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

September 17, 2007

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

José Sadurní
General Manager
Baxter Healthcare of Puerto Rico
State Road 721, Km. 0.3
Aibonito, PR 00705

SUBJECT: NRC INSPECTION REPORT NO. 03019882/2006003, BAXTER HEALTHCARE OF PUERTO RICO, AIBONITO, PUERTO RICO, AND NRC OFFICE OF INVESTIGATIONS REPORT NO. 1-2006-040

Dear Mr. Sadurní:

On May 8, 2006, Héctor Bermúdez and Orysia Masnyk Bailey of this office began a safety inspection at the above address of activities authorized by the above listed NRC license issued to Baxter Healthcare of Puerto Rico (Baxter). This inspection was continued by Ms. Masnyk Bailey with site visits on November 28-29, 2006, and April 19, 2007, and continued in-office review by both Mr. Bermúdez and Ms. Masnyk Bailey until May 31, 2007. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspectors, interviews with personnel, and selected examination of representative records. The results of the inspection activities are included in the enclosed Inspection Report No. 03019882/2006003.

Based on the initial NRC staff inspection findings, on June 1, 2006, the NRC Office of Investigations (OI), Region I Field Office, initiated an investigation to determine whether Baxter willfully violated NRC requirements related to inspection and maintenance activities, as well as personnel training and qualifications. The results of the OI Investigation are included in the enclosed Factual Summary of OI Report No. 1-2006-040.

As a result of the NRC inspection and OI investigation, the NRC identified three apparent violations of NRC requirements which are being considered for escalated enforcement in accordance with the NRC Enforcement Policy. These apparent violations were discussed during a final exit meeting by telephone with you, Peter Etienne of Baxter Corporation, and Marie Miller, Ms. Masnyk Bailey and Mr. Bermudez of my staff on August 2, 2007. The first apparent violation involves numerous examples of the deliberate failure by two Baxter 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). The second apparent violation involves the deliberate failure by three Baxter employees to conduct performance tests for two irradiator operators at least annually, as required by 10 CFR 36.51(d). The third apparent violation involves the deliberate failure by Baxter to maintain complete and accurate maintenance testing and annual performance testing records as required by 10 CFR 30.9.

Before the NRC makes its enforcement decision, the NRC would like to discuss these apparent violations with you at a Predecisional Enforcement Conference (PEC) at the Region I office. The conference will be closed to the public and transcribed. The decision to hold a PEC does not mean that the NRC has determined that violations have occurred or that enforcement action will be taken. The PEC will be held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The conference would provide you an opportunity to present your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

Instead of a PEC, Baxter may request Alternative Dispute Resolution (ADR) with the NRC. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC has decided to employ is mediation. In mediation, a neutral mediator with no decision-making authority helps parties clarify issues, explore settlement options, and evaluate how best to advance their respective interests. The mediator's responsibility is to assist the parties in reaching an agreement. However, the mediator has no authority to impose a resolution upon the parties. Mediation is a confidential and voluntary process. If the parties (the NRC and Baxter) agree to use ADR, they select a mutually agreeable neutral mediator and share equally the cost of the mediator's services. Additional information concerning the NRC's ADR process can be obtained at http://www.nrc.gov. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Intake neutrals perform several functions, including: assisting the parties in determining ADR potential for their case, advising parties regarding the ADR process, aiding the parties in selecting an appropriate mediator, explaining the extent of confidentiality, and providing other logistic assistance as necessary.

Please contact ICR at Cornell University at (877) 733-9415 within ten days of the date of this letter if you are interested in pursuing resolution of these issues through ADR.

As you know, the NRC issued a Confirmatory Order to you on January 26, 2005 which confirmed your commitments to take certain actions at your facility. The commitments were made as part of a previous Alternative Dispute Resolution to address a previously issued civil penalty. As part of the settlement agreement, Baxter agreed to pay a civil penalty in the amount of $31,200 and take additional corrective actions, including: (1) increasing management oversight of your irradiator program through monthly management reviews, annual internal audits; and (2) performing additional periodic audits by your corporate environmental health and safety group as well as an external auditor.

Notwithstanding these prior actions, you neither prevented nor identified these apparent violations. In addition, because multiple Baxter employees were involved in these apparent violations, we are concerned that your program may not be fully effective in continually reinforcing a culture committed to safety and regulatory compliance at Baxter. In the midst of this investigation you recognized the implications of these actions by your employees. Your

letters, dated November 3, 2006, November 20, 2006, and February 2, 2007, document corrective actions which you undertook. Regardless of whether you choose a PEC or ADR, please be prepared to summarize your corrective actions and discuss your oversight and implementation of a program that ensures for consistent, continued safe operation of your irradiator, with a work environment that reinforces a culture of safety.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," 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), accessible from the NRC web site at http://www.nrc.gov/reading-rm/adams.html. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Ms. Marie Miller at (610) 337-5205 within ten days of the date of this letter to notify the NRC of your decision to either participate in a PEC or ADR. Thank you for your cooperation.

