U. S. NUCLEAR REGULATORY COMMISSION

REGION II

Docket No.:	030-31873
License No.:	52-25114-01
Report No.:	96-01
Licensee:	José L. Fernández, M.D.
Location:	San Juan, Puerto Rico
Date:	August 7 and 9, 1996
Inspector:	José M. Díaz Vélez, Radiation Specialist Materials Licensing/Inspection Branch 2 Division of Nuclear Materials Safety
Approved by:	John P. Potter, Chief Materials Licensing/Inspection Branch 2 Division of Nuclear Materials Safety

Enclosure

Executive Summary

This routine, announced inspection was conducted to evaluate the licensee's materials program implemented at the San Juan, Puerto Rico Facility, and to review the licensee's accomplishment regarding patient notification from the Mayagüez facility in reference to previous inspection findings (See NRC Inspection Report No. 52-25114-01/95-01).

Patient Notification

The inspection determined that 33 percent (one of three) of Mayagüez's office patients contacted by the licensee on August 9, 1996, indicated that no notification about the misadministration had been received by them.

Use of Materials

The inspection determined that no use of the Strontium-90 eye applicators had occurred since October 19, 1995.

Additional Misadministrations, Root Cause and RSO's Investigation

The inspection determined that additional misadministrations (seven fractions administered to six patients) occurred at the San Juan Office. The misadministrations occurred because the licensee failed to adequately correct for decay the surface dose rate of the Strontium-90 eye applicator used. In particular the device was corrected for decay in 1982, and used until October 12, 1995 without any further correction.

Two apparent violations of NRC requirements were identified during the inspection. The violations included 1) the failure to maintain under 10 CFR 35.32(a) a Quality Management (QM) program that provided high confidence that Sr-90 doses would be administered as directed, and 2) the Radiation Safety Officer's (RSO's) failure to investigate misadministrations as required by 10 CFR 35.21.

Persons Contacted

C. Calcador, Administrator (San Juan Office)*
A. Dominici, Nurse*
W. Martínez, Administrator (Mayagüez Office)*x#
F. Maestre, M.D., Associate Physician
J. Fernández, M.D., Authorized User@

*Present during exit meeting held in San Juan office (August 7, 1996)
xPresent during exit meeting held in Mayagüez office (August 9, 1996)
#Contacted by telephone on September 6, 1996
@Contacted by telephone on September 11, 1996

Report Details

1.0 Management Oversight and RSO Duties

10 CFR 35.21 requires, in part that the RSO investigate misadministrations. Although previous inspections conducted at the licensee's Mayagüez's facility on October 18, 1995 and April 8-10, 1996 identified multiple issues of non-compliance and misadministrations (See NRC Inspection Report No. 52-25114-01/95-01), the scope of the licensee's RSO investigation of misadministrations, was not expanded to review the limited number (6) of cases treated in the San Juan office. The failure of licensee's RSO to investigate misadministrations at the San Juan office was identified as an apparent violation of 10 CFR 35.21.

2.0 Organization and Scope of the Licensee Program

License No. 52-25114-01 was issued on March 22, 1991, and amended on January 14, 1994. The license authorized the possession and use of byproduct materials (Strontium-90 eye applicator device) for the medical treatment of superficial eye conditions as identified in 10 CFR 35.400(e). The initial place of use was at 160 Ponce de Leon Avenue, Puerta de Tierra, San Juan, Puerto Rico, and the January 14, 1994 amendment incorporated the use of licensed material at La Palma Building, Suite 1-A, Peral-De Diego Street, Mayagüez, Puerto Rico and incremented the possession limits to two sources not to exceed 5.56 Giga bequerels (Gbq). The license exclusively authorized the use of byproduct materials by an specified individual, who also fulfills RSO duties. The inspector discussed with licensee personnel the organizational structure of the operations conducted at the San Juan office and determined that the RSO was the unique authorized user of licensed material under License No. 52-25114-01. Also based on discussions with licensee personnel, and review of patient dose administration records, the inspector determined that the scope of the licensee's program at the San Juan office was very small, in that only seven administrations had occurred since November 1994. Also the inspector reviewed licensee records and determined that the licensee had not conducted licensed activities since October 19, 1995.

