



NRC NEWS

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NRC ISSUES CONFIRMATORY ORDER TO PUERTO RICO MEDICAL FIRM AFTER AGREEMENT IS REACHED UNDER ALTERNATE DISPUTE RESOLUTION

A nuclear medicine practice in Guaynabo, Puerto Rico has agreed to pay a \$5,000 fine and implement a series of corrective actions related to radiation safety under an agreement reached with the Nuclear Regulatory Commission.

The settlement was achieved under the NRC's Alternate Dispute Resolution (ADR) process, which was initiated at the request of the firm, Beta Gamma Nuclear Radiology (BGNR). The objective was to address a deliberate violation of NRC regulations involving the creation, maintenance and submittal of inaccurate information to the agency related to the firm's previous failure to prepare written directives, or orders, prior to the administration of nuclear medicine treatments on certain occasions.

On April 8, 2008, the NRC issued a Notice of Violation to BGNR for not preparing written directives before diagnostic doses of radioactive iodine were administered on Sept. 14, 2005, and Feb. 19 and 28, 2008. Because BGNR's Authorized User (AU) physician – the individual who authorizes the administrations – had administered the radioactive iodine to the patients himself, the NRC classified the safety significance of the violation as Severity Level IV, the lowest end of the I to IV severity levels used by the agency. The company, in a May 5, 2008 response, maintained that written directives had, in fact, been prepared prior to the treatments. The firm stated that while the documents had been misplaced and could not be located during the NRC's inspection, they had since been located. Copies of the directives were enclosed.

However, an NRC review of the submittal determined the directive for administrations performed on Sept. 14, 2005 was dated Sept. 14, 2008, thus calling into question the validity of the dates on which this directive and others were prepared. A subsequent investigation by the NRC's Office of Investigations determined that the AU, who is also BGNR's Radiation Safety Officer (RSO), had deliberately created, maintained and submitted falsified written directives to the NRC on behalf of the firm, in violation of agency regulations.

BGNR and the AU were notified of the results of the NRC investigation on July 2, 2009, and both, in turn, informed the agency on July 6, 2009 that they were interested in the use of an ADR session to resolve the matter. ADR is a process in which a neutral mediator with no decision-

making authority assists the parties in reaching an agreement or resolving any differences regarding a dispute. An ADR mediation session took place on Oct. 27, 2009 and led to agreements with both BGNR and the AU containing the following elements, which are detailed in Confirmatory Orders newly issued by the NRC:

- The NRC, BGNR and the AU agree that two violations of agency requirements occurred, including the deliberate submittal of falsified written directives and BGNR's deliberate maintenance of incomplete or inaccurate information.
- The AU will remove himself as Radiation Safety Officer from any NRC or Agreement State licenses within 30 days of the order's issuance. He will not be redesignated to perform the RSO functions for any NRC or Agreement State licensees for two years from the date of issuance for the order.
- BGNR will contract with an RSO for the performance of comprehensive audits of the firm's radiation safety program, including a review of corrective actions.
- BGNR will request a license amendment from the NRC to designate a new RSO, who will be responsible for implementation and oversight of the radiation safety program for a period of two years.
- The firm will create a written policy and train employees regarding expectations for providing complete and accurate information to the NRC, compliance with agency regulations and the freedom to raise safety concerns with BGNR management and/or the NRC without fear of retaliation. That must occur within 30 days.
- The AU will write an article regarding lessons learned from the ADR experience, the importance of providing accurate information to the NRC and the importance of compliance with NRC requirements, and he will submit it to three specific publications.
- The AU will prepare a presentation on the same topics and deliver it to the Puerto Rico chapter of the Society of Nuclear Medicine. He will also 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.

In recognition of these actions, the NRC is issuing to BGNR a Severity Level III Notice of Violation and a reduced civil penalty of \$5,000 (rather than \$13,000). In addition, the NRC will not prohibit the AU's involvement in NRC-licensed activities. The AU will also receive a separate Severity Level III Notice of Violation.

Copies of the enforcement actions will be posted on the NRC web site at:
<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

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