Medication Delivery

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Baxter

July 24, 2008

Mr. Karl Farrar
Regional Counsel
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Reference: Commitments following ADR Session
EA-07-132
USNRC License 52-21175-01 (Docket No. 030-19882)

This letter is to inform you that we have completed all of our commitments made following the ADR session held on December 6, 2007, as required in item #5 of the "Notice Of Violation, Civil Penalty, and Confirmatory Order" dated February 26, 2008.

The attached table contains a detailed completion report of each of the Items listed in Items #3 and #4 of the "Notice Of Violation, Civil Penalty, and Confirmatory Order" dated February 26, 2008.

If you have any questions or require additional information, please contact me at (787) 954-2261, or (787)599-7013 or Peter Etienne, Senior Counsel at Baxter at (847) 948-4879.

Sincerely,

A Montes Manufacturing Director for Enrique Moran.

Enrique Moran, PE
Plant General Manager
Baxter Healthcare of PR
P.O. Box 1389
Aibonito, PR 00705

Cc :. Marc L. Dapas
Deputy Regional Administrator, Region I, NRC

Peter Etienne, Baxter

attachment

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Commitments Completion Detail

	Commitment	Completion Date
3(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	November 2006
3(b)	Revising procedure records to include attaching the computer printout from the console's PLC to confirm that certain event checks were conducted.	November 2006
3(c)	Training all irradiator operators on good documentation practices (GDP)	November 2006
3(d)	Completing annual performance tests and written tests for all irradiator operators in November 2006	November 2006
3(e)	Conducting two independent reviews of the irradiator's operation	November 2006 – Nordion August 2007 - RSCS
3(f)	Interviewing all irradiator operators to determine whether similar issues have occurred of which Baxter was not aware	November 2006
3(g)	Training all irradiator operators on the methods to report inappropriate behavior	February 2007
3(h)	In consultation with the irradiator manufacturer, reviewing monthly and weekly inspection tests to affirm the need and frequency of the tests, and to explore methods to make the tests less cumbersome	November 2007/Continuous
3(i)	Taking appropriate disciplinary action against the responsible individuals, commensurate with their actions	Done
3(j)	Having the Plant Manager attend monthly management meetings that discuss identified concerns	Ongoing
3(k)	Implementing the "Dupont STOP" peer observation and feedback process to focus on behavior change to improve safety	Done/Ongoing
3(l)	Implementing the "Toyota 5S" process, adding a sixth "S" for safety to improve facility performance and safety.	Done/Ongoing
4(a)	Using an independent outside organization to conduct a safety culture assessment of the Gamma sterilization department and include any identified recommendation in the Baxter corrective action program. This will be completed by 6/30/2008. The results will be communicated, as appropriate, to department employees and will be made available for NRC review during inspections	Completed 6/27/2008
4(b)	Conducting an 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.	Completed 6/5/2008
4(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.	Completed March 6, 2008
4(d)	Evaluating annual irradiator operator performance tests to ensure that they are consistent with Baxter's commitment to foster a safety conscious work environment.	Completed March 2008
5	Baxter agreed to send a letter to the NRC, within 30 days of completion of all the actions specified in items 3 and 4, informing the NRC that these actions are complete.	Today