

ENCLOSURE

NOTICE OF VIOLATION

Baxter Healthcare Corporation
Aibonito, Puerto Rico

Docket No. 030-19882
License No. 52-21175-01

During an NRC inspection conducted on February 16-17, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

- A. 10 CFR 36.23(b) requires, in part, that each entrance to a radiation room at a panoramic irradiator be equipped with an independent backup access control which, upon detection of personnel entry while the radioactive sources are exposed, must activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert of the entry at least one other individual who is onsite and who is trained on how to respond to the alarm and prepared to promptly render or summon assistance.

Contrary to the above, between July 1, 1993 and February 17, 1994:

1. The backup access controls at the licensee's personnel, product-in and product-out entrances into the radiation room did not have visible and audible alarms to make an individual entering the room, while the radioactive sources are exposed, aware of the hazard.
2. The alarms located at the irradiator's control console associated with the backup access controls at the licensee's personnel, product-in and product-out entrances into the radiation room were not capable of alerting at least one other (trained) individual of the entry when the control console was unattended.

This is a Severity Level IV violation (Supplement VI).

- B. 10 CFR 36.29(a) requires, in part, that irradiators with automatic product conveyor systems have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance.

Contrary to the above, between July 1, 1993 and February 17, 1994:

1. The radiation monitor in use at the licensee's product exit door did not have an audible alarm.
2. The alarm located at the irradiator's control console associated with the radiation monitor at the product exit was not capable of alerting an individual in the facility who is prepared to summon assistance when the control console was unattended.

This is a Severity Level IV violation (Supplement VI).

- C. 10 CFR 36.27(b) requires, in part, that the radiation room at a panoramic irradiator be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room.

Contrary to the above, between July 1, 1993 and February 17, 1994, the radiation room of the licensee's irradiator was not equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. Specifically, the licensee's fire control system was designed and installed to protect the radioactive sources in the event of a fire but was not capable of extinguishing a fire in the radiation room without the entry of personnel into the room.

This is a Severity Level IV violation (Supplement VI).

- D. 10 CFR 36.57(d) requires, in part, that water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming be monitored for radioactive contamination before release to unrestricted areas.

Contrary to the above, between July 1 and December 31, 1993, the licensee released to unrestricted areas consisting of the sanitary sewer system water used in the regeneration of pool water deionizer resins, a potentially contaminated liquid, without monitoring it for radioactive contamination.

This is a Severity Level IV violation (Supplement VI).

- E. 10 CFR 36.51(a) requires, in part, that before an individual is permitted to operate an irradiator without a supervisor present, the individual be instructed in, among other subjects, the proper use of survey meters.

Contrary to the above, on February 16, 1994, an individual authorized to operate the licensee's irradiator without a supervisor present indicated that he had not been instructed in the proper use of survey meters. The individual then demonstrated inadequate knowledge regarding the proper use of survey meters.

This is a Severity Level IV violation (Supplement VI).

- F. 10 CFR 36.53 requires, in part, that the licensee have and follow operating or abnormal event procedures for:

- Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
- Inspection and maintenance checks required by 10 CFR 36.61.
- A prolonged loss of electrical power.

- The jamming of automatic conveyor systems.
- An alarm indicating unauthorized entry into the radiation room or another alarmed area.
- Natural phenomena, as appropriate for the geographical location of the facility.

10 CFR 36.61(a)(14) requires that the licensee perform inspection and maintenance checks that include the amount of water added to the pool to determine if the pool is leaking.

10 CFR 36.61(a)(15) requires that the licensee perform inspection and maintenance checks of the electrical wiring on required safety systems for radiation damage.

The licensee's procedure for weekly safety checks specifies requirements associated with the amount of water added to the pool to determine if the pool is leaking.

Contrary to the above, as of February 17, 1994:

1. The licensee did not have operating or abnormal event procedures for: monitoring pool water for contamination before its release to unrestricted areas; inspection and maintenance checks of the electrical wiring on required safety systems for radiation damage; a prolonged loss of electrical power; the jamming of automatic conveyor systems; an alarm indicating unauthorized entry into the radiation room or another alarmed area; and response to hurricanes.
2. The licensee's procedure regarding the amount of water added to the pool to determine if the pool is leaking was inadequate in that the procedure only required data gathering regarding the amount of water added to the pool on a weekly basis and did not provide guidance on how to identify leakage from the pool or the actions to be taken if pool leakage was suspected.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Baxter Healthcare Corporation is hereby required to submit a written statement or explanation to the Regional Administrator, Region II, with a copy to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full

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compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated at Atlanta, Georgia
This 15th day of *March*, 1994