June 11, 1997

EA 97-137

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

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $8,000 (NRC INSPECTION REPORT NOS. 52-25114-01/95-01 AND 96-01 AND NRC ORDER MODIFYING LICENSE NO. 52-25114-01)

Dear Dr. Fernández:

This letter transmits a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) associated with the conduct of activities authorized under your Nuclear Regulatory Commission (NRC) License No. 52-25114-01. This action is based on inspections conducted on October 18, 1995, April 8-10, 1996, and August 7 and 9, 1996, and your actions in response to the "Order Modifying NRC Materials License No. 52-25114-01," (Order) issued by the NRC on October 21, 1996. Also, on March 31, 1997, as required by the Order, you submitted a report to the NRC discussing the results of your consultant's review of patient records, your enumeration of the number of misadministrations, and the status of patient and NRC notifications. The results of NRC's review of the issues associated with the subject documents were formally transmitted to you by letter dated April 11, 1997. That letter also provided you an opportunity to either respond to the apparent violations in writing or request a predecisional enforcement conference. Subsequently, you declined a conference and indicated your intention to respond to the apparent violations in writing. On May 9, 1997, you submitted additional information to us regarding the apparent violations, the reasons for the violations, and the corrective steps that had been taken, as requested in our letter dated April 11, 1997. We have reviewed the inspection results and the additional information you provided and have concluded that sufficient information is available to determine the appropriate enforcement action in this matter.

Based on the information developed during the inspections, your actions associated with the October 21, 1997, Order, and the information that was provided in your March 31 and May 9, 1997, submittals, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), and the circumstances surrounding them are described in detail in the previously referenced documents.

The violations involved numerous failures to comply with regulatory requirements and the conditions of your NRC license and included the following: (1) the failure to establish a Quality Management Program (QMP) for the administration of strontium-90 (Sr-90) brachytherapy doses; (2) the failure to appropriately secure and/or control licensed material located in an

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unrestricted area; (3) the failure to limit use of licensed material to only those individuals authorized to use licensed material by your NRC license; (4) the failure to notify three patients of misadministrations to them within 24 hours of discovery; (5) the failure to provide a written report to three individuals regarding misadministrations to them and the potential consequences of the misadministration within 15 days of discovery; (6) the failure to leak test sealed sources at six-month intervals; (7) the failure to conduct a physical inventory of brachytherapy sources every calendar quarter; (8) the failure to transfer licensed material to an authorized recipient; and (9) the failure to transfer licensed material within the 90 days specified in NRC's Order of October 21, 1996.

In your response dated May 9, 1997, you admitted the violations with the exception of Violation B related to the security of licensed material. In your response, you stated that the source was always kept in a locked room and that a key was maintained in a secure place in the administration office of the Mayagüez clinic. In evaluating your position, the NRC considered the circumstances of the violation and noted the following: (1) at the time of the October 18, 1995, inspection, the Sr-90 source was located in a small, unlabeled box; (2) the box containing the source was locked; however, it was located in an unlocked storage room which was accessible to clinic staff; and (3) although entry to the storage room was somewhat controlled by the presence of a receptionist, surveillance of the storage room was not constant such that access to the source was possible by unauthorized clinic staff, patients, and members of the public. Based on discussions with the clinic staff, these were also the same circumstances of source storage during the period January 1994 through October 1995, with the key to the storage box being placed in the possession of an individual who was not knowledgeable of source control requirements (and who apparently permitted access to the source by an unauthorized user). For these reasons, the NRC concluded that Violation B should be cited as originally described in our letter of April 11, 1997.

Several of the violations in the enclosed Notice stemmed from the failure to assure that one of your eye applicators containing Sr-90 and used for patient eye treatment was properly calibrated. As a consequence, more than 200 misadministrations occurred during the period January 1994 through October 1995. Eye doses to these patients were determined to be more than two times greater than the intended dose, with the maximum being approximately 13,600 centigrays. Although the ultimate health impact of the overexposures to the patients is not fully known at this time, the violations are of very significant regulatory concern. The NRC would have expected you would have acquired the calibration certificate for the Sr-90 eye applicator or had the device output determined by an accredited testing facility, rather than relying on the information labelled on the box. The violations represent a significant lack of program oversight and are clearly indicative of your careless disregard for regulatory requirements.