Sincerely,

/RA/

Brian E. Holian, Director
Division of Nuclear Materials Safety

Enclosures:
1. Factual Summary of OI Investigation Report No. 1-2006-040
2. NRC Inspection Report No. 03019882/2006003
3. Excerpts from NRC Information Notice 96-28, "Suggested Guidance Related to Development and Implementation of Corrective Action"
4. NUREG/BR-0317, "Post-Investigation ADR Program"

cc w/enclosures:
Angel Alicea, Radiation Safety Officer
Commonwealth of Puerto Rico

this investigation you recognized the implications of these actions by your employees. Your letters, dated November 3, 2006, November 20, 2006, and February 2, 2007, document corrective actions which you undertook. Regardless of whether you choose a PEC or ADR, please be prepared to summarize your corrective actions and discuss your oversight and implementation of a program that ensures for consistent, continued safe operation of your irradiator, with a work environment that reinforces a culture of safety.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," 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), accessible from the NRC web site at http://www.nrc.gov/reading-rm/adams.html. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Ms. Marie Miller at (610) 337-5205 within ten days of the date of this letter to notify the NRC of your decision to either participate in a PEC or ADR. Thank you for your cooperation.

Sincerely,
/RA/
Brian E. Holian, Director
Division of Nuclear Materials Safety

Enclosures:
1. Factual Summary of OI Investigation Report No. 1-2006-040
2. NRC Inspection Report No. 03019882/2006003
3. Excerpts from NRC Information Notice 96-28, "Suggested Guidance Related to Development and Implementation of Corrective Action"
4. NUREG/BR-0317, "Post-Investigation ADR Program"

cc w/enclosures:
Angel Alicea, Radiation Safety Officer
Commonwealth of Puerto Rico

Distribution:

ADAMS (PARS)	B Jones, OGC	T. Bloomer,	H Bell, OIG	D Holody, RI
SECY	(Bradley)	OEDO	G Caputo, OI	A DeFrancisco,
CA	J. Moore, OGC	Enforcement	T. Grancorvitz,	RI
OEMAIL	C Miller, FSME	Coordinators	OCFO	R Summers, RI
OEWEB	G Pangburn,	RII, RIII, RIV	D Screnci, PAO-	C O'Daniell, RI
L Reyes, EDO	FSME	L. Lopez, OE	RI	S. Villar, RI
M Virgilio,	J Schlueter,	R. Taylor, OE	N Sheehan, PAO-	RI DNMS Mail
DEDMRT	FSME	S. Woods, OE	RI	Region I OE Files
C Carpenter, OE	D Rathbun,	G. Veneziano,	B Holian, RI	(with
S Merchant, OE	FSME	OGC	M Miller, RI	concurrences)
S. Magruder, OE	M. Cox, OEDO	B. Hayden, OPA	K Farrar, RI	

SUNSI Review Complete: RRaglandHBermudez
DOCUMENT NAME: C:\FileNet\ML072610356.wpd
After declaring this document "An Official Agency Record" **it will** be released to the Public.
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	DNMS/RI	DNMS/RI	DNMS/RI	ORA/RI	OI/RI
NAME	H Bermudez/O. Masnyk Bailey	MMiller JAJ for	B Holian GLS for	KFarrar KLF	Ewilson MAM for
DATE	8/1/07 and 7/30/07 per email	9/14/07	8/22/07	8/23/07	8/23/07

OFFICE	ORA/RI	OE	FSME	OGC	DNMS/RI
NAME	DHolody DJH	NHilton	SWastler	JMartin	B Holian
DATE	8/23/07	9/11 /07	8/29/07	9/10/07	9/17/07

OFFICIAL RECORD COPY ML072610356

FACTUAL SUMMARY OF OI INVESTIGATION REPORT NO. 1-2006-040

On June 1, 2006, the U. S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), Region I (RI) Field Office, initiated an investigation to determine if Baxter Healthcare Corporation (BHC) personnel deliberately violated BHC's NRC license and NRC regulations by: (1) falsifying required preventative maintenance checks and annual testing records for irradiator operators; and, (2) deliberately incapacitating the irradiator low water alarm.

