in the amount of \$5,000, and to issue BGNR an NOV containing a SL III violation.

On January 12, 2010, BGNR consented to issuing this Order with the commitments, as described in Section V below. BGNR further agreed that this Order is to be effective upon issuance and that it has waived its right to a hearing.

IV

Since BGNR has agreed to take additional actions to address NRC concerns, as set forth in Item III above, the NRC has concluded that its concerns can be resolved through issuance of this Order.

I find that BGNR's commitments as set forth in Section V are acceptable and necessary and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that public health and safety require that the Licensee's commitments be confirmed by this Order. Based on the above and BGNR's consent, this Order is immediately effective upon issuance.

V

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 30
IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY:

- A. BGNR will contract with a current or former Radiation Safety Officer (RSO), who has been authorized in that capacity on an NRC or Agreement State medical license, to perform comprehensive audits of the radiation safety program, including a review of the corrective actions documented in this Confirmatory Order. This will include the following actions:
1. Within 30 days of the issuance date of this Order, BGNR will submit the qualifications of the selected auditor to the NRC in writing;
 2. Within 30 days of the NRC approval of the auditor, the auditor will conduct the first audit, and the auditor will complete the first audit report within 90 days of NRC approval of the auditor;
 3. Following the first audit, three additional audits will be conducted on a quarterly basis at BGNR (four audits completed within approximately one year); and,
 4. Within 30 days of completion of each audit, BGNR will submit the audit report to the NRC for review.
- B. BGNR will request a license amendment from the NRC to designate a new RSO on the BGNR license who will be responsible for implementation and oversight of the radiation safety program for a period of two years from the date of this Order. The license amendment request, including information regarding the qualifications of the proposed RSO in accordance with the requirements of 10 CFR Part 35, will be submitted to the NRC within 30 days of the date of Order issuance.

- C. BGNR will create a written policy, and train employees, regarding expectations for: (1) employees providing complete and accurate information to the NRC; (2) compliance with NRC regulations; and, (3) the freedom to raise safety concerns with BGNR management and/or to the NRC without fear of retaliation; within 30 days of the date of the Order. All new employees will also be trained on this policy.
- D. BGNR will pay a \$5000 civil penalty in two equal installments; the first installment to be paid within 90 days of the date of this Order, and the second installment to be paid within 180 days of the date of this Order.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

VI

Any person adversely affected by this Confirmatory Order, other than the Licensee, may request a hearing within 20 days of its publication in the *Federal Register*. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and include a statement of good cause for the extension.

A request for a hearing must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated in 72 Fed. Reg. 49,139 (Aug. 28, 2007). The E-Filing process requires participants to submit and serve documents over the internet or, in some cases, to mail copies on electronic

optical storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements associated with E-Filing, at least five (5) days prior to the filing deadline the requestor must contact the Office of the Secretary by e-mail at HEARINGDOCKET@NRC.GOV, or by calling (301) 415-1677, to request: (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any NRC proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances when the requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each requestor must download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at <http://www.nrc.gov/site-help/e-submittals/install-viewer.html>. Information about applying for a digital ID certificate also is available on NRC's public website at <http://www.nrc.gov/site-help/e-submittals/apply-certificates.html>.

Once a requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for a hearing through EIE. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public website at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the filer submits its document through EIE. To be timely, electronic filings must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to

participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, any others who wish to participate in the proceeding (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request is filed so that they may obtain access to the document via the E-Filing system.

A person filing electronically may seek assistance through the "Contact Us" link located on the NRC website at <http://www.nrc.gov/site-help/e-submittals.html> or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is (800) 397-4209 or (301) 415-4737.

Participants who believe that they have good cause for not submitting documents electronically must file a motion, in accordance with 10 C.F.R. 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville, Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at http://ehd.nrc.gov/EHD_Proceeding/home.asp, unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such

as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their works.

Any person that requests a hearing shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 C.F.R. 2.309(d) and (f).

If the hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained. In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received. A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Marc L. Dapas,
Deputy Regional Administrator

Dated this 21st day of January 2010

NOTICE OF VIOLATION

Beta Gamma Nuclear Radiology
Puerto Rico

Docket No. 03035572
License No. 52-25542-01
EA-09-147

During an NRC investigation initiated on July 10, 2008, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 30.9 requires, in part, that information provided to the Commission by a licensee, or information required by the Commission's regulations to be maintained by the licensee shall be complete and accurate in all material respects.

Contrary to the above, in a May 5, 2008 response contesting a Severity Level IV Notice of Violation, Beta Gamma Nuclear Radiology (BGNR) maintained, and provided to the NRC, information that was not complete and accurate in all material respects. Specifically, the BGNR response stated that three written directives for diagnostic doses of iodine-131, administered on September 14, 2005, and February 19 and 26, 2008, were written prior to the administrations, when in fact, the written directives were signed and dated after the administrations. The written directives were required to be maintained by 10 CFR 35.40(a), and were therefore, material to the NRC.

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in the letter and/or the Confirmatory Order transmitting this Notice of Violation (Notice). Therefore, you are not required to respond to this Notice.

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

Dated this 21st day of January 2010.