



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PA 19406-1415**

April 16, 2010

Docket No. 03019882  
EA-04-118

License No. 52-21175-01

Enrique Moran  
General Plant Manager  
Baxter Healthcare of Puerto Rico  
P. O. Box 1389  
State Road 721, Km 0.3  
Aibonito, PR 00705

**SUBJECT: ACTIONS TAKEN BY BAXTER HEALTHCARE OF PUERTO RICO AS SET FORTH IN THE LETTER DATED JANUARY 4, 2010, IN RESPONSE TO NRC CONFIRMATORY ORDER DATED JANUARY 26, 2005**

Dear Mr. Moran:

The purpose of this letter is to acknowledge actions taken by Baxter Healthcare of Puerto Rico (Baxter) in response to the Confirmatory Order (Order) (ADAMS Accession No. ML050260695) issued to Baxter by the U.S. Nuclear Regulatory Commission (NRC) on January 26, 2005. The actions were taken to fulfill commitments made by Baxter as part of a settlement agreement reached during a December 13, 2004, Alternative Dispute Resolution (ADR) mediation session between Baxter and the NRC. Baxter had requested the ADR in response to a Notice of Violation and Proposed Imposition of a Civil Penalty (Notice) issued by the NRC on October 25, 2004 (ML043000049) as the result of an Augmented Inspection Team (AIT) inspection conducted between April 22, 2004, and June 1, 2004.

The AIT reviewed the circumstances of an event that occurred at the Baxter facility on April 21, 2004, involving two individuals bypassing safety interlocks and entering the irradiator at a time when the irradiator source rack was stuck in an unshielded position. This created the potential for a lethal exposure to radiation for the two individuals who entered the area while the sources were exposed, since the individuals passed through an area with a radiation level at least as high as 1600 rads/hour, and were planning to enter an area with much higher radiation levels (as high as 100,000 rads/hour in the irradiator cell). By bypassing the safety interlocks, a system designed to prevent a serious safety event was rendered inoperable, which created the potential for significant injury and loss of life.

The October 25, 2004 Notice documented six violations of NRC requirements identified by the AIT. The three most significant violations included: 1) the failure to adhere to emergency and abnormal event procedures when the safety interlocks were bypassed; 2) the failure to perform an adequate survey prior to the two individuals entering the irradiator; and, 3) the failure by the irradiator operator to supply his assistant an individual radiation monitoring device when the two individuals entered the irradiator. The Notice also documented the NRC's determination that this third violation was willful, and proposed a \$44,400 civil penalty. Baxter requested use of the NRC's ADR process to resolve differences it had with the NRC regarding the Notice. ADR is a process in which a neutral mediator with no decision-making authority assists the NRC and

licensees in reaching an agreement on resolving any differences regarding an enforcement action.

Prior to the ADR session, Baxter initiated several corrective actions, including: 1) revising procedures for responding to emergency conditions and performing necessary surveys; 2) conducting an annual review of the standard operating procedures; 3) upgrading the training program and retraining staff on revised procedures, survey techniques, and dosimetry use; and 4) increasing management oversight of the irradiator program, including the performance of: a) monthly reviews of the irradiator department by the Plant General Manager, Manufacturing Director, Radiation Safety Officer (RSO), and the assistant RSO (ARSO); b) annual internal audits of the irradiator by the Environmental Health and Safety Manager and RSO; and c) additional periodic audits of the irradiator by the corporate environmental health and safety group as well as by an external consultant.

As part of the settlement agreement, Baxter agreed to pay a civil penalty in the amount of \$31,200 and to take additional corrective actions that involved providing for reviews by a qualified consultant of operations, maintenance, radiation safety and the RSO and ARSO functions. The reviews were to be conducted in 2005 and 2007, with the possibility of an additional review being required by the NRC in 2009. The results were to be documented and made available for the NRC to review during inspections.

Baxter paid the \$31,200 civil penalty, as acknowledged by the NRC in its letter dated March 1, 2005 (ML050610042). Through inspections and reviews conducted during the period of 2005 through 2010, the NRC reviewed both the completed actions Baxter initiated prior to the ADR and the actions required by the Confirmatory Order. The NRC's review of these actions is documented in the following reports or records: 1) NRC Inspection Record No. 03019882/2005001 (non-publicly available, because it contains security-related information), which documented Baxter's completion and/or implementation of the pre-ADR corrective actions and conduct of the 2005 external audit; 2) NRC Inspection Report No. 03019882/2006001 (non-publicly available, because it contains security-related information), which documented safety system upgrades implemented by Baxter in addition to the above-listed corrective actions; 3) NRC Inspection Report No. 03019882/2006003 (ML072610356), which documented Baxter's continued implementation of pre-ADR corrective actions; 4) NRC Inspection Report No. 03019882/2008001 (ML082810653), which documented Baxter's two additional independent reviews of irradiator operations and multiple actions to improve its safety culture; and 5) NRC Inspection Report No. 03019882/2009002, (ML100332383 and ML100332399, letter and report respectively), which documented the NRC's review of the report from the 2009 external program audit.

Based on the results of the NRC reviews and inspections from 2005 through 2010, the NRC has determined that Baxter has implemented the actions required by the Confirmatory Order. Consequently, we have concluded that Baxter has satisfactorily implemented the terms of the Confirmatory Order and have no further questions at this time.

Although these actions are being effectively implemented, the NRC reminds you of the importance of adhering to NRC requirements, given the seriousness of the violations in this case, as well as the potential for significant exposure that could have occurred as a result of these violations.

A copy of this letter will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions or comments, please contact Marie Miller, Chief, Materials Security and Industrial Branch, Division of Nuclear Materials Safety, Region I, at 610-337-5205.

Sincerely,

***/RA/***

Samuel J. Collins  
Regional Administrator

cc:  
Peter Etienne, Baxter Legal Counsel  
Commonwealth of Puerto Rico

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Sincerely,

**/RA/**

Samuel J. Collins  
Regional Administrator

cc:

Peter Etienne, Baxter Legal Counsel  
Commonwealth of Puerto Rico

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