Required maintenance checks were not performed and related records were falsified on several occasions, between December 1, 2003 and April 24, 2006. Maintenance checks, which were to have been performed by a maintenance technician (MT) or an alternate on his behalf (a superintendent) were checked off as completed, but in many instances the maintenance check was not performed or was not performed by the individual who signed the record. In particular: (1) on several occasions, no programmable logic controller (PLC) records exist of maintenance checks that were signed as completed by the MT and superintendent; (2) an MT acknowledged that he falsified certain required maintenance checks of the irradiator; (3) an MT signed a weekly maintenance check dated October 4, 2004, even though he was in Canada that day; and (4) the superintendent signed and dated a weekly maintenance check on a particular day even though he was on vacation that day.

Additionally, annual performance tests for two group leader/irradiator operators were not performed, yet records of such tests were falsified to state that the tests were completed. Two group leader/irradiator operators admitted to OI that they signed a written annual performance test that had already been filled out by the superintendent. The irradiator operators never performed the required annual tests, yet the superintendent signed off that the tests were completed.

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03019882/2006003
Docket No.	03019882
License No.	52-21175-01
Licensee:	Baxter Healthcare of Puerto Rico
Location:	Aibonito, PR
Inspection Dates:	May 8, 2006, November 28-29, 2006 and April 19, 2007, with in-office inspection through May 31, 2007

Inspectors:

Héctor Bermúdez
Senior Health Physicist

Orysia Masnyk Bailey
Health Physicist

Approved By:

/RA by J. A. Joustra Actg For/ ***9/14/07***

Marie Miller, Chief — date
Materials Security and Industrial Branch
Division of Nuclear Materials Safety

Document Name: C:\FileNet\ML072610356.wpd

EXECUTIVE SUMMARY

Baxter Healthcare of Puerto Rico
NRC Inspection Report No. 03019882/2006003

This unannounced inspection at the Aibonito facility on May 8, 2006, November 28-29, 2006, and April 19, 2007, with subsequent in-office inspection activities through May 31, 2007, was conducted to examine the licensee's inspection and maintenance and licensee's personnel training and qualifications programs.

Irradiator safety systems were operating as designed and records showed that required irradiator safety system maintenance tests and operator training were performed as required. A concern regarding the accuracy of irradiator maintenance and training records was referred to NRC's Office of Investigations (OI). On June 1, 2006, OI initiated an investigation of the licensee's inspection and maintenance and training and qualification programs.

As a result of the NRC inspection and OI investigation, three apparent violations were identified. These include: (1) failure to perform inspection and maintenance checks of safety systems at the frequency specified in the license application, as required by 10 CFR 36.61(a); (2) failure to conduct safety reviews for two irradiator operators at least annually, as required by 10 CFR 36.51(d); and (3) failure to maintain information, pursuant to 10 CFR 36.81, as required by Commission's regulations, complete and accurate in all material respects, as required by 10 CFR 30.9.

REPORT DETAILS

I. Testing and Maintenance, and Training and Qualifications

a. Inspection Scope

The inspectors performed a review of licensee programs for performing irradiator safety system inspection and maintenance tests, with trained and qualified personnel. Information was gathered through a review of inspection and maintenance records, training and qualification records, tours of the facility, and discussions with cognizant personnel.

b. Observations and Findings

10 CFR 36.61(a) requires, in part, that the licensee perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license application: (1) access control system, (2) source position indicator, (3) pool water contamination monitor, (4) product exit monitor, (5) emergency source return control, (6) water circulation system, (7) heat and smoke detectors and extinguisher system, (8) means of pool water replenishment, (9) high and low pool water indicators, (10) mechanism and cables used to raise and lower the sources, (11) carrier collision protection system, (12) pool leakage, (13) electrical wiring of safety systems, and (14) pool water conductivity measuring system.

Records of inspections and maintenance checks and licensee staff indicated that irradiator safety systems were inspected and tested as required by 10 CFR 36.61. During interviews, Irradiator Operators and the Maintenance Technician (MT) demonstrated thorough knowledge of irradiator system operation and safety system inspection and maintenance activities. Irradiator operators and MT indicated that irradiator safety systems were operating properly and no significant operational problems were identified.

A review of operator training and qualification records for the previous two years indicated that safety reviews for irradiator operators were conducted and documented on an annual basis and the training included the topics required by 10 CFR 36.51(d).

During the review of records, the inspectors identified an apparent conflict between maintenance and training records. The inspectors noted that maintenance records showed that a MT performed an irradiator maintenance check on October 4, 2004, and training records showed that the same MT attended vendor training in Canada on the same date. Licensee representatives were unable to immediately explain the apparent discrepancy; therefore, the NRC technical staff referred this concern to the NRC Office of Investigations (OI) for follow up. On June 1, 2006, OI initiated an investigation of the licensee's inspection and maintenance and training and qualification programs.

