

NUCLEAR REGULATORY COMMISSION

[Docket No. 03035572, License No. 52-25542-01, EA-09-147, NRC-2010-0028]

In the Matter of Beta Gamma Nuclear Radiology; 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.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139, August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the Internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at hearing.docket@nrc.gov, or by telephone at (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 proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/apply-certificates.html>. System requirements for accessing the E-

Submittal server are detailed in NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through EIE, users will be required to install a Web browser plug-in from the NRC Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing 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 E-Filing 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 documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC Web site at <http://>

www.nrc.gov/site-help/e-submittals.html, by e-mail at MSHD.Resource@nrc.gov, or by a toll-free call at (866) 672-7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 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. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

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, or the 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, unless an NRC regulation or other law requires submission of such information. 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 submission.

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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 CFR 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.

Dated this 21st day of January 2010.

Marc L. Dapas,

Deputy Regional Administrator.

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NUCLEAR REGULATORY COMMISSION

[IA-09-041]

Juan E. Pérez Monté, M.D.; 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.

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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