3.0 Facilities

License Condition No. 16 of License No. 52-25114-01 requires, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated December 13, 1990, and the letters dated February 26, 1991 and January 12, 1994, including any enclosures. Item 10.D. of the license application dated December 13, 1990 for License No. 52-25114-01, requires that the location of the Strontium-90 eye applicator while in it's storage box, will be in a locked cabinet in an examining room inside the licensee's facility. The inspector reviewed the licensee's San Juan facility and observed that the licensee stored the Strontium-90 eye applicator as stated in the license application. Based on those observations, the inspector determined that licensee's San Juan facility was appropriate for the scope of the licensed program. Specifically the inspector verified that measures established by the licensee were adequate to secure

licensed materials and prevent members of the public from receiving doses in excess of the limits specified in 10 CFR 20. No items of non-compliance were identified in this area.

4.0 Materials Receipt, Transfer and Control

10 CFR 30.41(a) and (b)(5) require, in part, that no licensee transfer byproduct material except to a person authorized to receive such byproduct material under the terms of a specific or general license issued by the Commission or Agreement State. The inspector interviewed licensee personnel, reviewed licensee records and determined that no material has been received or transferred since April 15, 1991, to and from the licensee's San Juan office. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. The inspector verified that the licensee has kept the sources at both offices under secured storage since October 19, 1995 (no use of material). No items of non-compliance were identified in this area.

5.0 Training, Retraining and Instructions to Workers

10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses. The inspector interviewed licensee personnel and determined that general training had been given to the worker present (nurse) during pterygium surgeries, although only the authorized user was involved in licensed activities. No items of non-compliance were identified in this area.

6.0 Radioactive Waste Management

10 CFR 35.92 states that, licensees can hold byproduct material with a physical half life of less that 65 days for decay-in-storage before disposal if they comply with some requirements specified therein. Strontium-90 physical half life is approximately 28.8 years, therefore any disposition of such devices will not be covered under the provisions of 10 CFR 35.92, but rather by the provisions under 10 CFR 20 Subpart K-Waste Disposal. The inspector interviewed licensee personnel, reviewed licensee records and determined that the licensee had not generated any radioactive waste. The licensee understands that both sources are still within the clinical use life, therefore they were not considered waste, but in storage. No items of non-compliance were identified in this area.

7.0 Record keeping for Decommissioning

10 CFR 30.35(g) requires, in part, that each person licensed under parts 32 through 35 of this chapter keep records of information important to the safe and effective decommissioning of the facility until the license is terminated by the Commission. The

inspector reviewed licensee records and determined that the licensee had maintained appropriate records to conduct an effective decommissioning of both facilities. No items of non-compliance were identified in this area.

8.0 Posting and Labeling

10 CFR 19.11 requires, in part, that each licensee post current copies of the regulations in part 19, 20, the license, license conditions or documents incorporated into a license by reference, and amendments thereto, operating procedures, or a notice describing the document and where it may be examined. 10 CFR 20.1902(e) requires that the licensee post a room in which the amount of used or stored material exceeds 10 times the quantity of such material specified in appendix C to part 20 with a conspicuous sign bearing the radiation symbol and the words "Caution, Radioactive Material." 10 CFR 21.6 requires, in part, that the licensee post a copy of the Section 206 of the Energy Reorganization Act of 1974. The inspector observed licensee's San Juan facility, and verified that all the necessary postings and labeling were properly done. Specifically the inspector verified that postings required by 10 CFR 20 and 19 and 21 were performed. No items of non-compliance were identified in this area.

9.0 Misadministration

a. Misadministration Event

10 CFR 35.2 defines a "recordable event" as an administered dose differing from the prescribed dose by more than ten percent. "Misadministrations" are defined as doses differing by more than 20 percent from that prescribed. In order to prevent a dose difference of 10 or 20 percent, brachytherapy sources must be corrected for decay. For Strontium-90 eye applicators, surface dose rate would have to be corrected for decay at intervals no greater than four years, to prevent deviations in dose administrations that result in recordable events (deviations of ± 10 percent), and should be corrected for decay at intervals no greater than nine years, to prevent deviations in dose administrations that result in misadministrations (deviations of ± 20 percent).