Based on NRC initial findings, Baxter initiated an internal review of the apparent discrepancies in maintenance and training records. The NRC staff reviewed the OI report and found that selected maintenance tests and required testing was not

conducted and that information required by the Commission requirements or license conditions was not complete and accurate in all material aspects. The licensee investigation also found that selected maintenance tests were not completed.

c. Conclusions

Irradiator safety systems were operating as designed. Irradiator safety system inspection and maintenance tests required by 10 CFR 36.61(a) indicated that irradiator safety systems were being properly maintained. The MT and irradiator operators were knowledgeable of irradiator and safety system operation and maintenance. Training records indicated that the licensee conducted and documented annual safety reviews as required by 10 CFR 36.51. A concern regarding the completeness and accuracy of irradiator maintenance tests and training records was referred to NRC's Office of Investigations. On June 1, 2006, OI initiated an investigation of the licensee's inspection and maintenance and training and qualification programs. From the review of the OI report, the NRC staff concluded that selected maintenance tests were not performed and related required records were falsified; and two annual written performance evaluations were not conducted and the related records were falsified, as required by 10 CFR 36.61(a), 10 CFR 36.51(d) and 10 CFR 30.9.

II. Status of Licensee Investigation and Corrective Measures

a. Inspection Scope

The inspector performed a review of Baxter's investigation of their maintenance and training programs as discussed in its letters to the NRC dated November 3 and 20, 2006, and February 2, 2007. Additionally the inspector reviewed the licensee's 2004 post event commitments to the NRC to determine the licensee's implementation of these commmitments.

b. Observations and Findings

The licensee's letter dated November 3, 2006, discussed the status of Baxter's internal investigation of testing and documentation irregularities, provided assurance of irradiator safety and delineated immediate steps and future plans related to these topics.

Baxter confirmed that the required monthly maintenance checks were not performed as documented on at least 10 occasions. They were either not done at all, partially done, or performed by an individual other than the one certifying to have done so. The tests that were not done routinely were the high temperature and smoke detector tests and some visual inspections. The temperature and smoke tests require the individual performing the test to push one of the product carriers out of the way, get on a ladder to access the heat sensor and smoke detector located on the ceiling of the cell above the irradiator pool, use a torch to activate the heat sensor and a smoke tester to activate the smoke detector. During the OI investigation the MT indicated this was too cumbersome and he did not perform these tests and visual inspections because he "knew" that everything was working properly and he was too busy with other duties.

As a corrective measure, Baxter now requires all weekly and monthly maintenance inspections to be performed by two individuals. The completed inspection form is now accompanied by a print out from the irradiator computer's Programmable Logic Controller (PLC) demonstrating that the tests were done. Training on good documentation practices has been provided to irradiator employees. All irradiator operators underwent annual performance testing and re-took the annual written test. The irradiator manufacturer, MDS Nordion, sent staff to Baxter on November 11-12, 2006, to perform a review of irradiator operations. The MT and Superintendent, who completed the documentation, but did not perform selected maintenance tests, are no longer employed by Baxter.

The licensee's letter dated November 20, 2006, contained more specificity regarding the items discussed in their November 3, 2006, letter. Additionally, Baxter advised that electronic records were reviewed for the past few years and that additional examples of document discrepancies were identified. The licensee provided some information concerning the ongoing investigation and the results of interviews conducted with irradiator personnel. The inspector found that Baxter staff reviewed all monthly and quarterly maintenance tests dating back to 2003. The information discerned during this NRC review provided information confirming falsification of some of these records.

Baxter also reaffirmed in its November 20, 2006, letter, the commitments made to the NRC in a letter dated August 23, 2004, following a stuck source and potential overexposure event. The inspector confirmed that Baxter was continuing to implement actions delineated in the 2004 letter.

The licensee's February 2, 2007, letter served to clarify previous statements made by Baxter and to update information on corrective and preventative measures as follows. Baxter further clarified the extent of record falsification uncovered during the internal investigation. On January 7, 2007, during annual radiation safety training, Baxter reiterated the means available to report safety concerns and inappropriate behavior. Baxter has initiated a review of the monthly and weekly maintenance inspection tests, in consultation with the manufacturer, to see if the tests are still appropriate and to see if they can be made less cumbersome or safer.

