

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 03019882/2008001
Docket No. 03019882
License No. 52-21175-01
EA No. EA-07-132
Licensee: Baxter Healthcare of Puerto Rico
Location: State Road 721, Km 0.3
Aibonito, PR 00705
Inspection Dates: July 7-11, 2008
Additional Information: Facsimile dated April 8, 2008
Letters dated April 9, 2008 and July 24, 2008

Inspectors:	<i>/RA/</i>	09/25/08
	_____ Kathy Dolce Modes Health Physicist	_____ date
	<i>/RA M. T. Miller for/</i>	09/25/08
	_____ Lizette Roldan, Ph.D. Health Physicist	_____ date
Approved By:	<i>/RA/</i>	09/25/08
	_____ Marie Miller, Chief Materials Security and Industrial Branch Division of Nuclear Materials Safety	_____ date

EXECUTIVE SUMMARY

Baxter Healthcare of Puerto Rico
NRC Inspection Report No. 03019882/2008001

This unannounced safety inspection at the Aibonito facility on July 8-10, 2008, with subsequent review of the licensee's letter submitted on July 24, 2008, was conducted to verify the licensee's completion of the commitments made during an Alternative Dispute Resolution (ADR) mediation session conducted on December 6, 2007, and subsequent issuance of NRC Confirmatory Order Modifying License (EA-07-132) dated February 26, 2008. The elements of the Confirmatory Order focused primarily on maintenance and repair of irradiator safety systems, irradiator operator training, and safety culture assessment of the gamma sterilization department.

Based on a review of these items, the inspectors verified that the licensee completed the corrective actions for the violations in accordance with the commitments of the Confirmatory Order. The licensee had implemented a robust program to ensure maintenance is completed in a timely manner and the associated paperwork accurately reflects the work. In addition, operators were trained and their skill levels assessed commensurate with the requirements of 10 CFR 36.51. The licensee also completed multiple actions to assess and improve the safety culture within the gamma sterilization department. The inspectors did not identify any safety concerns or violations.

REPORT DETAILS

I. Organization and Scope of Program

a. **Inspection Scope**

The inspection included a review of the licensee's organization and scope of activities related to their gamma sterilization department.

b. **Observations and Findings**

Baxter Healthcare of Puerto Rico operates a manufacturing and distribution facility for single-use medical equipment. The medical equipment is sterilized, prior to distribution, using a MDS Nordion Model JS 8900 irradiator loaded with cobalt-60 sealed sources. The last source re-load occurred in March 2007, and another reload is not planned prior to 2009. The irradiator is operated 24-hours per day, seven days per week, except holidays, by way of three 8-hour shifts during the weekdays and two 12-hour shifts on the weekends. The licensee generally conducts routine maintenance of the irradiator on Monday mornings, but is usually operational at all other times except for certain holidays when the facility is closed for business.

The licensee has six trained irradiator operators and one maintenance technician. The latest new employee hired is a former NRC employee who is being trained to take over the Radiation Safety Officer (RSO) responsibilities. He is currently the Assistant RSO. Since the last inspection, the licensee has assigned a new RSO, assistant RSO, two new irradiator operators and a new maintenance technician. No violations or safety concerns were identified.

c. **Conclusions**

The licensee's organization for the gamma sterilization department was fully staffed.

II. Status of Previous Violations from 2007 inspection

a. **Inspection Scope**

The inspector performed a review of selective maintenance and irradiator operator training and qualification records from March 2007 through the present and interviewed personnel and observed normal gamma sterilization department operations. The review focused on the licensee's corrective actions taken as a result of Severity Level III problem cited in the previous inspection and investigation. The problem was grouped into three examples: 1) the deliberate failure by two licensee employees to perform inspection and maintenance tests of safety systems at the frequency specified in the

license, as required by 10 CFR 36.61(a); 2) deliberate failure by three licensee employees to conduct performance tests for two irradiator operators at least annually, as required by 10 CFR 36.51(d); and 3) deliberate failure by licensee employees to maintain complete and accurate maintenance testing and annual performance testing records as required by 10 CFR 30.9.

