

January 21, 2010

IA-09-041

Juan E. Pérez Monté, M.D.  
[HOME ADDRESS WITHHELD  
UNDER 10 CFR 2.390]

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 you, 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 Beta Gamma Nuclear Radiology (BGNR) had submitted falsified written directives in a May 5, 2008 response to a 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 you, 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 you, on behalf of BGNR, deliberately submitted falsified written directives in violation of 10 CFR 30.10(a)(2), and as a result, caused BGNR to maintain inaccurate information, in violation of 10 CFR 30.10(a)(1).

The July 2, 2009 NRC letter informed you that the NRC was considering escalated enforcement for the apparent violation. On July 6, 2009, you 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 you as part 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, you agreed to issuance of this letter and Confirmatory Order.

As part of the settlement agreement, you agreed to take a number of actions, including providing outreach to the nuclear medicine community to help deter other licensees and

individuals from violating NRC regulations, and agreeing not to serve as Radiation Safety Officer at BGNR or other licensed facilities for at least two years. These actions are detailed in the attached 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 you an order prohibiting involvement in NRC-licensed activities, but rather, to issue you a Notice of Violation containing a Severity Level III violation. 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.

You are not required to respond to this letter. However, if you choose to provide a response, please provide it within 30 days at: 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](http://www.nrc.gov); select What We Do, Enforcement, Significant Enforcement Actions. Your response, if you choose 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). In addition, this letter will be maintained by the Office of Enforcement in an NRC Privacy Act system of records, NRC-3, "Enforcement Actions Against Individuals." The NRC-3 system notice, which provides detailed information about this system of records, can be accessed from the NRC Web site at <http://www.nrc.gov/reading-rm/foia/privacy-systems.html>.

Sincerely,

*/RA/*

Marc L. Dapas,  
Deputy Regional Administrator

Enclosures:

1. Confirmatory Order
2. Consent and Hearing Waiver Form

cc: Rafael Machargo, Counsel for Dr. Pérez

individuals from violating NRC regulations, and agreeing not to serve as Radiation Safety Officer at BGNR or other licensed facilities for at least two years. These actions are detailed in the attached 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 you an order prohibiting involvement in NRC-licensed activities, but rather, to issue you a Notice of Violation containing a Severity Level III violation. 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

Enclosures:

1. Confirmatory Order
2. Consent and Hearing Waiver Form

cc: Rafael Machargo, Counsel for Dr. Pérez

Distribution:

See next page

**SUNSI Review Complete:** AEP (Reviewer's Initials)

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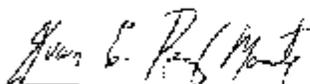
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Region I OE Files (with concurrences)

Enclosure 1

Consent and Hearing Waiver Form

Juan E. Pérez Monté, M.D. hereby agrees with the attached immediately effective Confirmatory Order. I recognize that by signing below, I consent to the issuance of the Confirmatory Order, effective immediately, containing commitments agreed on, as incorporated into the Confirmatory Order. The agreement was reached during a Alternative Dispute Resolution mediation session held at the NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406 office, on October 27, 2009. By agreeing to the attached Confirmatory Order, pursuant to 10 CFR 2.202(a)(3) and (d), I waive the right to request a hearing on all or any part of the Confirmatory Order.



Juan E. Pérez Monté, M.D.  
Director and Radiation Safety Officer  
Beta Gamma Nuclear Radiology, Inc.

January 12, 2010

Date

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

[7590-01-P]

In the Matter of

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)

Juan E. Pérez Monté, M.D.

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IA-09-041

CONFIRMATORY ORDER MODIFYING LICENSE  
(EFFECTIVE IMMEDIATELY)

I

Juan E. Pérez Monté, M.D. (Dr. Pérez) is named as the Radiation Safety Officer (RSO) on License No. 52-25542-01 issued by the NRC to Beta Gamma Nuclear Radiology (BGNR), a medical practice 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 U.S. Nuclear Regulatory Commission (NRC or Commission) issued a letter to Dr. Pérez, 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 Beta Gamma Nuclear Radiology (BGNR) had submitted falsified written directives in a May 5, 2008 response to a 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 Dr. Pérez, 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 Dr. Pérez, on behalf of BGNR, deliberately submitted falsified written directives in violation of 10 CFR 30.10(a)(2), and as a result, caused BGNR to maintain inaccurate information contrary to 10 CFR 30.9, in violation of 10 CFR 30.10(a)(1).

The July 2, 2009 NRC letter informed Dr. Pérez that the NRC was considering escalated enforcement for the apparent violation. On July 6, 2009, Dr. Pérez requested the use of an ADR mediation session to resolve this matter. On October 27, 2009, the NRC and Dr. Pérez 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 that ADR session, a preliminary settlement agreement was reached. The elements of the agreement consisted of the following:

- A. Dr. Pérez and the NRC agree that Dr. Pérez committed two violations of NRC requirements. Specifically, Dr. Pérez: (1) deliberately submitted falsified written directives to support BGNR's dispute of the April 8, 2008 NOV in violation of 10 CFR 30.10(a)(2); and, (2) deliberately caused BGNR to maintain incomplete or inaccurate information as required by 10 CFR 30.9, in violation of 10 CFR 30.10(a)(1).
  
