



# NRC NEWS

## U.S. NUCLEAR REGULATORY COMMISSION

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### **COMPANY AGREES TO ADDITIONAL CORRECTIVE ACTIONS AT PUERTO RICO IRRADIATION FACILITY UNDER ALTERNATE DISPUTE RESOLUTION SETTLEMENT**

As part of an agreement reached with the Nuclear Regulatory Commission, Baxter Healthcare Corp. has agreed to take additional corrective actions at a commercial irradiation facility it operates in Puerto Rico.

The agreement was achieved through the NRC's Alternate Dispute Resolution (ADR) Process, during which the agency and the company discussed the terms of a \$44,000 civil penalty levied against the company last year. That action stemmed from an event last April in which two workers failed to follow procedures at the facility, creating the possibility of a lethal exposure to radiation for the employees.

Under the agreement, Baxter has agreed to implement additional corrective actions, specifically reviews of irradiator operations, maintenance, radiation safety and the Radiation Safety Officer (RSO) and Assistant RSO functions by a qualified consultant. Those reviews will last at least until sometime in 2007. The settlement also calls for the NRC to change the amount of the proposed civil penalty for violations of agency requirements to \$31,200.

The new terms of the enforcement action have been confirmed via a Confirmatory Order issued by the NRC to the company.

"This demonstrates once again that the Alternate Dispute Resolution Process can work and achieve a result that protects the public health and safety while at the same time improving the efficiency and effectiveness of the enforcement process," said Frank J. Congel, Director of the NRC's Office of Enforcement.

Baxter requested the use of the ADR Process after the NRC issued the proposed civil penalty to the company on Oct. 25, 2004. ADR is a process in which a neutral mediator with no decision-making authority assists the NRC and licensees in reaching an agreement resolving any differences regarding an enforcement action. An ADR mediation session between the NRC staff and Baxter representatives – led by a professional mediator arranged through Cornell University's Institute of

Conflict Management – was held on Dec. 13, 2004, in Philadelphia. That session led to the settlement agreement.

The event that prompted the enforcement action occurred on April 21, 2004, when an irradiator operator and an assistant were performing work at Baxter’s Puerto Rico irradiator, which is used to sterilize medical equipment. To ensure that workers are not exposed to unacceptable levels of radiation, such irradiators are equipped with safety interlocks designed to prevent entry when the radioactive sources are in the unshielded position. During this event, however, the interlocks were bypassed, or temporarily disabled.

Consequently, the workers entered the irradiator at a time when a radioactive source rack was stuck in the unshielded position. They quickly left the area after a radiation monitor carried by the irradiator operator indicated elevated radiation levels.

The problem for which the fine is being issued involves a failure by Baxter employees to follow emergency and abnormal event procedures after the source rack fault indicator on the console was illuminated and the source travel alarm sounded for an extended period; the operators’ failure to adequately check the irradiator cell radiation monitor and radiation levels outside prior to entering the irradiator, and to perform other surveys; and a failure to supply an individual radiation monitoring device to a worker (the assistant operator) entering the irradiator and to require its use. The NRC staff and Baxter have agreed to disagree on whether the last violation was “willful.”

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