



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

30-31873

June 13, 1996

EA 96-154

José L. Fernández, M.D.
P. O. Box 3310
Mayagüez, Puerto Rico 00681

Dear Dr. Fernández:

This letter is in reference to the NRC inspections conducted at your Mayagüez, Puerto Rico, facility on October 18, 1995, and April 8-10, 1996. During the inspections, several violations of NRC requirements were identified, including a violation involving numerous patient misadministrations which occurred due to an improperly calibrated strontium-90 eye applicator during the period January 1994 through October 1995.

The NRC issued to you a Confirmatory Action Letter (CAL) on February 9, 1996, to confirm, in part, that you would: (1) review, within 30 days, all patient radiation dose administrations performed at the Mayagüez office to identify any medical misadministrations; and (2) maintain the strontium-90 sources in safe storage and refrain from using them until otherwise authorized by the NRC. However, you failed to adequately review all patient radiation dose administrations in that you have been unable to provide the NRC reliable and complete information concerning the patient misadministrations which occurred during the period January 1994 through October 1995.

Based on a June 11, 1996, discussion between Douglas Collins, Deputy Director, Division of Nuclear Materials Safety and you, we understand that you plan to hire an independent Health Physicist/Radiation Physicist consultant with expertise in therapy dosimetry calculations to perform a review of your patient administration records to identify all misadministrations, to assess the completeness and accuracy of misadministration records, to determine if any unauthorized uses of byproduct material have occurred, and to assist you in submitting a report to the NRC on the results of these reviews. In view of the June 11, 1996, discussion and your facsimile letter of June 11, 1996, to John Potter, Chief, Materials Licensing/Inspection Branch 2 confirming the above discussion, the NRC would like to receive, within 30 days of the date of this letter, the credentials of such consultant and a schedule for completion of such review. The consultant's credentials and the schedule for completion should be sent to the Regional Administrator, NRC Region II, 101 Marietta St., NW, Suite 2900, Atlanta, GA 30323-0199. Upon review of the consultant's credentials and the schedule for completion, the NRC will consider issuing a confirmatory order confirming your commitments.

The February 9, 1996 CAL confirmed your agreement to discontinue use of your licensed material and place it in safe storage until resolution of the safety issues and receipt of notification from the NRC to the contrary. To date, the NRC has not permitted you to resume use of the strontium-90 eye applicators. Additionally, your authority to use the applicators (licensed material) is now

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also prohibited by 10 CFR 30.36 because you permitted your license to expire on February 28, 1996. You must continue to maintain your licensed material in safe storage pending resolution of these issues as well as NRC action on your application for a new license dated April 9, 1996. Willful violation of 10 CFR 30.36 may subject you to criminal prosecution, pursuant to Section 223 of the Atomic Energy Act of 1954, as amended. A violation of that section may also subject you to a civil monetary penalty.

Questions concerning this letter should be addressed to me or Douglas Collins at 404-331-5514.

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

Sincerely,

Douglas M. Collins

for

Bruce S. Mallett, Director
Division of Nuclear Materials Safety

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

J. Fernández

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