

February 26, 2008

IA-07-041

Alex Ortiz

**HOME ADDRESS DELETED
UNDER 10 CFR 2.390(a)**

SUBJECT: NOTICE OF VIOLATION (NRC Investigation Report No. 1-2006-040)

Dear Mr. Ortiz:

This refers to an investigation conducted by the NRC's Office of Investigations (OI) completed on March 28, 2007, at Baxter Healthcare of Puerto Rico (Baxter) in Aibonito, PR. The investigation was conducted, in part, to determine whether you, while employed by Baxter as a maintenance technician at the time, deliberately failed to perform maintenance tests of irradiator safety systems and deliberately created records indicating that such tests had been performed when, in fact, such tests had not been performed.

In a letter to you dated September 17, 2007, we informed you that we had concluded that you had apparently violated NRC regulation 10 CFR 30.10, "Deliberate Misconduct." Specifically, you apparently deliberately failed to perform maintenance tests of irradiator safety systems on numerous occasions between December 1, 2003 and April 24, 2006, and deliberately created inaccurate records of these tests, which resulted in Baxter being in violation of 10 CFR 36.61(a) and 10 CFR 30.9, which required, in part, that (1) the licensee perform inspection and maintenance checks of safety systems at the frequency specified in the license; and, (2) information required by the Commission's regulations to be maintained by the licensee be complete and accurate in all material respects. Our September 17, 2007, letter also provided you with a copy of our letter issued to Baxter on the same date, and a Factual Summary of OI Investigation No. 1-2006-040. Finally, our September 17, 2007, letter offered you an opportunity to attend a predecisional enforcement conference (PEC), or participate in Alternate Dispute Resolution (ADR), in response to the apparent deliberate misconduct violation.

During a telephone conversation on November 30, 2007, you informed Marie Miller and Lizette Roldan of the Region I Office that you did not wish to attend a PEC or provide any additional written information at this time, nor request using ADR to resolve this matter. As a result, the NRC is proceeding with enforcement action against you based on the investigation findings.

Based on the investigation, the NRC staff has concluded that you violated 10 CFR 30.10, "Deliberate Misconduct." The violation is cited in the enclosed Notice of Violation (Notice) (Enclosure 1). 10 CFR 30.10 requires, in part, that an employee of a licensee may not engage in deliberate misconduct that causes a licensee to violate any regulation or any license issued by the Commission. Specifically, you deliberately failed to conduct numerous maintenance tests of the irradiator safety systems, and deliberately created inaccurate records of these maintenance tests, thereby causing Baxter to violate 10 CFR 36.61(a) and 10 CFR 30.9. You acknowledged to the OI investigator that you had signed the monthly maintenance checks knowing that you did not perform the high temperature and fire detector checks, and that there were times when you

did not perform the monthly maintenance checks at all, yet you signed and dated the forms as if you had completed the checks. The NRC has also issued an enforcement action to Baxter, as a result of an ADR mediation session for violations that were the subject of OI Investigation Report 1-2006-040. A copy of the enforcement action to Baxter is enclosed (Enclosure 2).

In evaluating the significance of the violation, the NRC considered that there were no health or safety consequences to the public because the safety systems of the irradiator were determined to be operable. However, because the deliberate actions extended over a period of time, significant potential existed for the safety systems to be degraded and that condition not detected. Also, a number of inaccurate records were created, which impacts the regulatory process, because the records of the safety systems checks are relied upon by the licensee and NRC to ensure safe operation of the irradiator. As a result, and in accordance with the Enforcement Policy, Supplement VII, the NRC has classified the violation at Severity Level III.

In determining the appropriate sanction to be issued in this case, the NRC considered issuing an order prohibiting your involvement in NRC-licensed activities. However, after consultation with the Director, Office of Enforcement, and after considering the circumstances of this case, including that: the safety consequences of the violation was low; you were not in a supervisory position and there was an apparent lack of management oversight; and, you are no longer employed at Baxter, I have decided to issue the enclosed Notice of Violation without an order prohibiting your involvement in NRC-licensed activities. You should be aware that if you engage in any deliberate violations of NRC requirements in the future, it could result in more significant NRC enforcement action, as well as criminal prosecution.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

Alternatively, you may request Alternate Dispute Resolution (ADR) with the NRC in an attempt to resolve the issues. If you request ADR in an attempt to resolve the issues, you will need to contact the Institute on Conflict Resolution (ICR) at 877-733-9415 within 10 days of the date of this letter. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC employs is mediation. Additional information concerning NRC's ADR program is described in the brochure (NUREG/BR-0317) that was provided to you in our September 17, 2007 letter, and can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The ICR at Cornell University has agreed to facilitate the NRC's program as an intake neutral.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov>.

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>.

Please feel free to contact Marie Miller of my staff at 610-337-5205 if you have any questions.

Sincerely,

**/RA/ Original Signed by Marc L. Dapas
for:**

Samuel J. Collins
Regional Administrator

Enclosures: 1. Notice of Violation
 2. Notice of Violation and Confirmatory Order to Baxter

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NOTICE OF VIOLATION

Alex Ortiz

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

IA-07-041

During an NRC investigation by the Office of Investigations (OI), completed on March 28, 2007, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 30.10 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 or any license issued by the Commission.

10 CFR 36.61(a) requires, in part, that the licensee perform inspection and maintenance checks of safety systems at the frequency specified in the license.

10 CFR 30.9 requires, in part, that information required by the Commission's statutes or regulations to be maintained by the licensee be complete and accurate in all material respects.

Contrary to the above, between 2003 and 2006, on numerous occasions (at least forty) you engaged in deliberate misconduct which caused the licensee (Baxter Healthcare of Puerto Rico) to violate NRC regulations. Specifically, as a maintenance technician at the licensee facility in Aibonito, PR, you deliberately failed to perform required weekly, monthly, and quarterly maintenance checks of safety systems, and deliberately created inaccurate records of these maintenance checks to reflect that the checks had been completed when, in fact, they were not completed as required.

This is a Severity Level III violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, you are hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Regional Administrator, Region I, 475 Allendale Rd., King of Prussia, PA 19406, and marked "Open by Addressee Only", within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; IA-07-041" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the

NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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>.

Dated this 26th day of February 2008.