

February 26, 2008

EA-07-132

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

SUBJECT: NOTICE OF VIOLATION, CIVIL PENALTY, AND CONFIRMATORY ORDER
(EFFECTIVE IMMEDIATELY) (NRC INSPECTION REPORT NO.
03019882/2006003, AND NRC OFFICE OF INVESTIGATIONS REPORT NO. 1-
2006-040)

Dear Mr. Moran:

In a letter dated September 17, 2007, the NRC provided the former general manager of your facility with the results of an NRC inspection and an investigation completed by the NRC Office of Investigations (OI), Region I Field Office, on March 28, 2007. The purpose of the investigation was to determine whether Baxter Healthcare of Puerto Rico (Baxter) willfully violated NRC requirements related to inspection and maintenance activities for the licensed irradiator at the site, as well as personnel training and qualifications for two irradiator operators. Our letter noted that, based on the evidence developed during the inspection and investigation, the staff had determined that three apparent violations of NRC regulations occurred, and that those violations resulted from the deliberate acts of certain Baxter employees. The apparent violations involved: (1) on numerous occasions between December 1, 2003 and April 24, 2006, inspection and maintenance tests of safety systems were not completed at the frequency specified in the license as required by 10 CFR 36.61(a); (2) on April 29, 2005, annual performance tests for two irradiator operators were not conducted as required by 10 CFR 36.51(d); and (3) the records associated with the above inspection and maintenance tests for the irradiator safety systems and the annual performance tests for the two irradiator operators were not complete and accurate in all material respects as required by 10 CFR 30.9, in that the records indicated that the activities were performed, when, in fact, the activities had not been performed.

The September 17, 2007, letter: (1) enclosed NRC Inspection Report No. 03019882/2006003 and a Factual Summary of the OI investigation; (2) informed the former general manager of your facility that the three apparent violations at the Baxter facility were being considered for escalated enforcement action in accordance with the NRC Enforcement Policy; and, (3) offered the former general manager of your facility the choice to discuss the apparent violations at a Predecisional Enforcement conference or to request use of Alternate Dispute Resolution (ADR) with the NRC.

At the request of the former general manager of your facility, on December 6, 2007, an ADR session was held in the Region I Office in King of Prussia, PA, between Baxter and the NRC.

Based on the discussions during the ADR sessions, a settlement agreement was reached regarding this matter. The elements of the settlement agreement are as follows:

1. The NRC and Baxter Healthcare of Puerto Rico (Baxter) agree that certain Baxter employees, including a first-level supervisor (superintendent), deliberately violated NRC requirements as evidenced by the following: (1) certain maintenance checks/inspections of the irradiator were not conducted at the Baxter facility, during the period December 1, 2003 to April 24, 2006, contrary to 10 CFR 36.61(a); and, (2) the records associated with these maintenance checks/inspections were inaccurate, contrary to 10 CFR 30.9.
2. The NRC maintains that additional deliberate violations of NRC requirements occurred in that: (1) annual performance (training) tests for two individuals were not performed as required in 2005, contrary to 10 CFR 36.51(d); and, (2) the records associated with these two annual performance tests were inaccurate, contrary to 10 CFR 30.9. Baxter maintains that based on their investigation of these issues that the evidence available to Baxter did not show that these violations occurred. The NRC and Baxter agree to disagree relative to these violations of 10 CFR 36.51(d) and associated record requirements.
3. Baxter took multiple corrective actions to address the violations, as documented in Baxter's letters dated November 30, 2007, February 2, 2007, November 20, 2006, and November 3, 2006, including: (a) revising appropriate procedures to require a second person for implementation of the maintenance checks/inspections, as well as a second signature to verify completion; (b) revising procedure records to include attaching the computer printout from the console's Programmable Logic Computer to confirm that certain event checks were conducted; (c) training all irradiator operators on good documentation practices; (d) completing annual performance tests and written tests for all irradiator operators in November 2006; (e) conducting two independent reviews of the irradiator's operation; (f) interviewing all irradiator operators to determine whether similar issues have occurred of which Baxter was not aware; (g) training all irradiator operators on the methods to report inappropriate behavior; (h) in consultation with the irradiator manufacturer, reviewing monthly and weekly maintenance inspection tests to affirm the need and frequency of the tests, and to explore methods to make the tests less cumbersome; (i) taking appropriate disciplinary action against the responsible individuals, commensurate with their actions; (j) having the Plant General Manager attend monthly management meetings that discuss identified concerns; (k) implementing the "Dupont STOP" peer observation and feedback process to focus on behavior change to improve safety; and, (l) implementing the "Toyota 5S" process, adding a 6th S for Safety to improve facility performance and safety.
4. During the ADR mediation session, Baxter recognized an opportunity for additional corrective actions to address the work environment concerns that were described in the NRC letter dated September 17, 2007. Therefore, Baxter agreed to take the following actions to sensitize the gamma sterilization department managers, supervisors, and employees to the importance of fostering and maintaining a safety culture which encourages all department employees to identify safety concerns and inappropriate behavior. These actions will consist of:

