

MAR 15 1994

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

Baxter Healthcare Corporation
ATTN: Mr. Rafael Diaz
Plant Manager
P.O. Box 1389
State Road 721
Aibonito, PR 00705

Gentlemen:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 52-21175-01/94-01)

This refers to the inspection conducted by Mr. H. Bermúdez of this office on February 16-17, 1994. The inspection included a review of activities authorized for your Aibonito facility. At the conclusion of the inspection, the findings were discussed with Mr. Allen Rodríguez, Production Manager.

The inspection was an examination of activities conducted under your license with respect to radiation safety and compliance with NRC regulations and the conditions of your license. It included selective examinations of procedures and representative records, interviews with personnel, and direct observations by the inspector.

Based on the results of this inspection, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Violation (Notice). The violations are of concern because they reflect an apparent lack of readiness for the implementation of new regulations contained in 10 CFR Part 36. We are also concerned about the apparent lack of familiarity with procedures incorporated into your license on the part of key individuals involved in the implementation of your licensed program. In addition, the inspector identified activities that violated NRC requirements that will not be subject to enforcement action because the licensee's efforts in identifying and/or correcting the violation meet the criteria for enforcement discretion specified in Section VII.B of the Enforcement Policy. The non-cited violation is the failure to calibrate survey instruments on two points in the two highest scales (scales IV and V). This item was discussed with Mr. Rodríguez during the meeting at the conclusion of the inspection.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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Baxter Healthcare Corporation

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In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and any reply will be placed in the NRC Public Document Room. Also, please note that, in accordance with 10 CFR 19.11(a)(4), a copy of the enclosed Notice and your response must be posted in accordance with 10 CFR 19.11(d) and (e).

The response directed by this letter and the enclosed Notice is not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Original Signed By
D. M. Collins

Douglas M. Collins, Chief
Nuclear Materials Safety and
Safeguards Branch
Division of Radiation Safety
and Safeguards

Enclosure:
Notice of Violation

cc w/encl:
Commonwealth of Puerto Rico

bcc w/encl:
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J. Glenn, NMSS

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