The inspector observed on a label attached to the source storage box, that a former health physics consultant to the licensee, documented a decay correction of the Strontium-90 eye applicator surface dose rate when performed in 1982. The inspector interviewed licensee personnel, reviewed dose administration records and determined that the licensee failed to correct for decay the Strontium-90 eye applicator surface dose rate since 1982. The inspector noted that approximately 13 years had elapsed between the 1982 calibration and the latest patient treatment conducted at the San Juan's office. The inspector determined that the decay correction factor for such a lapse of time was approximately 0.730, therefore a deviation (underdose) of more than 20 percent occurred at least on the last patient treated by the licensee. The inspector determined that six patients who received seven fractions were

underdosed by the licensee. The licensee concurred with the inspector findings and notified the NRC's Operation Center while the inspector was on site.

b. Immediate Cause

The inspector verified patient dose calculations and determined that the licensee's methodology was correct, however, an erroneous dose rate used resulted in erroneous treatment times, which resulted in total doses to be delivered in error. The inspector determined that the immediate cause of the event was the licensee's failure to properly correct for decay the Strontium-90 eye applicator surface dose rate before it's use for clinical treatment. This is another example of the licensee's failure to use correct dosimetric data to calculate the exposure time for the administration of radiation doses, which was similar to the immediate cause of the event described in the NRC Inspection Report No. 52-25114-01/95-01.

c. Contributing Factors

The inspector questioned licensee personnel as to why no corrections had been performed to the dosimetric data in such a long time and determined that corrections of the Strontium-90 eye applicator surface dose rate to account for decay, were normally performed by a former Health Physics Consultant who retired and did not offer his services any more. The licensee's lack of assistance from an individual with knowledge on how to decay correct a source surface dose rate was identified by the inspector as a contributing factor to the event. The inspector determined that the licensee's lack of a QM program (as previously identified in NRC's Inspection Report No. 52-25114-01/95-01) played a significant role in the licensee's failure to identify correctness of the dosimetric data. The licensee's lack of a QM program was identified as a contributing factor to the event. This is another example of the licensee's lack of a QM program, which was an apparent violation identified in the above referenced report.

d. Immediate and long term corrective actions

As of August 9, 1996, the licensee was prohibited from normal operations since October 19, 1995 due to a Confirmation of Action Letter (CAL), and by 10 CFR 30.36 due to an expired license. On August 20, 1996, the licensee notified the NRC of the intention to terminate the license, therefore, corrective actions required to prevent additional misadministration may not be needed since the licensee is not currently involved in use of the byproduct material and intends to terminate the license.

e. Notifications, Reports and Misadministration Records

10 CFR 35.33 require that for misadministrations, the licensee notify by telephone the NRC's Operation Center no later than the next calendar day

after the discovery of the misadministration. The licensee became aware of the misadministrations on August 7, 1996 and notified the NRC's Operations Center about the misadministrations on the same day. 10 CFR 35.33 requires that for misadministrations, the licensee notify the patient (with some exceptions therein) in writing within 15 days of the discovery of the misadministration. The licensee notified the six patients in writing about the misadministrations on the week of August 15, 1996.

While in the Mayagüez office (on August 9, 1996), the inspector observed licensee efforts to confirm that compliance with 10 CFR 35.33 was achieved regarding patients involved in the misadministration event described in the NRC Inspection Report No. 52-25114-01. The licensee attempted to contact 16 patients via telephone, and from 16 attempts, the licensee established positive communication with three patients. From the three patients contacted, two indicated that they received no communication from the licensee regarding the misadministration event and one indicated that he had received a written notification. During the week of August 15, 1996, the licensee re-mailed written notification to all patients involved in the referenced event via certified mail with return receipt requested.

10. Quality Management Program

10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written QM program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. Specifically, QM programs must include written policies and procedures to ensure that each dose administration is in accordance with the written directive. The inspector interviewed licensee personnel, and reviewed licensee dose administration records (at the San Juan office). The written directives requested a certain dose to be delivered for each of the 6 patients and 7 administrations. However, the source surface dose rate was not corrected and the incorrect dose was administered. Based on this, the inspector determined that the licensee failed to establish and maintain a written QM program at the San Juan facility, in that the dose administered was not in accordance with the written directive. The licensee's failure to establish and maintain a written QM program at the San Juan facility was identified as an apparent violation of 10 CFR 35.32. NRC Inspection Report No. 52-25114-01/95-01 identified a similar apparent violation of this requirement. This is another example of the licensee's failure to comply with the requirements of 10 CFR 35.33 which resulted in multiple misadministrations.

Exit Meeting Summary

An exit meeting was held with licensee representatives on August 7 and 9, 1996. The overall findings from the inspection were discussed with individuals identified in this report. An additional exit via telephone was held on September 6, 1996 with licensee and the violations were discussed. No dissenting comments were received from the licensee, and the licensee did not specify any information reviewed during the inspection as proprietary in nature.

Acronyms Used in this Report

CAL	Confirmation of Action Letter
CFR	Code of Federal Regulations
NRC	Nuclear Regulatory Commission
QM	Quality Management
RSO	Radiation Safety Officer