



NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION

Office of Public Affairs, Region I
475 Allendale Road, King of Prussia, Pa. 19406
E-mail: opal@nrc.gov
Site: <http://www.nrc.gov>

No. I-08-007

Feb. 27, 2008

Contact: Diane Screnci, 610/337-5330
Neil Sheehan, 610/337-5331

PUERTO RICO FIRM TO RECEIVE \$15,000 FINE, MAKE CHANGES UNDER SETTLEMENT AGREEMENT WITH NRC

Baxter Healthcare of Puerto Rico has agreed to pay a \$15,000 civil penalty and implement a broad range of corrective actions related to its irradiator operations under an agreement reached with the Nuclear Regulatory Commission. The settlement with the company was achieved under the NRC's Alternate Dispute Resolution (ADR) process. It is in response to three apparent violations identified by the agency during an inspection and an investigation by its Office of Investigations.

Irradiators are facilities that expose products such as food and medical supplies to radiation to eliminate harmful bacteria, germs and insects, or for other purposes. In this case, Baxter Healthcare uses an irradiator at its facility in Aibonito, Puerto Rico to sterilize medical supplies.

In a letter sent to the company on Sept. 17, 2007, the NRC provided the results of the inspection and investigation. The investigation, which was completed on March 28, 2007, was conducted to determine whether Baxter Healthcare willfully violated NRC requirements related to inspections and maintenance tests for its licensed irradiator at the Aibonito site, as well as personnel training and qualifications for two irradiator operators.

Based on the reviews, the NRC identified three apparent violations of agency requirements by the company: (1) On numerous occasions between Dec. 1, 2003 and April 24, 2006, inspections and maintenance tests on irradiator safety systems were not completed at the frequency specified in the company's license; (2) on April 29, 2005, annual performance tests for two irradiator operators were not conducted as required under NRC regulations; and (3) the records associated with the safety system inspections and maintenance tests and the operator performance tests were not complete and accurate in all material respects because they indicated the activities had been performed when, in fact, that was not the case. The NRC also notified the company that it had determined the apparent violations resulted from deliberate acts on the part of certain employees.

In the same correspondence, the agency offered the company the opportunity to discuss the apparent violations at a predecisional enforcement conference or to request the use of ADR. Baxter Healthcare requested ADR, which, in this context, refers to a process in which a neutral mediator with no decision-making authority assists the NRC and license-holders in reaching an agreement resolving any differences regarding an enforcement action.

An ADR session involving NRC staff and Baxter Healthcare took place on Dec. 6, 2007, at the agency's Region I Office in King of Prussia, Pa. As a result of the discussions during that session, a settlement agreement was reached. The terms have now been confirmed by the NRC via a Confirmatory Order issued to the company. Under the agreement, the NRC and Baxter Healthcare agree that a non-compliance with regulatory requirements occurred. The violation has been classified as a Severity Level III problem and is cited in a Notice of Violation. (The NRC classifies violations from Severity Level I to IV, with I being the most significant.) The company also agrees to pay a \$15,000 civil penalty.

Other specific details of the agreement include the following:

- The NRC and Baxter Healthcare agree that certain company employees, including a first-level supervisor, deliberately violated NRC requirements by not carrying out certain irradiator maintenance checks/inspections from Dec. 1, 2003 to April 24, 2006, and that records associated with these checks/inspections were inaccurate.

- The NRC maintains that additional deliberate violations of NRC requirements occurred in that (1) additional performance tests for two individuals were not performed as required in 2005; and (2) the records associated with these two tests were inaccurate. Baxter Healthcare maintains that based on its investigation of these issues that the available evidence did not show that the violations occurred. The NRC and the company agree to disagree with regard to these violations.

- There is an acknowledgement that Baxter Healthcare, both before and after the ADR mediation session, took multiple corrective actions to address the violations.

- As a result of the ADR session, the company has agreed to take additional corrective actions, including: using an independent outside organization to conduct a safety culture assessment of the gamma sterilization department and include any identified recommendations in the Baxter Healthcare corrective action program, with the work to be completed by June 30; conducting in-person training of the gamma sterilization department employees concerning the raising of safety issues without fear of retaliation, and stressing the importance of radiological safety, with this work also due for completion by June 30; and evaluating annual irradiator operator performance tests to ensure they are consistent with the company's commitment to foster a safety conscious work environment.

The agreement also requires that Baxter Healthcare send a letter to the NRC within 30 days of the completion of all of the corrective actions.

A copy of the enforcement action will be posted on the NRC web site at:
<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

#