

Baxter**Baxter Healthcare Corporation**

Medication Delivery
P. O. Box 1389
Aibonito, Puerto Rico 00705

Fax Cover Sheet

DATE: April 8, 2008 **PHONE:** (610)337-5205
TO: Marie Miller **FAX:** (610)337-5269
C/O USNRC
FROM: Enrique Moran **PHONE:** (787) 954-2261
Baxter-Aibonito **FAX:** (787) 735.6343

RE: COPY OF LETTER TO STERILIZATION AREA EMPLOYEES

DEAR MS. MILLER:

ATTACHED IS A COPY OF THE ENGLISH VERSION OF MY LETTER TO THE STERILIZATION AREA EMPLOYEES ON THE LESSONS LEARNED FROM OUR EXPERIENCES, FOR YOUR REFERENCE.

THE LETTER WAS TRANSLATED TO SPANISH, DISCUSSED BY ME PERSONALLY WITH THE AREA EMPLOYEES, AND POSTED IN THE AREA BULLETION BOARDS.

PLEASE CONTACT ME IF YOU HAVE ANY FURTHER QUESTIONS OR COMMENTS.

SINCERELY,



ENRIQUE MORAN

PLANT GENERAL MANAGER

3 pages including cover:

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Baxter

Interoffice Memorandum-For Internal Use Only

To: Sterilization Area Employees

Date: February 29, 2008

Cs:

From: Enrique Moran

Subject: Gamma Sterilization Safety

Last year, Baxter Aibonito was involved in an NRC investigation covering the Gamma Sterilization area. The investigation revealed that a few employees had not conducted inspections but prepared documents saying that they did. Baxter received a fine for violation of training and documentation requirements related to his matter.

Specifically, alarms that should have been recorded in the Gamma console system, and that needed to be verified for the inspections to be effective, were not reflected on a printout of the console system memory, proving that contrary to what was written on the inspection form, those specific tests were not actually performed. As a lesson learned from this experience, we have taken corrective actions that include having a second person participate in each inspection verifying (and signing to that respect) that every inspection item has been performed as required. In order to facilitate the auditing by the person signing in the "Supervised by" space of the inspection form, we now require that a printout of the console system memory for the day, where the alarms related to the inspection items performed are recorded, be attached to the inspection form, with the related alarms highlighted for easy identification. By doing this, the operators will have a chance to verify themselves that they have completed all the required items. As required by good documentation practices, any inspection item that for whatever reason was not completed during the inspection, must have a note to that respect, explaining why it has not been completed, and plans to complete as required. No item that has not been completed can be assigned an "OK", and needs to be communicated to the RSO. The RSO, will only sign the "Supervised by" space in the form after verifying that all the alarms related to the inspection appear in the PLC printout.

Another item raised in the NRC inspection report refers to doubt cast on the "Operator's Annual Performance Test" documentation process. Although Baxter's own investigation did not produce any proof to substantiate this concern, we are reviewing the Annual Performance Test to better represent the testing requirement, and simplify its documentation. It is very important for the operators to review the filled-out test form when they complete the test and before signing it. If there is any doubt as to the accuracy of what is documented, the operator should promptly raise

the concern to the examiner and/or RSO (or to management as appropriate), and make sure the doubt is cleared before signing the test.

We take our employee's safety very seriously. We also do not tolerate any violation of the law or of our own procedures. The employees who violated our procedures have been disciplined.

In addition, we recognized that we must continue to build a safety-conscious work environment where employees should feel free to raise issues of safety or other concerns without feel of retaliation. I personally have an open door policy so you can raise any concerns you may have to me. You can also raise issues to your supervisor or Human Resources manager. You can also contact the company's ethics hotline – 1.877.229.8383 or the United States Nuclear Regulatory Commission (USNRC) at 1-800-695-7403. In the next few weeks we will conduct additional trainings to focus on these areas.

We value all of your hard work, and I know that we can build an environment in the area where we enjoy working and will look out for each other's safety. Again, please feel free to make safety suggestions or raise concerns to me or others as appropriate.

Thanks!