

October 31, 1996

CAL No. 2-96-016

Baxter HealthCare, Inc.
ATTN: Mr. Edwin Betancourt
Plant Manager
P. O. Box 1389
State Road 721, Km 0.3
Aibonito, PR 00705

SUBJECT: CONFIRMATORY ACTION LETTER

Dear Mr. Betancourt:

This refers to our inspection of your license during October 29, 1996, including followup on recent NRC Information Notices and vendor irradiator service information. As part of this review, we noted that certain safety systems failed to perform as designed, and appeared to have been altered or repaired by Baxter without NRC consent in writing.

Pursuant to a telephone conversation between you and Mr. Douglas Collins of our office, on October 30, 1996, it is our understanding that you have taken or will take the following actions which will be completed by the dates specified:

1. You will conduct a performance check of each safety system on October 30, 1996, to verify proper operation.
2. By November 9, 1996, a representative of Nordion will review the actual as-built configuration of your safety systems to determine whether they meet the design. If differences are identified, repairs or modifications will be made in accordance with License Condition 14 to return the system to the appropriate design. You will provide the NRC a copy of the Nordion report of their review and findings within 30 days of completion of their work.
3. Your staff will be retrained by November 8, 1996, in the limitations on repairs and/or alterations to safety system as specified in License Condition 14, i.e. that such work must be done by the irradiator manufacturer or other persons specifically licensed by the Commission or an Agreement State or you will obtain specific authorization in writing from the Commission before you perform such work yourself.
4. You will preserve the switch removed from the carrier safety interlock so that the NRC may conduct tests of the switch as appropriate.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, you are required to:

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1. Notify me immediately if your understanding differs from that set forth above;
2. Notify me if for any reason you cannot complete the above actions, and advise me in writing of any modifications, in advance of the change.

Issuance of this Confirmatory Action Letter does not preclude issuance of an order formalizing the above commitments or requiring other actions on the part of the licensee; nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and your response will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Should you have any questions concerning this letter, please contact me at 404/331-5514 (voice) or 404/331-5559 (facsimile).

Sincerely,

(original signed by
D. M. Collins)

Bruce S. Mallett, Director
Division of Nuclear Materials Safety

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

cc: Commonwealth of Puerto Rico

Distribution: See page 3

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Bruce S. Mallett, Director
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SIGNATURE	<i>[Signature]</i>	<i>[Signature]</i>			<i>F. Corby</i>	
NAME	JPotter	DMCollins	BUryc	CEvans	<i>[Signature]</i>	
DATE	10 / 30 / 96	10 / 30 / 96	10 / / 96	10 / / 96	10 / 30 / 96	10 / / 96
COPY?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO

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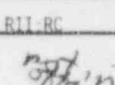
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*See previous concurrence.

OFFICE	RII DNMS	RII DNMS	RII DECS	RII RC	HO NMSS	
SIGNATURE						
NAME	JPotter *	DMCollins *	BUryc	CEvans	FCombs *	
DATE	10 / 31 / 96	10 / / 96	10 / 01 / 96	10 / / 96	10 / / 96	10 / / 96
COPY?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

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