- a. Using an independent outside organization to conduct a safety culture assessment of the gamma sterilization department and include any identified recommendations in the Baxter corrective action program. This will be completed by June 30, 2008. The results will be communicated, as appropriate, to department employees and will be made available for NRC review during inspections;
 - b. Conducting in-person training of the gamma sterilization department employees concerning raising safety issues without fear of retaliation, stressing the importance of radiological safety. This will be completed by June 30, 2008. Baxter will provide a lesson plan for this training activity to the NRC at least 30 days prior to conducting the training;
 - c. Issuing a lessons-learned letter from the Plant General Manager to the gamma sterilization department employees regarding the violations described herein, and the underlying causes. This will be completed by March 31, 2008; and,
 - d. Evaluating annual irradiator operator performance tests to ensure that they are consistent with Baxter's commitment to foster a safety conscious work environment.
5. Baxter agreed to send a letter to the NRC, within 30 days of completion of all of the actions specified in Items 3 and 4, informing the NRC that these actions are complete.
 6. In light of the actions Baxter took as described in Item 3, and those actions Baxter has committed to take as described in Items 4 and 5, as well as Baxter's agreement to pay a \$15,000 civil penalty, the NRC agrees to characterize the violations as one Severity Level III problem with three examples, rather than issuance of separate civil penalties for each of the violations. The NRC will issue a letter with the aforementioned Notice of Violation, and a Confirmatory Order to Baxter confirming the commitments set forth herein, including the agreed upon civil penalty. The letter, the Notice of Violation and the Confirmatory Order will be publicly available in ADAMS, and will appear on the NRC "Significant Enforcement Actions" website.
 7. Baxter agrees to the issuance of the letter, the Notice of Violation and the Confirmatory Order confirming this agreement, and also agrees to waive any request for a hearing regarding the aforementioned Confirmatory Order.

Baxter's agreement, in principle, at the December 6, 2007, ADR session was confirmed on February 15, 2008, when the Consent and Hearing Waiver form, a copy of which is enclosed, was signed. Also enclosed with this letter are the Notice of Violation (Notice) and the Confirmatory Order (Order) I have been authorized to issue after consultation with the Director, Office of Enforcement.

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.

You are not required to respond to this letter. However, in accordance with the settlement agreement, you are required to respond to the Order, including payment of the civil penalty. Your written response to the Order should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Regional Administrator, Region I, 475 Allendale Road, King of Prussia, PA 19406, and marked "Reply to Confirmatory Order; (EA-07-132)" within the dates specified herein.

You should pay the civil penalty in accordance with NUREG/BR-0254 (enclosed) and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a letter clearly marked "Statement as to Payment of Civil Penalty EA-07-132," indicating when and by what method payment was made. Upon failure to pay any civil penalty due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Atomic Energy Act, 42, U.S.C. 2282c. The "Statement as to Payment of Civil Penalty" should be addressed to: Cynthia Carpenter, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy addressed to: Samuel Collins, Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, PA 19406-1415.

A copy of this letter and its enclosures 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 Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC will also include this letter and its attached Confirmatory Order, on its website. Your response will also be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS).

If you have any questions or comments concerning this letter, please contact Mr. Karl Farrar of my staff at 610-337-5301.

Sincerely,

/RA/

Marc L. Dapas
Deputy Regional Administrator

Docket No. 03019882
License No. 52-21175-01

Enclosures:

1. Consent and Hearing Waiver Form
2. Notice of Violation
3. Confirmatory Order
4. NUREG/BR0254 Payment Methods (Licensee Only)

E. Moran

5

cc:
Evete Vera, Radiation Safety Officer
Commonwealth of Puerto Rico

E. Moran

You are not required to respond to this letter. However, in accordance with the settlement agreement, you are required to respond to the Order, including payment of the civil penalty. Your written response to the Order should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Regional Administrator, Region I, 475 Allendale Road, King of Prussia, PA 19406, and marked "Reply to Confirmatory Order; (EA-07-132)" within the dates specified herein.

