

December 30, 1997

EA 97-518

Baxter Healthcare Corporation of Puerto Rico
ATTN: Mr. Edwin A. Betancourt
General Manager
P. O. Box 1389
Aibonito, PR 00705

SUBJECT: CONFIRMATION OF ENFORCEMENT CONFERENCE ARRANGEMENTS
(OFFICE OF INVESTIGATIONS REPORT NO. 2-96-040)
(NRC INSPECTION REPORT NOS. 52-21175-01/96-02 AND 52-21175-01/97-01)

Dear Mr. Betancourt:

This refers to the Nuclear Regulatory Commission (NRC) Office of Investigations (OI) investigation completed on November 19, 1997, and NRC inspections conducted at your facility on October 29, 1996 and April 2, 1997. During the inspections, the inspectors identified four examples where licensee employees performed maintenance on safety systems in violation of Condition 14 of your NRC license. The reports documenting these inspections were issued on November 27, 1996 and June 3, 1997, respectively.

As a result of the apparent unauthorized maintenance, OI initiated an investigation to determine whether employees and/or management of the licensee deliberately bypassed and defeated an irradiator roof plug radiation safety interlock in order to prevent the interruption of commercial irradiation operations at the licensee's facility in Aibonito, Puerto Rico. The investigation also addressed whether licensee employees or management deliberately violated License Condition 14 of the NRC materials license which prohibited unauthorized repairs or alterations to the irradiator. The evidence developed during the OI investigation substantiated that the licensee's Radiation Safety Officer (RSO) deliberately authorized operation of the licensee's irradiator in an altered condition that was prohibited by Condition 14 of the licensee's material license. The evidence also substantiated that the RSO deliberately caused the irradiator to be operated while a safety interlock system was inoperable, in violation of NRC regulations. Information also obtained during the investigation, indicates that licensee employees apparently provided inaccurate information to NRC inspectors during the October 29, 1996 inspection.

Based on the results of the OI investigation and the two inspections conducted on October 29, 1996, and April 2, 1997, apparent violations were identified that are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy). NUREG-1600.

One key apparent violation involves the apparent deliberate actions taken by licensee employees that caused Baxter Healthcare Corporation of Puerto Rico (BHC) to be in violation of License Condition 14 when the unauthorized

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alteration of the inside roof plug interlock switch system, a safety system, was performed. Another key apparent violation concerns licensee employees providing inaccurate information to NRC inspectors during the inspection conducted on October 29, 1996. These apparent violations are of particular concern to the NRC because one of the licensee employees involved (the RSO) is entrusted with the responsibility for ensuring that BHC complies with NRC regulations and license conditions.

In addition seven other apparent violations also are being considered for enforcement action; including:

- Three examples of unauthorized repairs to the irradiator control console, "on-off" mechanisms and/or safety systems following the issuance of a Confirmation of Action Letter on October 31, 1996, which reiterated the limitations on repairs and/or alterations as specified in License Condition 14.
- Failure to calibrate the pool water conductivity meter
- Failure to conduct irradiator operator annual audits
- Failure to train maintenance personnel
- Failure to have a roofplug interlock
- Failure to maintain records of repairs
- Failure to implement electrical wiring procedure

Accordingly, no Notice of Violation is presently being issued for these investigation and inspection findings. In addition, please be advised that the number and characterization of apparent violations described above and in the respective inspection reports which were previously forwarded to you may change as a result of further NRC review.

A closed and transcribed predecisional enforcement conference to discuss these apparent violations has been scheduled for January 12, 1998, at 10:00 a.m. at your facility. At NRC's request, you agreed that the former RSO involved in the aforementioned apparent violations will be in attendance at the conference. The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that violations have occurred or that enforcement action will be taken. This conference is being held to obtain information to enable the NRC to make an enforcement decision, such as a common understanding of the facts, root causes, missed opportunities to identify the apparent violations sooner, corrective actions, significance of the issues and the need for lasting and effective corrective action. In addition, this is an opportunity for you to point out any errors in our investigation and inspection reports and for you to provide any information

concerning your perspectives on 1) the severity of the violations, 2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.B.2 of the Enforcement Policy, and 3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section VII. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," (Enclosure 1) may be helpful.

This conference will be closed to public observation in accordance with the Commission's program as discussed in the enclosed excerpt from the Enforcement Policy (Enclosure 2).

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

Should you have any questions concerning this letter, please contact me at (404) 562-4700.