- B. Dr. Pérez will write an article regarding: (1) lessons learned from the ADR experience; (2) the importance of providing accurate information to the NRC; and, (3) compliance with NRC requirements; and will complete the following actions:
  - 1. Within six months of the date of the Order, Dr. Pérez will submit the article for publication to the following: Galenus (Puerto Rico), the Journal of the Health Physics Society, and the Journal of Nuclear Medicine; and,
  
  - 2. Dr. Pérez will also submit the article to the NRC for approval, at least two weeks prior to submitting to the publications listed above.
  
- C. Dr. Pérez will write a presentation regarding: (1) lessons learned from the ADR experience; (2) the importance of providing accurate information to the NRC; and, (3) compliance with NRC requirements. Dr. Pérez will submit to the NRC the planned presentation for approval

at least two weeks before delivering the actual presentation to the Puerto Rico chapter of the Society of Nuclear Medicine.

- D. Dr. Pérez will offer to make the same or a similar presentation at the next scheduled national meetings of the Health Physics Society and the Society of Nuclear Medicine. If the request to make a presentation is accepted, he will submit the planned presentation to the NRC for approval at least two weeks before delivery of the presentation at these meetings.
- E. Dr. Pérez will remove himself as RSO from any NRC or Agreement State licenses within 30 days of Order issuance, and will not be re-designated or perform the functions of RSO for any NRC or Agreement State license for two years from the date of Order issuance.

In recognition of these actions, the NRC agreed to not issue Dr. Pérez an order prohibiting involvement in NRC-licensed activities, but rather, to issue a Notice of Violation containing a Severity Level III violation. On January 12, 2010, Dr. Pérez consented to issuing this Order with the commitments, as described in Section V below. Dr. Pérez further agreed that this Order is to be effective upon issuance and that he has waived his right to a hearing.

#### IV

Since Dr. Pérez 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 Dr. Pérez' 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 Dr. Pérez' commitments be confirmed by this Order. Based on the above and Dr. Pérez' 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. Dr. Pérez will write an article regarding: (1) lessons learned from the ADR experience; (2) the importance of providing accurate information to the NRC; and, (3) compliance with NRC requirements; and will complete the following actions:
1. Within six months of the date of the Order, Dr. Pérez will submit the article for publication to the following: Galenus (Puerto Rico), the Journal of the Health Physics Society, and the Journal of Nuclear Medicine; and,
  2. Dr. Pérez will also submit the article to the NRC for approval, at least two weeks prior to submitting to the publications listed above.
- B. Prior to the next scheduled national meetings of the Health Physics Society and the Society of Nuclear Medicine, Dr. Pérez will write a presentation regarding: (1) lessons learned from

the ADR experience; (2) the importance of providing accurate information to the NRC; and, (3) compliance with NRC requirements. Dr. Pérez will submit to the NRC the planned presentation for approval at least two weeks before delivering the actual presentation to the Puerto Rico chapter of the Society of Nuclear Medicine.

- C. Dr. Pérez will offer to make the same or a similar presentation at the next scheduled national meetings of the Health Physics Society and the Society of Nuclear Medicine. If the request to make a presentation is accepted, he will submit the planned presentation to the NRC for approval at least two weeks before delivery of the presentation at these meetings.
- D. Dr. Pérez will be removed as RSO from any NRC or Agreement State licenses within 30 days of Order issuance, and will not be re-designated or perform the functions of RSO for any NRC or Agreement State licenses for two years from the date of Order issuance.

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 Dr. Pérez, 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](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 21<sup>st</sup> day of January 2010

## NOTICE OF VIOLATION

Juan E. Pérez Monté, M.D.

IA-09-041

[HOME ADDRESS DELETED  
UNDER 10 CFR 2.790(a)]

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 30.10(a)(1) requires, in part, that an employee of a licensee may not engage in deliberate misconduct that causes a licensee to be in violation of any regulation.

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.

10 CFR 30.10(a)(2) requires, in part, that an employee of a licensee may not deliberately submit to the NRC information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

Contrary to the above, in a response contesting a Severity Level IV Notice of Violation dated May 5, 2008, Juan E. Pérez Monté, M.D. submitted information known to be inaccurate in some respect material to the NRC, in violation of 10 CFR 30.10(a)(2); and as a result, caused Beta Gamma Nuclear Radiology (BGNR) to maintain inaccurate information contrary to 10 CFR 30.9, in violation of 10 CFR 30.10(a)(1). Specifically, BGNR's May 5, 2008 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.

This action will be maintained by the Office of Enforcement in an NRC Privacy Act system of records, NRC-3, "Enforcement Actions Against Individuals." The NRC-3 system notice, which provides detailed information about this system of records, can be accessed from the NRC Web site at <http://www.nrc.gov/readingrm/foia/privacy-systems.html>.

Dated this 21<sup>st</sup> day of January 2010