You should pay the civil penalty in accordance with NUREG/BR-0254 (enclosed) and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a letter clearly marked "Statement as to Payment of Civil Penalty EA-07-132," indicating when and by what method payment was made. Upon failure to pay any civil penalty due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Atomic Energy Act, 42, U.S.C. 2282c. The "Statement as to Payment of Civil Penalty" should be addressed to: Cynthia Carpenter, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy addressed to: Samuel Collins, Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, PA 19406-1415.

A copy of this letter and its enclosures 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 Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC will also include this letter and its attached Confirmatory Order, on its website. Your response will also be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS).

If you have any questions or comments concerning this letter, please contact Mr. Karl Farrar of my staff at 610-337-5301.

Sincerely,
/RA/
Marc L. Dapas
Deputy Regional Administrator

Docket No. 03019882
License No. 52-21175-01

Enclosures:

1. Consent and Hearing Waiver Form
2. Notice of Violation
3. Confirmatory Order
4. NUREG/BR0254 Payment Methods (Licensee Only)

DO NOT PLACE IN PDR UNTIL THE NOTICE OF VIOLATION AND ORDER ARE ISSUED

SUNSI Review Complete: ___rjs___ (Reviewer's Initials) ADAMS Accession No.: ML080580506

DOCUMENT NAME: S:\Enf-allg\Enforcement\Proposed-Actions\Region1\Baxter ADR\Baxter ADR Confirmation of Commitments.doc

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	RI/ORA		RI/DNMS		RI/DNMS		RI/OI		RI/RC		RI/ORA	
NAME	*RSummers		*MMiller/JDK for		*BHolian/SDW fir		*EWilson/JAT for		*KFarrar		*DHolody/AEP for	
DATE	12/21/07		12/31/07		12/27/07		12/29/07		01/02/08		02/11/08	
OFFICE	HQ/FSME		HQ/OGC	E	OE	E	RI/DRA					
NAME	*GMorell		*MClark		*NHilton for CCarpenter		MDapas					
DATE	01/16/08		2/06/08		2/07/08		02/27/08					

DISTRIBUTION w/encl:

ADAMS (PARS)

SECY

CA

OEMAIL

OEWEB

LReyes, EDO

MVirgilio, DEDMRT

CMiller, FSME

GPangburn, FSME

RLewis, FSME

DRathbun, FSME

CCarpenter, OE

SMagruder, OE

SWoods, OE

SMerchant, OE

LSreenivas, OE

LLopez, OE

CMarco, OGC

R. Romine, OGC

MClark, OGC

GCaputo, OI

HBell, OIG

TGrancorvitz, OC

EHayden, OPA

Enforcement Coordinators RII, RIII, RIV

SCollins, RA

MDapas, DRA

BHolian, RI

MMiller, RI

KFarrar, ORA

DHolody, ORA

ADeFrancisco, ORA

RSummers, ORA

DScrenci, PAO-RI

NSheehan, PAO-RI

Region I OE Files (with concurrences)

Region I Docket Room (with concurrences)

NOTICE OF VIOLATION

Baxter Healthcare of Puerto Rico
Aibonito, PR

Docket No. 030-19882
License No. 52-21175-01
EA-07-132

During an inspection conducted on May 8, November 28, and 29, 2006, and April 19 through May 31, 2007, and during an investigation completed by the NRC Office of Investigations on March 28, 2007, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed as a single Severity Level III Problem below:

1. 10 CFR 36.61(a) requires, in part, that the licensee perform inspection and maintenance checks of safety systems specified therein at the frequency specified in the license.

Contrary to the above, between 2002 and 2006, on numerous occasions (at least forty), Baxter Healthcare of Puerto Rico failed to perform required weekly, monthly, and quarterly preventative maintenance checks of safety systems.

2. 10 CFR 36.51(d) requires, in part, that the licensee conduct safety reviews for irradiator operators at least annually and that the licensee give each operator a brief written test on the safety information.