b. Observations and Findings

The licensee revised its program, so all irradiator operators share in the safety performance review tests and some minor maintenance. Routine maintenance continues to be conducted primarily by the maintenance technician during the Monday day-shift, but he is on call 24-hours per day. The licensee maintains a spreadsheet as to who can perform which type of maintenance. An extraordinary maintenance package requires a Programmable Logic Computer (PLC) printout to be attached and has been signed off by the RSO and the plant manager. Maintenance records were reviewed and were found to be complete. Extraordinary maintenance packages were generated for several repairs and systems improvements, including: replacement of seismic sensor, deionizer radiation monitor, source pass cables, source solenoid valve, carrier collision device switches, source down switch cable, a section of the tube connecting to the smoke detector, relay backup access for the maze door, water float switch, and repair to the outlet backup access control. Since the new maintenance technician took over this responsibility in January 2008, the licensee has had the best source up time, with the irradiator running without a problem more consistently. For example, between August and December 2007, there were 18-79 hours per month of non-planned maintenance events. In comparison, between January and June 2008, there were 19-36 hours per month of non-planned maintenance. Non-planned maintenance may occur when the carrier is congested, a power failure due to weather, no carrier in position or a piston problem. The inspector also observed two irradiator operators and the maintenance technician demonstrate completing the required paperwork.

Irradiator operators undergo training throughout the year. The records for the annual radiation safety training indicated all irradiator operators' performance had been evaluated, and the written examination was completed in their own handwriting. Also, the records showed that the facility conducted annual (unannounced) drills. For example, drills for 2007 through the present included: a fire drill, a radiation monitor alarm drill, a contamination drill, and an outlet monitor alarm drill. The drills are varied to ensure that personnel are prepared. In addition to the records review, the inspector interviewed the operators and verified compliance with annual safety and performance evaluation requirements. Irradiator operators were cognizant of their duties and when to enlist the assistance of the maintenance technician and RSO. No violations or safety concerns were identified.

c. Conclusions

The licensee had implemented a robust program to ensure maintenance is completed in a timely manner and the associated paperwork accurately reflects the work. In addition, operators were trained and their skill levels assessed commensurate with the requirements in 10 CFR 36.51. Based on this information, the previous three violations (inspection and maintenance tests of safety systems are being performed at the frequency, as required by 10 CFR 36.61(a); performance tests for all irradiator operators are conducted at least annually, as required by 10 CFR 36.51(d); and maintenance testing and annual performance testing records are maintained as required by 10 CFR 30.9) are closed.

III. Status of Licensee Compliance with Confirmatory Order (EA-07-132)

a. Inspection Scope

As a result of an agreement reached during an alternative dispute resolution (ADR) mediation session conducted on December 6, 2007, the NRC issued Confirmatory Order Modifying License on February 26, 2008. The licensee's compliance with the elements of the settlement agreement were reviewed as part of this inspection.

b. Observations and Findings

The elements of the settlement agreement and the status of compliance are as follows:

ELEMENT 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.

As discussed above in Section II of this report, the inspector reviewed maintenance records and observed gamma sterilization department operations. The licensee has complied with the maintenance requirements in accordance with 10 CFR 36.61.

ELEMENT 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.

As discussed above in Section II of this report, the inspector reviewed training records and observed gamma sterilization department operations. The licensee has complied with the training requirements in accordance with 10 CFR 36.51.

ELEMENT 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 Toyota 5S process, adding a 6th S of safety to improvement facility safety performance, and (l) implementing site-wide the "Dupont STOP" peer observation and feedback process to focus on behavior change to improve safety.

The inspector reviewed selective procedures to verify the licensee made the appropriate modifications and interviewed personnel to ensure their understanding of the new changes to the procedures. The inspector observed operators at shift changes and during normal operations to ensure safe operation of the irradiator. The inspector reviewed maintenance logs which were completed with second signatures and printouts of the PLC. Additional training was also conducted with irradiator operators regarding documentation expectations. Interviews with the operators, RSO, ARSO and Plant General Manager showed that senior management is involved, had more interactions with the gamma sterilization department, and initiated safety tools to reinforce safety compliance.