Sincerely,
(original signed by
C. M. Hosey)

Douglas M. Collins, Director
Division of Nuclear Materials Safety

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

Enclosures: 1. NRC Information Notice 96-28
2. Enforcement Policy, Section V,
"Predecisional Enforcement Conferences"

cc w/encls:
Commonwealth of Puerto Rico

Distribution w/encls (See Page 4)

Baxter Healthcare Corporation
of Puerto Rico

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28:

SUGGESTED GUIDANCE RELATING TO DEVELOPMENT
AND IMPLEMENTATION OF CORRECTIVE ACTION

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy (NUREG-1600)¹ 60 FR 34381, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VII.B.1 of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence. In some cases, such violations are documented on Form 591 (for materials licensees)

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¹Copies of NUREG-1600 can be obtained by calling the contacts listed at the end of the Information Notice.

which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional enforcement conference may be held to discuss those actions. The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation. Typically, such reviews include:

Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.

Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the current requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide an auditable record and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns and prevent recurrence of the violation.

It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, immediate corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?
2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?
3. Have precursor events been considered and factored into the corrective actions?
4. In the event of loss of radioactive material, should security of radioactive material be enhanced?
5. Has your staff been adequately trained on the applicable requirements?
6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?
7. Has your staff been notified of the violation and of the applicable corrective action?
8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?
10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?
11. Is a system in place for keeping abreast of new or modified NRC requirements?
12. Does your staff appreciate the need to consider safety in approaching daily assignments?
13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?
14. Have work hours affected the employees' ability to safely perform the job?
15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?
16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?
17. Has management established a work environment that encourages employees to raise safety and compliance concerns?
18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?
19. Has management communicated its expectations for safety and compliance?
20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

Elizabeth Q. Ten Eyck, Director
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Donald A. Cool, Director
Division of Industrial
and Medical Safety
Office of Nuclear Material Safety
and Safeguards

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Daniel J. Holody, RI
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Gary F. Sanborn, RIV
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or non-supervisory employee), the significance of any underlying violation, the intent of the violator (i.e., careless disregard or deliberateness), and the economic or other advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation. However, if a licensee refuses to correct a minor violation within a reasonable time such that it willfully continues, the violation should be categorized at least at a Severity Level IV.

D. Violations of Reporting Requirements

The NRC expects licensees to provide complete, accurate, and timely information and reports. Accordingly, unless otherwise categorized in the Supplements, the severity level of a violation involving the failure to make a required report to the NRC will be based upon the significance of and the circumstances surrounding the matter that should have been reported. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event that it failed to report. A licensee will, on the other hand, normally be cited for a failure to report a condition or event if the licensee knew of the information to be reported, but did not recognize that it was required to make a report.

V. PREDECISIONAL ENFORCEMENT CONFERENCES

organizational structure and the individual's responsibilities relative to the oversight of licensed activities and to the use of licensed material.

Whenever the NRC has learned of the existence of a potential violation for which escalated enforcement action appears to be warranted, or recurring nonconformance on the part of a vendor, the NRC may provide an opportunity for a predecisional enforcement conference with the licensee, vendor, or other person before taking enforcement action. The purpose of the conference is to obtain information that will assist the NRC in determining the appropriate enforcement action, such as: (1) a common understanding of facts, root causes and missed opportunities associated with the apparent violations, (2) a common understanding of corrective actions taken or planned, and (3) a common understanding of the significance of issues and the need for lasting comprehensive corrective action.

If the NRC concludes that it has sufficient information to make an informed enforcement decision, a conference will not normally be held unless the licensee requests it. However, an opportunity for a conference will normally be provided before issuing an order based on a violation of the rule on Deliberate Misconduct or a civil penalty to an unlicensed person. If a conference is not held, the licensee will normally be requested to provide a written response to an inspection report, if issued, as to the licensee's views on the apparent violations and their root causes and a description of planned or implemented corrective actions.

During the predecisional enforcement conference, the licensee, vendor, or other persons will be given an opportunity to provide information consistent with the purpose of the conference, including an explanation to the NRC of the immediate corrective actions (if any) that were taken following identification of the potential violation or nonconformance and the long-term comprehensive actions that were taken or will be taken to prevent recurrence. Licensees, vendors, or other persons will be told when a meeting is a predecisional enforcement conference.

A predecisional enforcement conference is a meeting between the NRC and the licensee. Conferences are normally held in

the regional offices and are normally open to public observation. Conferences will not normally be open to the public if the enforcement action being contemplated:

- (1) Would be taken against an individual, or if the action, though not taken against an individual, turns on whether an individual has committed wrongdoing;
- (2) Involves significant personnel failures where the NRC has requested that the individual(s) involved be present at the conference;
- (3) Is based on the findings of an NRC Office of Investigations report that has not been publicly disclosed; or
- (4) Involves safeguards information, Privacy Act information, or information which could be considered proprietary;

In addition, conferences will not normally be open to the public if:

- (5) The conference involves medical misadministrations or overexposures and the conference cannot be conducted without disclosing the exposed individual's name; or
- (6) The conference will be conducted by telephone or the conference will be conducted at a relatively small licensee's facility.