Contrary to the above, as of April 29, 2005, Baxter Healthcare of Puerto Rico failed to conduct annual safety performance reviews and tests for two irradiator operators.

3. 10 CFR 30.9 requires, in part, that information provided to the Commission by the licensee or information required by statute or by the Commission's regulations or license conditions to be maintained by the licensee, be complete and accurate in all material respects. 10 CFR 36.81 requires, in part that the licensee shall maintain records of inspection and maintenance checks required by 10 CFR 36.61, and records of the annual evaluations of the safety performance of irradiator operators required by 10 CFR 36.51.

Contrary to the above, certain records required to be maintained pursuant to 10 CFR 36.81 were not accurate in all material respects. Specifically, numerous records of required maintenance checks for the irradiator safety systems were not accurate, in that the records indicated the checks were performed when, in fact, the checks were not performed. Additionally, the records of two annual safety reviews for two irradiator operators were not accurate in that the records indicated that the annual safety reviews were conducted as required, when, in fact, the reviews had not been conducted. The inaccurate records were material because they concealed violations of 10 CFR 36.61(a) and 10 CFR 36.51(d).

This is a Severity Level III problem.

The NRC has concluded that the information regarding the reason for the violations, the corrective actions taken to correct the violations and prevent recurrence, and the date when full compliance was achieved has been already adequately addressed in the letter forwarding this Notice, and at the ADR mediation session held on December 6, 2007. Therefore, you are not

required to respond to this Notice. However, if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-07-132" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice.

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.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 26th day of February 2008.

Enclosure 1

Consent and Hearing Waiver Form

Baxter Healthcare of Puerto Rico (Baxter) hereby agrees with the attached Notice of Violation (NOV) and immediately effective Confirmatory Order. I recognize that by signing below, Baxter consents to the issuance of the NOV and Confirmatory Order, effective immediately, containing commitments agreed to as incorporated into the Confirmatory Order, including payment of the civil penalty. The agreement was reached during the ADR mediation session held in the NRC Region I Office in King of Prussia, PA, on December 6, 2007. By agreeing to the attached NOV and Confirmatory Order, pursuant to 10 CFR 2.202(a)(3) and (d), Baxter waives the right to request a hearing on all or any part of the Confirmatory Order.

EM
Plaxit Enrique Moran
General Manager
Baxter Healthcare of Puerto Rico
Aibonito, PR


Date: February 15, 2008

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

[7590-01-P]

In the Matter of
Baxter Healthcare,
Aibonito, Puerto Rico

) Docket No.: 030-19882
License No: 52-21175-01
) EA-07-132

CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

I

Baxter Healthcare of Puerto Rico (Baxter) is the holder of NRC Material License No. 52-21175-01 pursuant to 10 CFR Part 30 on July 11, 2005, which authorizes the Licensee to operate an irradiator at its facility in Aibonito, Puerto Rico.

This Confirmatory Order (Order) is the result of an agreement reached during an alternative dispute resolution (ADR) mediation session conducted on December 6, 2007.

II

An investigation was initiated by the NRC Office of Investigations (OI) on June 1, 2006, at the Baxter facility in Aibonito, Puerto Rico. This investigation was initiated, in part, to determine if Baxter employees willfully violated NRC requirements related to inspection and maintenance activities for the licensed irradiator at the site, as well as personnel training and qualifications for two irradiator operators. As noted in an NRC letter to Baxter on September 17, 2007, OI

substantiated, based on the evidence developed during its investigation and a related NRC inspection, that certain Baxter employees, including a first-level supervisor (superintendent), deliberately violated NRC requirements as evidenced by the following: (1) certain maintenance checks/inspections of the irradiator were not conducted at the Baxter facility, during the period of December 1, 2003 to April 24, 2006, contrary to 10 CFR 36.61(a); (2) the records associated with these maintenance checks/inspections were inaccurate contrary to 10 CFR 30.9; (3) the annual performance (training) tests for two individuals were not performed as required in 2005, contrary to 10 CFR 36.51(d); and, (4) the records associated with these two annual performance tests were inaccurate, contrary to 10 CFR 30.9. The September 17, 2007 letter offered Baxter the opportunity to either attend a Predecisional Enforcement Conference or to request use of ADR, to resolve this matter. In response to the September 17, 2007 letter, Baxter requested the use of ADR to resolve this matter with the NRC.

