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Baxter

December 17, 2004

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

**RE: Agreement Between U.S. NRC and Baxter
To Settle NRC Enforcement Action
EA 04-118**

Dear Mr. Farrar:

Following up on the mediation session between Baxter and the NRC in Philadelphia on December 13, 2004, in connection with the above-referenced Notice of Violation, this letter confirms the Agreement of the parties as described below:

- A. Baxter agrees to pay a civil penalty of \$31,200.00 for Violations I.A, I.B and I.C. The NRC will characterize these violations as a Severity Level II problem.
- B. Baxter and the NRC agree to disagree on the willful characterization of Violation I.C.
- C. NRC agrees to treat Violations II.A, II.B, and II.C as non-cited violations.
- D. Baxter agrees to implement the corrective action as documented in Baxter's letter dated 8/23/04 except that with respect to item 1(c) in that letter, ("Additional External Review by Outside Consultant"), that item is replaced by the terms of the December 13, 2004 settlement as described herein. Baxter agrees to provide for reviews of irradiator operations to be conducted by a qualified consultant, such review to include a review of operations, maintenance, radiation safety and the RSO and ARSO functions. Review

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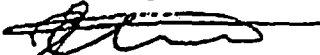
results will be documented and made available to NRC during inspections conducted by NRC. Such reviews to be conducted as noted below.

- E. A review by the qualified external consultant will be conducted in 2005 of the RSO and ARSO function to supplement the reviews done in 2004.
- F. In 2007, a qualified external consultant will conduct a full review as listed in Item D.
- G. In 2007 after the full review, Baxter will discuss with NRC whether Baxter will need to continue to use a qualified external consultant. It is anticipated that the last external consultant review will be completed in 2007. In no event shall such review extend beyond one additional review in 2009 in the context of this Agreement.
- H. Baxter will submit to the NRC a letter within two weeks (by December 27, 2004) which documents this Agreement. (Met by this letter).
- I. Upon issuance of a Confirmatory Order by the NRC, confirming the Agreement reached by the parties on December 13, Baxter will pay the Civil Penalty in the amount of \$31,200.00 within thirty days of the date of issuance of that Confirmatory Order.

Baxter appreciates the willingness of the NRC to mediate this matter to a mutually satisfactory agreement.

If you have any questions regarding the above, please call.

Sincerely,



Peter Etienne
Senior Counsel

PE/laf-b