



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555 - 0001

January 26, 2005

EA 04-118

Jorge A. Perera  
Plant General Manager  
Baxter Healthcare Corporation  
P. O. Box 1389  
State Road 721, Km. 0.3  
Aibonito, PR 00705

SUBJECT: CONFIRMATORY ORDER (EFFECTIVE IMMEDIATELY)

Dear Mr. Perera:

The enclosed Confirmatory Order is being issued to the Baxter Healthcare Corporation (Baxter) to confirm recent commitments made to the NRC. The commitments were made by Baxter as part of a settlement agreement between Baxter and the NRC concerning a Notice of Violation and Proposed Imposition of a Civil Penalty (Notice) issued by the NRC on October 25, 2004. In that Notice, the NRC (1) documented six violations of NRC requirements, (2) characterized one of the six violations as willful, and (3) proposed a civil penalty in the amount of \$44,400 for the three violations that were set forth in Section I of the Notice. A civil penalty was not proposed for the other three violations that were set forth in Section II of the Notice.

In response to that Notice, Baxter requested use of the NRC Alternate Dispute Resolution Process (ADR) to resolve differences it had with the NRC concerning the Notice. An ADR mediation session was held between Baxter and NRC in Philadelphia, Pennsylvania on December 13, 2004, at which the settlement agreement was reached. The elements of the settlement agreement were formulated and agreed to at the mediation session, were documented in a letter from Mr. Peter Etienne, Senior Counsel, Baxter, to the NRC on December 17, 2004, and are also contained in Section III of the enclosed Order.

As part of the settlement agreement, Baxter agreed to pay a civil penalty in the amount of \$31,200 and take additional corrective actions. The NRC agreed to characterize the three violations in Section I of the Notice as a one Severity Level II problem, and to characterize the other violations in Section II of the Notice as noncited violations. Baxter and the NRC also agreed to disagree on the willful characterization of Violation I.C.

Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate, any provision of this Order shall be subject to criminal prosecution as set forth in that section. Violation of this Order may also subject the person to civil monetary penalties.

Questions concerning this Order should be addressed to Sally Merchant, Office of Enforcement, who can be reached at 301-415-2747.

Mr. Jorge A. Perera

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A copy of this letter and its enclosure 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, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. The NRC also includes significant enforcement actions on its Web site at [www.nrc.gov](http://www.nrc.gov); select **What We Do, Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

**/RA/**

Frank J. Congel, Director  
Office of Enforcement

Docket No. 030-19882  
License No. 52-21175-01

Enclosure: Confirmatory Order (Effective Immediately)

Distribution  
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DATE	12/22/04	12/22/04	12/22/04	12/22/04
OFFICE	OE	NMSS	OGC	OE
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DATE	01/26/05	01/03 /05	01/14/05	01/26/05

\* See previous concurrence

**OFFICIAL RECORD COPY**

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

In the Matter of  
Baxter Health Care  
Aibonito, Puerto Rico

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Docket No. 30-19882  
License No. 52-21175-01  
EA-04-118

CONFIRMATORY ORDER MODIFYING LICENSE  
(EFFECTIVE IMMEDIATELY)

I

Baxter Health Care Corporation (Baxter or Licensee) is the holder of NRC License No. 52-21175-01 (License) which authorizes the Licensee to operator an irradiator at its facility in Aibonito, Puerto Rico.

II

On October 25, 2004, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the amount of \$44,400 to Baxter Healthcare Corporation (Baxter) based on six violations of NRC requirements. The circumstances associated with these violations were reviewed by the NRC during an Augmented Inspection Team (AIT) inspection conducted between April 22, 2004, and June 1, 2004, after a Baxter representative informed the NRC on April 21, 2004, that an event had occurred at the facility. The event involved two individuals (an irradiator operator and assistant) bypassing safety interlocks and entering the irradiator at a time when an irradiator source rack (containing 2,000,000 curies of cobalt-60) was stuck in an

unshielded position.