The inspector reviewed the transcripts of the employee interviews conducted by a Baxter corporate attorney and a San Juan, PR based attorney and discussed the conduct of these interviews with Baxter personnel and the corporate attorney. The transcripts consisted of a synopsis of the interviews that were read and signed by the interviewees. Translations into English were provided for the NRC to review. The attorneys did not develop a list of questions that were uniformly asked of all irradiator personnel. The questions seemed to be a re-verification by Baxter of issues raised by the NRC during previous site visits and did not include questions of all irradiator personnel concerning possible wrongdoing. However, both the NRC OI and the licensee's records review would provide information of incomplete safety inspections and inaccurate safety inspection records.

c. Conclusions

The inspector found that the licensee had implemented the corrective measures discussed in its November 3 and 20, 2006, and February 2, 2007, letters. The licensee was continuing to implement actions delineated in its August 23, 2004, letter. The licensee's investigative efforts to date seemed to be a re-affirmation of issues and concerns raised by the NRC rather than an expansion of inquiry to determine the possible extent of any other documentation inconsistencies.

III. Current Safety Status of Facility

a. Inspection Scope

The inspector reviewed records, interviewed cognizant personnel, and observed irradiator safety and maintenance tests to evaluate the licensee's efforts to demonstrate the safety of the irradiator. This included a review of required safety and maintenance tests for the previous six months and observations of work activities and post maintenance safety inspection conducted by a MDS Nordion employee upgrading the irradiator control panel. The inspector also reviewed the licensee's maintenance of the shielding surrounding the source rack hoist cables in the irradiator penthouse in January 2005.

b. Observations and Findings

MDS Nordion staff performed a safety review of irradiator operations on November 11-12, 2006, in response to the identification of testing and documentation irregularities. Additionally, MDS Nordion performed a safety review of irradiator operations following any modifications to, or source loads of, the irradiator. The MDS Nordion safety tests included all safety tests done by Baxter during their routine safety tests. These types of safety tests were performed by MDS Nordion on May 1, 2004, January 11, 2005, August 22, 2005, February 23, 2006, and April 29, 2006. Review of the MDS Nordion documentation disclosed that no items of non-compliance or concern were identified during the tests. The inspector observed safety tests performed by MDS Nordion and Baxter staff following a system modification during this NRC inspection. No items of non-compliance or concern were identified.

In January 2005, MDS Nordion loaded additional cobalt sources into the Baxter irradiator, replaced the product carriers, and replaced the source up and source down switches. The licensee reported that lead blocks and sand bags were placed around the source up switch access hole to reduce external radiation fields. MDS Nordion confirmed that the maximum radiation field in the area was less than 2 milliRoentgen per hour (mR/hr). Subsequently, lead shot was obtained by Baxter and Baxter's RSO replaced the sand bags and lead blocks with this lead shot, using instructions provided by MDS Nordion. The RSO's post-work survey showed radiation levels below 2 mR/hr. The inspector reviewed the licensee's retrofit of the shielding surrounding the source

rack hoist cables in the irradiator penthouse in January 2005 and found that the change to the facility had been conducted in accordance with license conditions.

c. Conclusions

All recent safety and maintenance tests have been performed as required. Recent safety tests performed by MDS Nordion and Baxter and observed by the inspector demonstrated that the safety features of the irradiator operated in accordance with design specifications and regulatory requirements. Additionally, safety inspections done by MDS Nordion on five occasions in the 2004 - 2006 time frame demonstrated the efficacy of the irradiator's safety features.

IV. Exit Meeting

A preliminary exit meeting regarding the inspection details was conducted on April 19, 2007, with the Plant Manager. The results of the OI investigation, which was initiated on June 1, 2006, were not discussed with the licensee during this exit meeting. A final exit meeting with Mr. Sadurni and Mr. Etienne and Ms. Miller and the inspectors was conducted on August 2, 2007. The licensee expressed a concern that their investigation did not conclude that selected training records had been falsified; however, they would review the available information provided in the OI summary and be prepared to discuss this concern during either a Predecisional Enforcement Conference or Alternative Dispute Resolution meeting.

PARTIAL LIST OF PERSONS CONTACTED

Angel Alicea, Sterilization Engineer and Radiation Safety Officer
Luis Borges, Irradiator Operator (IO)
Margarita Cruz, Supply Chain Director
*Peter Etienne, Attorney, Baxter Corporate Office
Chris McCarthy, MDS Nordion Maintenance Controls Engineer
Enrique Morán, Engineering Director
Sixto Rivera, Product Handler
*José Sadurní, Plant General Manager
Evette Vera, Assistant Radiation Safety Officer

*Denotes attendance at final exit meeting.