As delineated in the Notice, the violations are not isolated to one program area (i.e., the failure to have a QMP); they encompass numerous facets of your NRC regulated brachytherapy program. Notwithstanding the programmatic scope of the identified noncompliances, your overall record of poor performance prior to and after identification of these issues further reflects the lack of

importance you placed on regulatory compliance. Examples of this lack of regard include: (1) your failure to verify the output of the Sr-90 source prior to using it for brachytherapy treatments, even though no certification or traceable calibration was available to support the annotated source output; (2) your failure to establish and implement a QMP by July 1994 when the requirement became effective; (3) your failure to establish and implement a QMP as advised in Information Notice (IN) 94-17, "Strontium-90 Eye Applicators: Submission of Quality Management Plan (QMP), Calibration, and Use," dated March 11, 1995, a notice you acknowledged receiving; (4) your lack of rigor in the initial reviews of patient records to identify the total number of misadministrations which necessitated an NRC Order for you to obtain an independent consultant to accurately complete the review; (5) the protracted period of time you needed to contract the services of a qualified consultant to perform the records review; (6) your delay in transferring both of your Sr-90 sources when required to do so by an NRC Order; and (7) your failure to transfer the two Sr-90 sources to an authorized recipient.

The NRC distinguishes between the unavoidable risks attendant in properly following prescribed procedures and the unacceptable risk of improper or careless use of licensed material. The NRC is responsible, as part of its public health and safety mission, for establishing and enforcing regulations that protect the public from the risk of improper and careless use of licensed material. Therefore, based on the circumstances described above, the violations are classified in the aggregate in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, as a Severity Level II problem.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $4,400 is considered for a Severity Level II problem occurring on or continuing after November 12, 1996 (61 Federal Register 53554). However, since most of the violations occurred prior to November 12, 1996, the base civil penalty considered for this case is $4,000 (NUREG-1600, July 1995). In accordance with the civil penalty assessment process described in Section VI.B.2 of the Enforcement Policy, the NRC considered whether credit was warranted for the factors of Identification and Corrective Action. The NRC determined that credit for Identification was not warranted in that the violations cited in the Notice were identified by NRC. Regarding Corrective Action, since October 1995, you obtained a source calibration for the eye applicator located at the Mayagüez clinic; discontinued use of both Sr-90 sources possessed under your NRC license; submitted a QMP to the NRC; completed a review of the total number of misadministrations; reported the records review results to patients and the NRC; and implemented the actions described in your March 31 and May 9, 1997, responses. Based on the above and the fact that significant NRC involvement and intervention[1] were required to ensure that actions were appropriately completed, the NRC concluded that

[1] This involvement included October 19, 1995, and February 9, 1996, Confirmatory Action Letters, an October 21, 1996, Order Modifying License, and numerous pieces of correspondence, indicating the need for you to comply with regulatory requirements.

credit was not warranted for Corrective Action which results in a civil penalty assessment of two times the base amount.

Therefore, to emphasize the importance of conducting safe and compliant brachytherapy programs and the need for prompt and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $8,000 for the Severity Level II problem.

Also, please be aware that, contrary to the statements in your March 31 and May 9, 1997, letters to the NRC, your NRC byproduct material License No. 52-25114-01 has not been terminated, although it expired on February 28, 1996. We recognize that you transferred your licensed material pursuant to the October 21, 1996, Order and that your August 20, 1996, letter to Mr. José Díaz Vélez of the NRC Region II office indicated your intent to terminate the license. However, in accordance with 10 CFR 30.36(c), your license is not terminated until NRC formally notifies you in writing of such termination. We will address this matter in future correspondence.

The NRC has concluded that information regarding the reason for the violations and the corrective actions taken are already adequately addressed on the docket in your letters to the NRC dated March 31 and May 9, 1997. Therefore, you are not required to comply with the provisions of 10 CFR 2.201 unless the description therein does not accurately reflect your actions or position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice. You are, however, required to respond to the proposed imposition of civil penalty and should do so in accordance with the instructions in the enclosed Notice.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and any response you may provide will be placed in the NRC Public Document Room (PDR).

Sincerely,

Original Signed by
Luis A. Reyes

Luis A. Reyes
Regional Administrator

Docket No. 030-31873
License No. 52-25114-01

Enclosure: Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl: (See Page 5)

cc w/encl:
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Board of Medical Examiners

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