The three most significant violations cited by the NRC in its October 25, 2004 Notice were described in Section I. The first violation cited in Section I of the Notice involved the failure to adhere to emergency and abnormal event procedures when the safety interlocks were bypassed even though the irradiator source rack fault indicator was illuminated and the source travel alarm had sounded for an extended period. This occurred on at least three occasions, including when the source rack was stuck in the unshielded position on April 21, 2004. This created the potential for a lethal exposure to radiation for the two individuals who entered the area while the sources were exposed, since, as previously indicated, 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. Therefore, in the Notice, the NRC classified this violation at Severity Level II and proposed a civil penalty in the amount of \$28,800 (\$9,600 for each of the minimum three occasions that the violation occurred).

The second violation cited set forth in Section I involved the failure to perform an adequate survey prior to the two individuals entering the irradiator on April 21, 2004. Prior to the entry, the operators did not adequately check the irradiator cell radiation monitor, did not adequately check the radiation levels outside the irradiator facility, and did not adequately do other such surveys as were reasonable to determine that a source rack was stuck in the unshielded position and had not returned to the fully shielded position. The NRC also classified this violation at Severity Level II and proposed a \$9,600 civil penalty for the violation.

The third violation cited by the NRC in Section I of the Notice involved the failure by the irradiator operator to supply his assistant an individual radiation monitoring device when the two individuals entered the irradiator on April 21, 2004, while a source rack was stuck in the unshielded position. Based on the OI investigation, the NRC concluded that this violation was willful. The NRC classified this violation at Severity Level III and proposed a \$6,000 civil penalty.

The letter transmitting the Notice also described the Licensee's corrective actions, which included, but were not limited to: (1) revision to procedures for responding to emergency conditions and performing necessary surveys; (2) plans to annually review the standard operating procedures for adequacy; (3) upgrade of the training program and retraining of staff on revised procedures, survey techniques, and dosimetry use; and (4) increased management oversight of the irradiator program, including: (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.

The other three violations cited in the Notice were described in Section II and the NRC classified those violations at Severity Level IV.

### III

In response to the October 25, 2004 Notice, Baxter requested use of the NRC Alternate Dispute Resolution Process (ADR) to resolve differences it had with the NRC concerning the

Notice. ADR is a process in which a neutral mediator with no decision-making authority assists the NRC and Baxter in reaching an agreement on resolving any differences regarding the enforcement action. An ADR session was held between Baxter and NRC in Philadelphia, Pennsylvania on December 13, 2004, and was mediated by a professional mediator, arranged through Cornell University's Institute of Conflict Management. During that ADR session, a settlement agreement was reached. The elements of the settlement agreement, which were documented in a letter from Mr. Peter Etienne, Senior Counsel, Baxter, to the NRC on December 17, 2004, consisted of the following:

- A. Baxter agrees to pay a civil penalty of \$31,200.00 for Violations I.A, I.B and I.C. The NRC will characterize these violations as a Severity Level II problem.
- B. Baxter and the NRC agree to disagree on the willful characterization of Violation I.C.
- C. NRC agrees to treat Violations II.A, II.B, and II.C as non-cited violations.
- D. Baxter agrees to implement the corrective action as documented in Baxter's letter dated August 23, 2004, except that with respect to item 1©) in that letter, ("Additional External Review by Outside Consultant"), that item is replaced by the terms of the December 13, 2004, settlement. Specifically, Baxter agrees to provide for reviews of irradiator operations to be conducted by a qualified consultant, with such review to include a review of operations, maintenance, radiation safety and the RSO and ARSO functions. Review results will be documented and made available to NRC during inspections conducted by the NRC. Such reviews to be conducted as noted below.