On December 6, 2007, the NRC and Baxter met in an ADR session mediated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution. ADR is a process in which a neutral mediator with no decision-making authority assists the parties in reaching an agreement on resolving any differences regarding the enforcement action. This Confirmatory Order is issued pursuant to the agreement reached during the ADR process.

III

During that ADR session, a settlement agreement was reached. The elements of the settlement agreement consisted of the following:

- A. The NRC and Baxter Healthcare of Puerto Rico (Baxter) agree that certain Baxter employees, including a first-level supervisor (superintendent), deliberately violated NRC

requirements as evidenced by the following: (1) certain maintenance checks/inspections of the irradiator were not conducted at the Baxter facility, during the period December 1, 2003 to April 24, 2006, contrary to 10 CFR 36.61(a); and, (2) the records associated with these maintenance checks/inspections were inaccurate contrary to 10 CFR 30.9;

- B. The NRC maintains that additional deliberate violations of NRC requirements occurred in that (1) annual performance (training) tests for two individuals were not performed as required in 2005, contrary to 10 CFR 36.51(d); and, (2) the records associated with these two annual performance tests were inaccurate, contrary to 10 CFR 30.9. Baxter maintains that based on their investigation of these issues that the evidence available to Baxter did not show that these violations occurred. The NRC and Baxter agree to disagree relative to these violations of 10 CFR 36.51(d) and associated record requirements;
- C. Baxter took multiple corrective actions to address the violations, as documented in Baxter's letters dated November 30, 2007, February 2, 2007, November 20, 2006, and November 3, 2006, including: (1) revising appropriate procedures to require a second person for implementation of the maintenance checks/inspections, as well as a second signature to verify completion; (2) revising procedure records to include attaching the computer printout from the console's Programmable Logic Computer to confirm that certain event checks were conducted; (3) training all irradiator operators on good documentation practices; (4) completing annual performance tests and written tests for all irradiator operators in November 2006; (5) conducting two independent reviews of the irradiator's operation; (6) interviewing all irradiator operators to determine whether similar issues have occurred of which Baxter is not aware; (7) training all irradiator operators on the methods to report inappropriate behavior; (8) in consultation with the irradiator

manufacturer, reviewing monthly and weekly maintenance inspection tests to affirm the need and frequency of the tests, and to explore methods to make the tests less cumbersome; (9) taking appropriate disciplinary action against the responsible individuals, commensurate with their actions; (10) Plant General Manager attending monthly management meetings that discuss identified concerns; (11) implementing the “Dupont STOP” peer observation and feedback process to focus on behavior change to improve safety; and, (12) implementing the “Toyota 5S” process, adding a 6th S for Safety to improve facility performance and safety;

D. During the ADR mediation session, Baxter recognized an opportunity for additional corrective actions to address the work environment concerns that were described in the NRC letter dated September 17, 2007. Therefore, Baxter agreed to take the following actions to sensitize the gamma sterilization department managers, supervisors, and employees to the importance of fostering and maintaining a safety culture which encourages all department employees to identify safety concerns and inappropriate behavior. These actions will consist of:

1. Using an independent outside organization to conduct a safety culture assessment of the gamma sterilization department and include any identified recommendations in the Baxter corrective action program. This will be completed by June 30, 2008. The results will be communicated, as appropriate, to department employees and will be made available for NRC review during inspections;
2. Conducting in-person training of the gamma sterilization department employees concerning raising safety issues without fear of retaliation, stressing the importance of radiological safety. This will be completed by June 30, 2008.

Baxter will provide a lesson plan for this training activity to the NRC at least 30 days prior to conducting the training;

3. Issuing a lessons-learned letter from the Plant General Manager to the gamma sterilization department employees regarding the violations described herein, and the underlying causes. This will be completed by March 31, 2008; and,
 4. Evaluating annual irradiator operator performance tests to ensure that they are consistent with Baxter's commitment to foster a safety conscious work environment;
- E. Baxter agreed to send a letter to the NRC, within 30 days of completion of all of the actions specified in Items C and D, informing the NRC that these actions are complete;
- F. In light of the actions Baxter took as described in Item C, and those actions Baxter has committed to take as described in Items D and E, as well as Baxter's agreement to pay a \$15,000 civil penalty, the NRC agreed to characterize the violations as one Severity Level III problem with three examples, rather than issuance of separate civil penalties for each of the violations. The NRC will issue a letter with the aforementioned Notice of Violation, Civil Penalty, and a Confirmatory Order to Baxter confirming the commitments set forth herein. The letter, the Notice of Violation, Civil Penalty and the Confirmatory Order will be publicly available in ADAMS, and will appear on the NRC "Significant Enforcement Actions" website; and
- G. Baxter agreed to the issuance of the letter, the Notice of Violation, Civil Penalty, and the Confirmatory Order confirming this agreement, and also agrees to waive any

request for a hearing regarding the aforementioned Confirmatory Order.

