



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

March 10, 2020

Miguel E. Miranda, General Manager
Baxter Healthcare of Puerto Rico
P.O. Box 1389
Aibonito, Puerto Rico 00705

SUBJECT: BAXTER HEALTHCARE OF PUERTO RICO, NRC INSPECTION REPORT
03019882/2020001 AND NOTICE OF VIOLATION

Dear Mr. Miranda:

This letter refers to the inspection conducted on February 10, 2020, at your Aibonito, Puerto Rico facility, and continuing in-office until March 2, 2020. This inspection examined activities conducted under your license as they relate to public health and safety, and was performed to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room located at NRC Headquarters in Rockville, MD, and from the NRC's document system, the Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. However, the material enclosed herewith contains Security-Related Information as described above. Therefore, the material in the enclosures will not be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS).

The enclosures contain Sensitive Unclassified Non-Safeguards Information. Upon separation, this cover letter is DECONTROLLED.

M. Miranda

2

If you have any questions regarding this matter, please contact Randolph Ragland of my staff at 610-337-5083 or via electronic mail at Randolph.Ragland@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

Chris G. Cahill, Chief
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

Docket No. 03019882
License No. 52-21175-01

Enclosures:

1. Notice of Violation (Non-Public)
2. Determination of Severity Level and
Description of Corrective Actions (Non-Public)

cc w/Encl: Marco Torres-Delgado, Radiation
Safety Officer

M. Miranda

3

BAXTER HEALTHCARE OF PUERTO RICO, NRC INSPECTION REPORT
03019882/2020001 AND NOTICE OF VIOLATION DATED __3/10/20__.

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OFFICE	RI DNMS	RI DNMS	RI:DNMS		
NAME	R. Ragland/rr	JPfingsten/jp	CCahill/cc		
DATE	03/9/2020	03/9/2020	03/10/2020		

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