- E. A review by the qualified external consultant will be conducted in 2005 of the RSO and ARSO function to supplement the reviews done in 2004.
- F. In 2007, a qualified external consultant will conduct a full review as listed in Item D.
- G. In 2007 after the full review, Baxter will discuss with NRC whether Baxter will need to continue to use a qualified external consultant. It is anticipated that the last external consultant review will be completed in 2007. In no event shall such review extend beyond one additional review in 2009 in the context of this Agreement.
- H. Baxter will submit to the NRC a letter within two weeks (by December 27, 2004) which documents the Agreement. (Met by Baxter's December 17, 2004 letter).
- I. Upon issuance of a Confirmatory Order by the NRC, confirming the Agreement reached by the parties on December 13, Baxter will pay the Civil Penalty in the amount of \$31,200.00 within thirty days of the date of issuance of that Confirmatory Order.

#### IV

Since the licensee has agreed to take additional actions to address NRC concerns, as set forth in Item III above, the NRC has concluded that its concerns can be resolved through the NRC's confirmation of the licensee commitments as outlined in this Order.

I find that the licensee's commitments as set forth in Section III above are acceptable and conclude that with these commitments, the public health and safety are reasonably assured. However, in view of the foregoing, I have determined that public health and safety require that



these commitments be confirmed by this Order. Based on the above and the licensee's consent, this Order is immediately effective upon issuance. The licensee is required to provide the NRC with a letter summarizing all of its actions, up to and including, its last external consultant review that is to be completed in 2007.

V

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 C.F.R. §2.202 and 10 C.F.R. Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY THAT:

- B. Baxter pay a civil penalty of \$31,200.00 for Violations I.A, I.B and I.C. set forth in the NRC October 25, 2004 Notice. (The NRC will characterize these violations as a Severity Level II problem. Also, Baxter and the NRC agree to disagree on the willful characterization of Violation I.C, and the NRC agrees to treat Violations II.A, II.B, and II.C as non-cited violations).
  
- C. Baxter implement the corrective actions a documented in its August 23, 2004, letter except that with respect to item 1©) in that letter ("Additional External Review by Outside Consultant"), that item is replaced by the terms of the December 13, 2004, settlement. Specifically, Baxter will provide for reviews of irradiator operations to be conducted by a qualified consultant with such review to include a review of operations, maintenance, radiation safety and the RSO and ARSO functions. Review results will be documented and made available to NRC during inspections conducted by NRC. Such reviews to be conducted as noted below.

1. A review by the qualified external consultant will be conducted in 2005 of the RSO and ARSO function to supplement the reviews done in 2004.
2. In 2007, a qualified external consultant will conduct a full review as listed in Item B.
3. In 2007 after the full review, Baxter will discuss with NRC whether Baxter will need to continue to use a qualified external consultant, although it is anticipated that the last external consultant review will be completed in 2007, and in no event, shall such review extend beyond one additional review in 2009 in the context of the Agreement.

The Director, Office of Enforcement may relax or rescind, in writing, any of the above conditions upon a showing by the licensee of good cause.

## VI

Any person adversely affected by this Confirmatory Order, other than the licensee, may request a hearing within 20 days of its issuance. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and must include a statement of good cause for the extension. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Rulemaking and Adjudications Staff, Washington, D.C. 20555. Copies of the hearing request shall also be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington D.C. 20555, to the Assistant General Counsel for

Materials Litigation and Enforcement, to the Director of the Division of Regulatory Improvement Programs at the same address, and to Baxter. Because of continuing disruptions in delivery of mail to United States Government offices, it is requested that answers and requests for hearing be transmitted to the Secretary of the Commission either by means of facsimile transmission to 301-415-1101 or by e-mail to [hearingdocket@nrc.gov](mailto:hearingdocket@nrc.gov) and also to the Office of the General Counsel by means of facsimile transmission to 301-415-3725 or e-mail to [OGCMailCenter@nrc.gov](mailto:OGCMailCenter@nrc.gov). If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 C.F.R. § 2.309(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order shall be sustained.

AN ANSWER OR A REQUEST FOR A HEARING SHALL NOT STAY THE EFFECTIVENESS DATE OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

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Frank Congel, Director  
Office of Enforcement

Dated this 26<sup>th</sup> day of January 2005