On February 15, 2008, the Licensee, Baxter, consented to issuing this Order with the commitments, as described in Section V below. The Licensee further agreed that this Order is to be effective upon issuance and that it has waived its right to a hearing.

IV

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

I find that Baxter's commitments as set forth in Section V are acceptable and necessary and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that public health and safety require that the Licensee's commitments be confirmed by this Order. Based on the above and Baxter's consent, this Order is immediately effective upon issuance.

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 and 35, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY THAT LICENSE NO. 52-21175-01 IS MODIFIED AS FOLLOWS:

- A. Baxter will pay a civil penalty in the amount of \$15,000 for the violation described in the accompanying NOV. The method of payment is described in the letter transmitting this Order, as well as in NUREG/BR-0254;
- B. Baxter will use an independent outside organization to conduct a safety culture assessment of the gamma sterilization department and include any identified recommendations in the Baxter corrective action program. This will be completed by June 30, 2008. The results will be communicated, as appropriate, to department employees and will be made available for NRC review during inspections;
- C. Baxter will conduct in-person training of the gamma sterilization department employees concerning raising safety issues without fear of retaliation, stressing the importance of radiological safety. This will be completed by June 30, 2008. Baxter will provide a lesson plan for this training activity to the NRC at least 30 days prior to conducting the training;
- D. Baxter will issue a lessons-learned letter from the Plant General Manager to the gamma sterilization department employees regarding the violations described herein, and the underlying causes. This will be completed by March 31, 2008:
- E. Baxter will evaluate annual irradiator operator performance tests to ensure that they are consistent with Baxter's commitment to foster a safety conscious work environment;
- F. Baxter will send a letter to the NRC, within 30 days of completion of all of the actions specified in Sections V.A-E of this order, informing the NRC that these actions are complete; and
- G. Baxter will implement the procedures, training, and other actions identified in Section III.C

of this Order.

The NRC Region I Regional Administrator may relax or rescind, in writing, any of the above conditions upon demonstration by Baxter of good cause.

VI

Any person adversely affected by this Confirmatory Order, other than Baxter, may request a hearing within 20 days of its issuance. Where good cause is shown, consideration will be given to extending the time to answer or request a hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, and include a statement of good cause for the extension.

A request for a hearing must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated in August, 2007, 72 Fed. Reg. 49,139 (Aug. 28, 2007). The E-Filing process requires participants to submit and serve documents over the internet or, in some cases, to mail copies on electronic optical storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements associated with E-Filing, at least five (5) days prior to the filing deadline the requestor must contact the Office of the Secretary by e-mail at HEARINGDOCKET@NRC.GOV, or by calling (301) 415-1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any NRC proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances when the requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate).

Each requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at <http://www.nrc.gov/site-help/e-submittals/install-viewer.html>. Information about applying for a digital ID certificate also is available on NRC's public website at <http://www.nrc.gov/site-help/e-submittals/apply-certificates.html>.

Once a requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for a hearing through EIE. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public website at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the filer submits its document through EIE. To be timely, electronic filings must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, any others who wish to participate in the proceeding (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request is filed so that they may obtain access to the document via the E-Filing system.

A person filing electronically may seek assistance through the "Contact Us" link located on the NRC website at <http://www.nrc.gov/site-help/e-submittals.html> or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is (800) 397-4209 or locally, (301) 415-4737.

Participants who believe that they have good cause for not submitting documents electronically must file a motion, in accordance with 10 C.F.R. 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville, Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at http://ehd.nrc.gov/EHD_Proceeding/home.asp, unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, Participants are requested not to include copyrighted materials in their works.

If 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) and (f).

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, this Order shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received.

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

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Marc L. Dapas

Deputy Regional Administrator

Dated this the 26th day of February 2008