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NRC PROPOSES $44,400 CIVIL PENALTY FOR BAXTER HEALTHCARE CORP. OVER IRRADIATOR EVENT AT PUERTO RICO FACILITY

The Nuclear Regulatory Commission staff has proposed a $44,400 fine against Baxter Healthcare Corp. for three violations stemming from an event earlier this year in which two workers failed to follow procedures at a Puerto Rico commercial irradiator. That failure could have resulted in a lethal exposure to radiation for the employees.

On April 21, an irradiator operator and an assistant were performing work at the company's Aibonito, 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.

As a result, the workers entered the irradiator at a time when a radioactive source rack was stuck in the unshielded position. (The direct cause of the source becoming stuck was a ladder that had been left over the irradiator pool after the individuals worked on switches earlier that day.) They quickly left the area after a radiation monitor carried by the irradiator operator indicated elevated radiation levels.

Subsequent testing indicated the operator and assistant received exposures of 4.4 and 2.8 rem, respectively. Because the annual exposure limit for the workers is 5 rem, the exposures were within regulatory limits. However, an NRC Augmented Inspection Team (AIT) review conducted following the event determined that had the employees continued on their intended path through the irradiation room, the doses would have been at least 450 rem. Those doses could be potentially lethal.

"The bypassing of the interlocks after the source rack fault indicator had illuminated and after the source travel alarm sounded for an extended period (without performing the required tests of radiation levels and source rack position, and without the irradiator manufacturer being contacted for assistance, contrary to the procedures) is a very significant violation," NRC Region I Administrator Samuel J. Collins wrote in a letter to Baxter Healthcare discussing the enforcement action. "... By bypassing the safety interlocks, a system designed to prevent a serious safety event was rendered inoperable, which created the potential for significant injury and loss of life."

The three violations for which the fine has been proposed are:

- A failure by Baxter Healthcare 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. This occurred twice on April 21 and on at least one previous occasion.
- Prior to entry into the irradiator, the operators did not adequately check the irradiator cell radiation monitor and radiation levels outside. They also failed to adequately perform other surveys to determine if the source rack was stuck in the unshielded position.
- A failure to supply an individual radiation monitoring device to a worker entering the irradiator and to require its use. Specifically, the assistant to the irradiator operator was not wearing a monitoring device or pocket dosimeter during entry into the irradiator. An investigation by the NRC's Office of Investigations concluded this violation was willful because (1) the irradiator operator admitted he was familiar with the company's procedure requiring operators to obtain dosimetry for the assistant if entering the irradiator; and (2) the irradiator operator had assigned dosimetry to the assistant for two previous irradiator entries on the same day.

Baxter Healthcare has informed the NRC that it has implemented a number of corrective actions, including (1) revisions to procedures for responding to emergency conditions and performing necessary surveys; (2) plans for an annual review of standard operating procedures for adequacy; (3) an upgrade of the training program and retraining of staff on revised procedures, survey techniques and dosimetry use; and (4) increased management oversight of the irradiator program.

The company has up to 30 days to respond in writing to the enforcement action.

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