

September 10, 1996

EA 96-154

José L. Fernández, M.D.
Ponce de León 160
San Juan, Puerto Rico 00901

SUBJECT: NRC INSPECTION REPORT NO. 52-25144-01/96-01

Dear Dr. Fernández:

This refers to the inspection conducted on August 7 and 9, 1996, at your San Juan and Mayagüez, Puerto Rico facilities. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with you and those members of your staff identified in the enclosed report, and were subsequently discussed on September 6, 1996, in a telephone conversation held between W. Martínez from your office and J. Díaz Vélez from my staff; and on September 11, 1996, in a telephone conversation between Mr. Díaz Vélez and you.

The inspection identified that you failed to correct for decay, the surface dose rate of your strontium-90 eye applicator used in your San Juan office, which resulted in the misadministration of seven dose fractions to six patients. In addition, the inspection identified two apparent violations of NRC requirements. The apparent violations involved the failure of the licensee to maintain, under 10 CFR 35.32(a), a Quality Management (QM) program that provided high confidence that Sr-90 doses would be administered as directed, and the Radiation Safety Officer's failure to investigate under 10 CFR 35.21(b)(1), misadministrations that occurred at your San Juan, Puerto Rico facility.

The apparent violations are under review by the NRC for escalated enforcement action in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600. Accordingly, no Notice of Violation is presently being issued for these apparent violations. In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review.

We are providing you this report at this time for information purposes only. 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, its enclosure, and any reply will be placed in the NRC Public Document Room.

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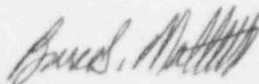
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José L. Fernández, M.D.

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

Sincerely,




Bruce S. Mallett, Director
Division of Nuclear Materials Safety

Docket No. 030-31873
License No. 52-25144-01

Enclosure: NRC Inspection Report
No. 52-25144-01/96-01

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