

January 15, 2010  
EN 10-004

OFFICE OF ENFORCEMENT  
NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION

Licensee: Beta Gamma Nuclear Radiology, Inc. (EA-09-147)  
Guaynabo, PR 00970-7891  
Docket No. 03035572

Individual: Mr. Juan E. Perez Monté, M.D. (IA-09-041)

Subject: TWO CONFIRMATORY ORDERS (EFFECTIVE IMMEDIATELY), TWO  
NOTICES OF VIOLATION AND A CIVIL PENALTY - \$5,000

This is to inform the Commission that a Confirmatory Order, Severity Level (SL) III Notice of Violation (NOV) and Civil Penalty of \$5,000 will be issued on or about Thursday, January 21, 2010, to Beta Gamma Nuclear Radiology, Inc. (BGNR), confirming commitments reached as part of an alternative dispute resolution (ADR) mediation settlement agreement. Additionally, as a result of the same ADR session, a Confirmatory Order will be issued, on or about the same date, which will prohibit Dr. Perez Monté, a BGNR employee, from serving as Radiation Safety Officer (RSO) at BGNR or other licensed facilities for two years. An investigation was conducted to determine whether BGNR had submitted falsified written directives while disputing a previously issued SL IV NOV. Based on information developed during the investigation, an apparent violation was identified involving the submittal of falsified written directives by Dr. Perez Monté, contrary to 10 CFR 30.9.

The previously issued SL IV NOV involved BGNR's failure to prepare written directives prior to administering diagnostic doses of radioactive iodine on a number of dates. In a May 2008 response, BGNR disputed the SLIV NOV stating that Dr. Perez Monté, as the Authorized User, had, in fact, prepared written directives for the administrations prior to conducting them, and that although the written directives had been misplaced, since the inspection, they had been located. During the review of the letter and written directives provided with the May 2008 response, the staff identified that the written directive for an administration 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.

Enforcement was pursued against Dr. Perez Monté as a result of his apparent deliberate acts associated with the deliberate submittal of falsified written directives in violation of 10 CFR 30.10(a)(2) which, as a result, caused BGNR to deliberately maintain inaccurate information, in violation of 10 CFR 30.10(a)(1).

The joint ADR mediation session was conducted on October 27, 2009, and settlement agreements were reached. As part of its agreement, BGNR acknowledged both the previously issued SL IV NOV and the current apparent violation involving completeness and accuracy of information. BGNR agreed to take a number of actions including, but not limited to, performing

quarterly comprehensive radiation safety audits and authorizing a new RSO for a two year period. In addition to agreeing not to serve as RSO at BGNR or other licensed facilities for at least two years, Dr. Perez Monté agreed to provide outreach to the nuclear medicine community to help deter others from violating NRC regulations.

In recognition of these actions, the NRC agreed to issue to BGNR a civil penalty in the amount of \$5,000 and will also issue an NOV containing a SL III violation of 10 CFR 30.9. The NRC agreed to not issue Dr. Perez Monté an Order prohibiting involvement in NRC-licensed activities other than the two year restriction on serving as RSO, and will also issue him an NOV containing a SL III violation of 10 CFR 30.10.

The schedule of issuance and notification is:

Mailing of Notice and Order	January 21, 2010
Telephone Notification	January 21, 2010

The Commonwealth of Puerto Rico will be notified.

Contacts: Nicole Coleman, OE, 415-1048    Nick Hilton, OE, 415-3055

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