Notwithstanding meeting any of these criteria, a conference may still be open if the conference involves issues related to an ongoing adjudicatory proceeding with one or more intervenors or where the evidentiary basis for the conference is a matter of public record, such as an adjudicatory decision by the Department of Labor. In addition, notwithstanding the above normal criteria for opening or closing conferences, with the approval of the Executive Director for Operations, conferences may either be open or closed to the public after balancing the benefit of the public's observation against the potential impact on the agency's decision-making process in a particular case.

The NRC will notify the licensee that

the conference will be open to public observation. Consistent with the agency's policy on open meetings, "Staff Meetings Open to Public," published September 20, 1994 (59 FR 48340), the NRC intends to announce open conferences normally at least 10 working days in advance of conferences through (1) notices posted in the Public Document Room, (2) a toll-free telephone recording at 800-952-9674, (3) a toll-free electronic bulletin board at 800-952-9676, and on the World Wide Web at the NRC Office of Enforcement homepage (www.nrc.gov/OE). In addition, the NRC will also issue a press release and notify appropriate State liaison officers that a predecisional enforcement conference has been scheduled and that it is open to public observation.

The public attending open conferences may observe but may not participate in the conference. It is noted that the purpose of conducting open conferences is not to maximize public attendance, but rather to provide the public with opportunities to be informed of NRC activities consistent with the NRC's ability to exercise its regulatory and safety responsibilities. Therefore, members of the public will be allowed access to the NRC regional offices to attend open enforcement conferences in accordance with the "Standard Operating Procedures for Providing Security Support For NRC Hearings and Meetings," published November 1, 1991 (56 FR 56251). These procedures provide that visitors may be subject to personnel screening, that signs, banners, posters, etc., not larger than 18" be permitted, and that disruptive persons may be removed. The open conference will be terminated if disruption interferes with a successful conference. NRC's Predecisional Enforcement Conferences (whether open or closed) normally will be held at the NRC's regional offices or in NRC Headquarters Offices and not in the vicinity of the licensee's facility.

For a case in which an NRC Office of Investigations (OI) report finds that discrimination as defined under 10 CFR 50.7 (or similar provisions in Parts 30, 40, 60, 70, or 72) has occurred, the OI report may be made public, subject to withholding certain information (i.e., after appropriate redaction), in which case the associated predecisional enforcement conference will normally be open to public observation. In a conference where a particular individual is being considered potentially responsible for the discrimination, the conference will remain closed. In either case (i.e., whether the conference is open or closed), the employee or former employee who was the subject of the alleged discrimination (hereafter referred to as "complainant") will normally be provided an opportunity to participate in the predecisional enforcement conference with the licensee/employer. This participation will normally be in the form of a complainant statement and comment on the licensee's presentation, followed in turn by an opportunity for the licensee to respond to the complainant's presentation. In cases where the complainant is unable to attend in person, arrangements will be made for the complainant's participation by telephone or an opportunity given for the complainant to submit a written response to the licensee's presentation. If the licensee chooses to forego an enforcement conference and, instead, responds to the NRC's findings in writing, the complainant will be provided the opportunity to submit written comments on the licensee's response. For cases involving potential discrimination by a contractor or vendor to the licensee, any associated predecisional enforcement conference with the contractor or vendor would be handled similarly. These arrangements for complainant participation in the predecisional enforcement conference are not to be conducted or viewed in any respect as an adjudicatory hearing. The purpose of the complainant's participation is to provide information to the NRC to assist it in its enforcement deliberations.

A predecisional enforcement conference may not need to be held in cases where

there is a full adjudicatory record before the Department of Labor. If a conference is held in such cases, generally the conference will focus on the licensee's corrective action. As with discrimination cases based on OI investigations, the complainant may be allowed to participate.

Members of the public attending open conferences will be reminded that (1) the apparent violations discussed at predecisional enforcement conferences are subject to further review and may be subject to change prior to any resulting enforcement action and (2) the statements of views or expressions of opinion made by NRC employees at predecisional enforcement conferences, or the lack thereof, are not intended to represent final determinations or beliefs.

When needed to protect the public health and safety or common defense and security, escalated enforcement action, such as the issuance of an immediately effective order, will be taken before the conference. In these cases, a conference may be held after the escalated enforcement action is taken.

VI. ENFORCEMENT ACTIONS

This section describes the enforcement sanctions available to the NRC and specifies the conditions under which each may be used. The basic enforcement sanctions are Notices of Violation, civil penalties, and orders of various types. As discussed further in Section VI.D, related administrative actions such as Notices of Nonconformance, Notices of Deviation, Confirmatory Action Letters, Letters of Reprimand, and Demands for Information are used to supplement the enforcement program. In selecting the enforcement sanctions or administrative actions, the NRC will consider enforcement actions taken by other Federal or State regulatory bodies having concurrent jurisdiction,