

SUPPLEMENTARY INFORMATION: On September 21, 1999, the National Science Foundation issued a five-year permit (ACA #2000-001) to Dr. Steven D. Emslie after posting a notice in the August 17, 1999 **Federal Register**. Public comments were not received. A request to modify the permit was posted in the **Federal Register** on December 20, 2004. No public comments were received. The modification was issued by the Foundation on January 19, 2005.

Polly A. Penhale,

Environmental Officer.

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NUCLEAR REGULATORY COMMISSION

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

Baxter Health Care, Aibonito, PR; Confirmatory Order Modifying License (Effective Immediately)

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

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.

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(c) 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.

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.

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 CFR 2.202 and 10 CFR part 30, *It is hereby ordered*, effective immediately that:

A. 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).

B. Baxter implement the corrective actions as documented in its August 23, 2004, letter except that with respect to item 1(c) 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.

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, DC 20555. Copies of the hearing request shall also be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington DC 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 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. 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 CFR 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.

Dated this 26th day of January 2005.

For the Nuclear Regulatory Commission.

Frank Congel, Director,

Office of Enforcement.

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SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application of Boston Restaurant Associates, Inc. To Withdraw Its Common Stock, \$.01 par value, From Listing and Registration on the Boston Stock Exchange, Inc.; File No. 1-13320

January 28, 2005.

On January 11, 2005, Boston Restaurant Associates, Inc., a Delaware corporation ("Issuer"), filed an application with the Securities and Exchange Commission ("Commission"), pursuant to Section 12(d) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 12d2-2(d) thereunder,² to withdraw its common stock, \$.01 par value ("Security"), from listing and registration on the Boston Stock Exchange, Inc. ("BSE").

On December 23, 2004, the Board of Directors ("Board") of the Issuer approved a resolution to withdraw the Issuer's Security from listing and registration on the BSE. The Issuer stated: (1) That on December 20, 2004, the BSE notified the Issuer that the BSE would suspend trading of the Security at the close of business that same day. The suspension was the result of a failure of the Issuer to maintain a minimum of \$500,000 of stockholder's equity as required by the BSE. (2) After careful consideration the Issuer decided to request a voluntary delisting of the Security from the BSE. The Issuer stated that the Security currently trades on the OTC Bulletin Board.

The Issuer stated in its application that it has complied with BSE

¹ 15 U.S.C. 78j(d).

² 17 CFR 240.12d2-2(d).