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JUL 19 1990

Docket Nos. 030-13584 and 030-31462
License Nos. 52-01946-07 and
52-01946-09(08)
EA 90-076

University of Puerto Rico
Office of the Chancellor
ATTN: Jose M. Saldana, D.M.D., M.P.H.
Medical Science Campus
G.P.O. Box 5067
San Juan, PR 00936

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES -
\$12,500 (NRC INSPECTION REPORT NOS. 030-13584/90-01 AND
030-31462/90-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted on April 2-3, 1990, at the University of Puerto Rico, of activities authorized by NRC License Nos. 52-1946-07 and 52-1946-09(08). The report documenting this inspection was sent to you by letter dated April 25, 1990. As a result of this inspection, the NRC identified significant failures to comply with NRC regulatory requirements. NRC concerns relative to the inspection findings were discussed in an Enforcement Conference held on May 3, 1990. The letter summarizing this Conference was sent to you on May 14, 1990.

The violations described in Sections I and II of the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice), include failures: to maintain control and surveillance of licensed material; of the therapy physicist to perform full calibration of the teletherapy system; to perform various types of required surveys; to perform leak tests and physical inventories for sealed sources; of the Radiation Safety Committee to perform an annual review of the radiation safety program; of the therapy physicist to review monthly spot checks of the teletherapy system; and of the Radiation Safety Officer (RSO) to review and sign records of dose calibrator tests. Although Violations F and J in Section I of the Notice were inadvertently left out of the NRC's April 25, 1990 inspection report, they were discussed with you at both the inspection close out interview and the Enforcement Conference, and therefore these violations are documented in the enclosed Notice.

The large number of violations identified during this inspection is of concern to the NRC. However, of even greater concern is your apparent inability to develop, implement, and maintain an adequate management oversight program to assure lasting corrective actions for previously identified radiation safety program deficiencies. Your inability to assure lasting corrective action is demonstrated by the fact that Violations C, D, E, G, H, and I in Section I and Violations A and B in Section II of the Notice have been previously

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identified during inspections in 1985, 1987, or 1989. Repetitious violations are of particular concern and cannot be tolerated. The NRC expects its licensees to take effective and lasting corrective actions when violations are identified.

Violation C in Section I of the Notice, failure to maintain constant surveillance and immediate control of licensed material in an unrestricted area, is a safety significant violation, and could be considered for separate action. However, the NRC considered all the violations in Section I of the Notice collectively, as they are indicative of lack of management control and supervisory oversight of your nuclear medicine program, as well as lack of an effective audit program to detect and correct violations of NRC requirements. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), 10 CFR Part 2, Appendix C, the violations in Section I of the enclosed Notice are classified in the aggregate as a Severity Level III problem.

Violation B in Section II, failure of the qualified and NRC authorized Teletherapy Physicist to perform the annual calibration of the teletherapy system was previously cited in NRC inspections of September 1987, April 1989, and August 1989. This violation is of significant concern to the NRC because in your response to the NRC's September 30, 1987, Notice of Violation, involving the failure of the teletherapy physicist (qualified expert) to perform the annual full calibrations conducted on June 9, 1986 and June 9, 1987, you stated (in the letter dated October 29, 1987) that the individual who performed the annual calibration "... does not meet the minimum academic requirements as stated in 10 CFR 35.961." The letter further stated that your corrective action included "...the appointment of a half time teletherapy physicist as defined by the new 10 CFR Part 35, paragraph 35.691 with the specific duty of performing full calibration measurements every year..." that "...We do not foresee any further violation in this respect," and that "...Full compliance is expected for January 15, 1988." Notwithstanding, your stated corrective actions were ineffective, as you did not assure that a Therapy Physicist qualified in accordance with 10 CFR 35.691, and authorized by the NRC by name on License No. 52- 01946-09(08) performed the annual full calibrations of the teletherapy unit on June 9, 1988 and June 9, 1989. In fact, the teletherapy physicist did not perform a full calibration of the teletherapy unit until April 6, 1990, three days after the NRC's April 2-3, 1990 inspection. The calibrations prior to April 6, 1990, were performed by the same individual you stated in your October 29, 1987 letter, did not meet the qualifications in 10 CFR 35.691, and was later denied authorization to be the Therapy Physicist by the NRC on July 26, 1989, in response to your requests for an exception to 10 CFR 35.961, dated April 13, 1987 and January 29, 1988. This violation, which could have been considered for separate action, was considered collectively with Violations A and C in Section II of the Notice as they are associated with your teletherapy program. Collectively these violations demonstrate a significant failure to assure that the duties of the Therapy Physicist are performed by a qualified and authorized individual. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), 10 CFR Part 2, Appendix C, the violations in Section II of the enclosed Notice are classified in the aggregate as a Severity Level III problem.

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To emphasize the need for stronger management oversight, more effective controls of your licensed radiation program, and to assure a qualified and NRC authorized individual performs the duties of the Therapy Physicist, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$12,500 for the violations described in Sections I and II of the enclosed Notice. The base value of a civil penalty for a Severity Level III problem is \$2500. The escalation and mitigation factors in the Enforcement Policy were considered for each Severity Level III problem.

For the Severity Level III problem in Section I of the Notice, the base civil penalty has been increased by 50 percent because the violations were identified by NRC. Had an effective management review program been implemented, these violations may have been identified and corrected internally. The base civil penalty has also been increased by an additional 100 percent because of your poor past performance. In addition to the repetitive violations discussed above, 32 violations have been identified during NRC inspections over the past three years. As a result of the NRC's concerns about implementation of your management controls, an enforcement conference was held with you on April 15, 1987. However, violations continued to occur, including an employee over-exposure of 1.82 rem which occurred during the third quarter of 1989. For the Severity Level III problem in Section II of the Notice, the base civil penalty has also been increased by 50 percent because the NRC identified the violations and by an additional 100 percent because of your poor past performance. Neither escalation nor mitigation of the base civil penalty for the violations in Section I or II of the Notice was warranted for your corrective action to prevent recurrence. Although it was considered comprehensive, it was not prompt. The planned actions which you described at the enforcement conference, if effectively implemented, should substantially improve your safety program. These actions include retaining a new teletherapy physicist and minimizing the teaching responsibilities of the Radiation Safety Officer (RSO) in order that he may apply more time and attention to the RSO duties, and assigning an experienced technician to perform more radiation safety functions, as well as certain procedural and facility changes. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty of the violations in Sections I and II of the Notice is considered appropriate.

Therefore, based on the above, the base civil penalty of each Severity Level III problem in the enclosed Notice has been increased by 150 percent.

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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In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

[Faint signature]

Stewart D. Ebnetter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

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