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· PDR

March 31, 1997

Regional Administrator
U.S. Nuclear Regulatory Commision
Region 11
101 Marietta St., N.W.
Suit 2900
Atlanta, GA. 30323-0199

Updated/Final Report
Order Modifyding License 52-25114-01

Licensee name
José L. Fernández

License no.
52-25114-01

UPDATED FINAL REPORT

Description of the event

Pterygium patients were treated with a Sr-90 source incorrectly calibrated as having an output of 24cGy per second while the correct output was 53cGy per second. The correct output was determined by Dupont which acquired the source manufacturer. These patients received a therapy dose of more than 20% higher than the prescribed dose. This resulted in a misadministation as defined in 10CFR35.33 (2) (ii). As a matter of fact the excess applied dose was 2.2 times the prescribed dose.

Effect on the patients

Cataract, Scleromalasia or damage to the cornea are typically associated with excessive radiation exposure to the eye. We are of the opinion that no major advise effects have resulted as of now. All exposed patients, have been requested, if they wish, to report to

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office in order to be examined free of charge, as explained in our comunication to them.

Summary of all misadministrations

In the first written report to NRC pursuant to 10CFR35.33 (a) (2), seventy-one (71) patients were reported. All of them were notified of the misadministration both by telephone and, first by regular mail, and them by certified mail. The certified mail receipt is attached to the record. During an NRC visit on April 8-10, 1996, a group of another sixteen (16) patients were discovered. During the period of January 1994 through October 1994 another group of seventeen (17) patiens were identified for a total of one hundred four (104) misadministration patients identified up to that moment. All of these patients have had their misadministration doses calculated and documented. All of them were notified as required by 10CFR35.33 (a) (3). The records containing all the information of the misadministration and notification will be maintained in our office for five (59) years as required by law.

In our search, for all pterygium patients, forty nine (49) additional misadministration patients were found for the period of January 1994 through October 1995. These patients were not included in the previous ones notified to NRC, but all of them were notified by certified mail and by telephone. The certified mail receipt is attached to the record. Both the misadministration calculations and notifications to the patients have been performed and documented. The consultant reviewed all of the misadministrations calculations and found them correct and accurate. The details of each case is contained in the patient record. At the beginning of the week of March 24 through the 28th, 1997, new records which not were present in our computer records, were found These records were distributed from January 1994 through October 1995. The

misadministration doses were calculated and documented for each one and we proceeded to notify the patients within 24 hours by telephone and at the same time the same letter was submitted by certified mail. The NRC office in Atlanta was notified by telephone on Monday, March 24, 1997. We hope this final report will satisfy the requirements of notifyding NRC in 15 days. As in the previous cases, all the misadministration calculations were reviewed by the consultant as well as the notification records. The records will be maintained in our office for at least five (5) years as required by law. In some instances the telephone number in our records was no longer in service , no one answer or the number did not belong any longer to the patient. This information is recorded in the record. Since the written notification was submitted the same day of the intended telephone call, all the patients were informed promptly.
Up to the present time we have identified a total of ninety six (96) misadministration patients for the covering January 1st througth December 31, 1994 and one hundred six (106) patients for the period of January 1st, 1995 through October 31, 1995 for a grand total of two hundred two (202) patients for the whole period. We believe that this is the entire and final number of patients treated with the beta source during this period at my Mayagüez office.

Improvements to prevent recurrence

No further misadministration will occur since, per our request, License 52-25114-01 was terminated. The beta source were transfered to an authorized user, Dr.Rafael Cavero on New York City on ____/ /97 & / /97.

José L. Fernández, MD
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