

March 3, 1998

CAL No. 2-98-001

Miguel A. Santiago Garcia, M.D.
Call Box 990
Hato Rey, PR 00919-0990

SUBJECT: CONFIRMATORY ACTION LETTER

Dear Dr. Santiago Garcia:

This is in reference to preliminary findings from an NRC inspection conducted on March 3, 1998, which identified your conduct of ophthalmic radiotherapy without a calibration certificate for your strontium 90 (Sr-90) eye applicator.

Pursuant to a telephone conversation between Mr. Edward McAlpine of this Office, and you on March 3, 1998, it is our understanding that you have taken (or will take) the following actions (which will be completed by the dates specified):

1. Effective immediately, you will suspend the use of your strontium-90 eye applicator and will place it in safe storage.
2. You will not use the Sr-90 eye applicator until you submit a copy of the original calibration certificate to this office or have the Sr-90 eye applicator calibrated by an accredited laboratory and submit a certificate for that calibration to this office.
3. If the source strength, based on either decay calculations from the calibration certificate value or from the re-calibration should differ more than ± 10 percent from the previously used value, review all patient radiation dose administrations at your Carolina office to identify medical misadministrations, if any, within 30 days.
4. 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 than 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

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- 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
- 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.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, and 10 CFR 2.204, 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.

Dr. Santiago Garcia

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

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

If you have any questions, please call me at (404) 562-4700.

Sincerely,

*original signed by
E. McAlpine for:*

Douglas M. Collins, Director
Division of Nuclear Materials Safety

Docket No. 030-33153
License No. 52-25245-01

cc: Commonwealth of Puerto Rico

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