

July 1, 2011

EA-09-147

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

SUBJECT: CONFIRMATION OF COMPLETION OF ACTIONS TAKEN BY BETA GAMMA  
NUCLEAR RADIOLOGY, INC., AS SET FORTH IN NRC CONFIRMATORY  
ORDER DATED JANUARY 21, 2010

Dear Mr. Pérez :

The purpose of this letter is to acknowledge the actions Beta Gamma Nuclear Radiology, Inc. (BGNR) has taken in response to the Confirmatory Order (Order) (ADAMS Accession No. ML100210602<sup>1</sup>) issued to you by the U.S. Nuclear Regulatory Commission (NRC) on January 21, 2010. The actions were taken to fulfill commitments that were made as part of a settlement agreement reached during an October 27, 2009, Alternative Dispute Resolution (ADR) mediation session between BGNR and the NRC. BGNR requested the ADR mediation session in response to a letter the NRC issued on July 2, 2009 (ML0918313702<sup>2</sup>), which enclosed a summary of an investigation conducted by the NRC Office of Investigations (OI). The OI investigation reviewed the circumstances associated with the apparent submission of falsified written directives in a May 5, 2008 response (ML081300465) to an April 8, 2008 Notice of Violation (NOV) containing a Severity Level (SL) IV violation (ML081010261) issued by the NRC. Based on evidence developed during the investigation, the NRC identified an apparent violation that the BGNR Director, on behalf of BGNR, submitted falsified written directives to support BGNR's dispute of the SL IV NOV; and that as a result, BGNR maintained incomplete and inaccurate written directives in violation of 10 CFR 30.9, "Completeness and accuracy of information."

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 (RSO) for a two year period. In recognition of these actions, the NRC agreed to issue a SL III violation and a civil penalty of \$5,000, rather than the \$13,000 civil penalty suggested by the NRC Enforcement Policy. The commitments contained in the Order, BGNR's actions, and a summary of the NRC's evaluation, are described in the enclosed table (Enclosure). Based on a review of the actions, the NRC has determined that BGNR has satisfied all of the terms of the Order, including requesting a license amendment from the NRC to designate a new RSO on the BGNR license who will be responsible for implementation and

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<sup>1</sup> Designation in parentheses refers to an Agencywide Documents Access and Management System (ADAMS) accession number. Most of the documents referenced in this letter are publicly-available using the accession number in ADAMS (exceptions to public availability are noted)

<sup>2</sup> Non-publicly available

oversight of the radiation safety program for a period of two years from the date of the Order. The NRC expects BGNR to maintain compliance with this requirement until at least January 21, 2012. Your cooperation in this matter is appreciated.

A copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room located at NRC Headquarters in Rockville, MD, and from ADAMS. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. 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).

We have no further questions at this time, and you are not required to submit any further correspondence to the NRC on these matters. However, if you have any questions or comments, please contact Marc S. Ferdas, Chief, Medical Branch, Division of Nuclear Materials Safety, Region I, at 610-337-5022.

Sincerely,

/RA/

William M. Dean  
Regional Administrator

Enclosure:  
Completion of Actions Set Forth in the Confirmatory Order

cc: Rafael Machargo, Counsel for Dr. Pérez  
Commonwealth of Puerto Rico

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cc: Rafael Machargo, Counsel for Dr. Pérez  
Commonwealth of Puerto Rico

**SUNSI Review Complete:**   AEP  

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Completion of Actions Set Forth in the Confirmatory Order

<b>Confirmatory Order Commitment</b>	<b>Actions by BGNR</b>	<b>NRC's Evaluation</b>
<p>A. BGNR will contract with a current or former Radiation Safety Officer, 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 the Confirmatory Order dated January 21, 2010. This will include the following actions:</p> <ol style="list-style-type: none"> <li>1. Within 30 days of the issuance of the date of the Order, BGNR will submit the qualifications of the selected auditor in writing;</li> <li>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 the NRC approval of the auditor;</li> <li>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,</li> <li>4. Within 30 days of the completion of each audit, BGNR will submit the audit report to the NRC for review.</li> </ol>	<p>BGNR submitted credentials of the selected contract auditor on February 16, 2010. <i>(Ref. ML100541021(not publicly available)<sup>1</sup>)</i></p> <p>BGNR submitted the first quarterly audit report on June 21, 2010. <i>(Ref. ML101760007)</i></p> <p>BGNR submitted the second quarterly audit report on September 20, 2010. <i>(Ref. ML102720106)</i></p> <p>BGNR submitted the third quarterly audit report on December 17, 2010. <i>(Ref. ML103550417)</i></p> <p>BGNR submitted the fourth quarterly audit report on March 18, 2011. <i>(Ref. ML110810690)</i></p>	<p>The NRC reviewed the credentials of BGNR's selected auditor and determined that BGNR could proceed with conducting the quarterly audits, as documented in NRC letter dated February 25, 2010. <i>(Ref. ML100560485)</i></p> <p>The auditor qualifications and first quarterly audit were reviewed and found to be acceptable to the terms of the Order, as documented in NRC Inspection Report 2010-001, dated July 14, 2010. <i>(Ref. ML102160153)</i></p> <p>The second, third and fourth quarterly audits were reviewed and found to be acceptable to the terms of the Order, as documented in NRC Inspection Report 2011-001, dated May 16, 2011. <i>(Ref. ML111570016)</i></p>

<sup>1</sup> This document is not publicly available because it contains sensitive, personally-identifiable information.

<b>Confirmatory Order Commitment</b>	<b>Actions by BGNR</b>	<b>NRC's Evaluation</b>
<p>B. BGNR will request a license amendment from the NRC to designate a new Radiation Safety Officer 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 the 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.</p>	<p>BGNR submitted the license request to name the new Radiation Safety Officer on February 16, 2010. (Ref. ML100541021(not publicly available)<sup>1</sup>)</p>	<p>The NRC processed and approved the license amendment request to name the new Radiation Safety Officer as documented on the NRC letter dated March 19, 2010. (Ref. ML100780188, ML100780191)</p>
<p>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.</p>	<p>BGNR submitted the written policy, program plan, and certification of employee attendance to training, on February 22, 2010. (Ref. ML100700109)</p>	<p>The written policy, program plan, and certification of employee attendance to training were reviewed and found to be acceptable to the terms of the Order, as documented in NRC Inspection Report 2010-001, dated July 14, 2010. (Ref. ML102160153)</p>
<p>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.</p>	<p>BGNR submitted its first installment on April 20, 2010 and the second installment on July 6, 2010. (Ref. ML101121030, ML101900607)</p>	<p>By letter dated May 7, 2010, the NRC acknowledged receipt of the first installment. By letter dated August 2, 2010, the NRC acknowledged receipt of the second installment. (Ref. ML101260205, ML102140486)</p>