September 18, 1996

EA 96-154

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

SUBJECT: MANAGEMENT MEETING ANNOUNCEMENT - DOCKET NO. 030-31873

Dear Dr. Fernández:

This letter confirms the telephone conversation between you and Mr. José Díaz Vélez of this office concerning a management meeting which has been scheduled for Friday, September 27, 1996, at 8:30 a.m., at the Sands Hotel, Isla Verde, Puerto Rico. On multiple occasions this year, we have requested you to obtain an individual, independent of your organization, to identify all misadministrations and notify patients as a result of your use of a miscalibrated strontium-90 applicator. As indicated in our August 7, letter, you have not completed this action to date. The purpose of this September 27, meeting is for you to discuss 1) the reasons why you have not completed actions to identify all misadministrations and notify patients, and 2) the steps you will take to accomplish these actions and when they will be completed. This should include your progress in obtaining the services of a consultant to perform a complete patient record review, to identify misadministrations, to identify potential unauthorized use of radioactive materials, and to report the results to NRC.

We plan to discuss options available to the NRC to address 1) your lack of completion of the actions described above and 2) the apparent violations identified in the June 6 and September 10, 1996 inspection reports to you. This meeting will not be open to the public, since it would result in an inappropriate disclosure of preliminary information. This is in accordance with "Staff Meetings Open to the Public; Final Policy Statement" (September 20, 1994; 59 FR 48340).

Should you have any questions concerning this meeting, please contact me at (404) 331-5514.

Sincerely,

Bruce S. Mallett, Director
Division of Nuclear Materials Safety

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

Enclosure: CAL dated February 9, 1996

cc w/encl: Commonwealth of Puerto Rico

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-25114-

February 9, 1996

CAL No. 2-96-003

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

SUBJECT: CONFIRMATORY ACTION LETTER

Dear Dr. Fernández:

This is in reference to the information you provided on February 8, 1996 to the NRC regarding the recalibration of your strontium 90 eye applicator as a result of the NRC inspection of your facility conducted on October 18, 1995. This recalibration shows the dose rate from the source is 53 cGy per second rather than the 24 cGy per second you used for administrations. This indicates that there could have been misadministrations resulting from use of this source.

Pursuant to a telephone conversation between you and Douglas M. Collins, Deputy Director, Division of Nuclear Materials Safety, on February 9, 1996, it is our understanding that you have taken (or will take) the following actions (which will be completed by the dates specified):

1. Review all patient radiation dose administrations at your Mayagüez office to identify medical misadministrations, if any, within 30 days.

2. If you identify any misadministration, comply with the requirements of 10 CFR 35.33 "Notifications, reports, and records of misadministrations" (within the time frame specified in the regulation) which include:

   a. Notify the NRC Operations Center (301-816-5100) no later than the next calendar day of the discovery of any misadministration, and

   b. Notify the referring physician and the patient of the misadministration no later that 24 hours after its discovery, unless the referring physician personally informs the licensee (you) either that he or she will inform the patient or that, based on medical judgment, telling the patient would be harmful, and

   c. Submit a written report to this office, including the licensee's name (your name); prescribing physician (the authorized user); a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian and if not, why not; and if the patient was notified, what information was provided to the patient. The report must not include the patient's name, or other information that could lead to identification of the patient, and

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Enclosure

d. If the patient was notified of the misadministration, you will furnish (within 15 days after the discovery of the misadministration) a written report to the patient by sending either: (1) a copy of the report submitted to the NRC; or (2) a brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the licensee, and

e. Create and retain a record of each misadministration for five years. This record must contain: (1) the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician); (2) the patient's social security number or identification number, if one has been assigned; (3) a brief description of and reason for the misadministration; (4) the effect on the patient; and (5) actions and improvements taken to prevent recurrence.

3. Maintain your strontium 90 sources in safe storage and refrain from using them, until you receive notification from this office indicating that you can resume operations.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, you are required to:

1. Notify me immediately if your understanding differs from that set forth above;

2. Notify me if for any reason you cannot complete the actions within the specified schedule and advise me in writing of your modified schedule in advance of the change; and

3. Notify me in writing when you have completed the actions addressed in this Confirmatory Action Letter.

Issuance of this Confirmatory Action Letter does not preclude issuance of an order formalizing the above commitments or requiring other actions on the part of the licensee; nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Sincerely,

(original signed by
D. M. Collins)

Bruce S. Mallett, Director
Division of Nuclear Materials Safety

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

Enclosures: 1. NRC Information Notice 93-04
2. NRC Information Notice 93-36
3. 10 CFR 35
4. 10 CFR 30

cc w/encls:
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