ELEMENT 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 and the status of these actions are as follows:

- a. Used an independent outside organization to conduct a safety culture assessment of the gamma sterilization department and included any identified recommendations in the Baxter corrective action program. This was completed by June 30, 2008, and included thirty-six participants. The results were communicated to department employees;
- b. Conducted in-person training of the gamma sterilization department employees concerning raising safety issues without fear of retaliation, stressing the importance of radiological safety. This was completed by June 30, 2008. Baxter provided the draft lesson plan for this training activity to the NRC on March 28, 2008, which was at least 30 days prior to conducting the training;
- c. Issued 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 was completed on March 6, 2008, prior to the commitment of March 31, 2008; and,
- d. Evaluated annual irradiator operator performance tests to ensure that they are consistent with Baxter's commitment to foster a safety conscious work environment. This was completed by March 31, 2008.

The licensee committed to conducting two independent reviews of the irradiator's operation and maintaining a safety conscious work environment. In a facsimile dated April 8, 2008, the licensee provided the NRC with a copy of an internal office memorandum sent to all Baxter sterilization area employees from the Plant General Manager. This lessons-learned memorandum described the outcome of the previous NRC inspection and investigation and informed employees that they should feel free to raise issues of safety or other concerns without fear of retaliation. In a letter dated April 9, 2008, the licensee provided the NRC with a copy of their final presentation slides which focused on additional in-person training for the gamma sterilization group regarding fostering a safety conscious work environment. The training was completed before June 30, 2008.

The licensee also hired 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 was completed by June 30, 2008. The results were communicated, as appropriate, to department employees and were made available for review during this inspection. The independent firm conducted the survey in April 2008, and used a series of questions to assess safety

on three scales, which were safety perception, safety management system, and actively caring. Several corrective actions to improve the safety culture were documented in a corrective action plan dated June 27, 2008. The inspector discussed the status of the corrective actions with the general plant manager. Significant progress was noted, such as re-vamping the participants on the safety committee, plans to expand the safety culture assessment throughout the entire site, increasing management presence during back-shifts, and promoting programs to help employees understand the reasons for strict safety compliance.

ELEMENT 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.

In a letter dated July 24, 2008, the licensee informed the NRC that they had completed all of the commitments made during the ADR session which were documented in the Confirmatory Order. In summary, the licensee revised and updated their maintenance procedures, re-trained all gamma sterilization personnel, re-tested all irradiator operators, conducted two independent reviews of the irradiator's operation, conducted a safety culture assessment of the gamma sterilization department, and where necessary, the licensee took disciplinary action against select employees.

c. Conclusions

Based on the observations made during the on-site inspection in July 2008, the review of selective records, and a review of the subsequent paperwork provided by the licensee, all commitments from Confirmatory Order EA-07-132 were completed.

IV. Exit Meeting

A preliminary exit meeting regarding the inspection details was conducted on July 10, 2008 by the inspectors with the Plant General Manager, RSO and ARSO. On September 25, 2008, a final exit meeting was held by telephone among Ms. Modes and Ms. Miller of this office and Mr. Moran, Ms. Vera and Mr. Arroyo of Baxter to discuss the results of the safety inspection and that subsequent correspondence would document the NRC position regarding compliance with the commitments of the Confirmatory Order.

PARTIAL LIST OF PERSONS CONTACTED

#^ Enrique Moran, Plant General Manager 787-954-2261
#* Evet Vera, RSO 787-954-2228
#* Jose Arroyo, Assistant RSO (RSO in training)
Orlando Aponte, irradiator operator
Jose Rivera, irradiator operator
Sixto Rivera, irradiator operator
Aniris Colon, irradiator operator
Luis Borges, irradiator lead technician (maintenance technician)

Individual(s) present at entrance meeting
* Individual(s) present at exit meeting on-site
^ Individual present at final exit via telephone
