

ENCLOSURE

NOTICE OF VIOLATION

Luis A. Vazquez, M.D.  
Mayaguez, Puerto Rico

Docket No. 030-32477  
License No. 52-16660-03

During an NRC inspection conducted on February 11, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1991), the violations are listed below:

- A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on February 11, 1992, licensed material consisting of a strontium-90 eye applicator located in an unlocked storage room between operating room numbers 1 and 2, an unrestricted area, was not secured against unauthorized removal, and was not under constant surveillance and immediate control of the licensee.

This is a Severity Level IV violation (Supplement IV).

- B. Condition 16 of NRC License No. 52-16660-03 requires that licensed material be used and possessed in accordance with the statements, representations and procedures described in the license application dated August 15, 1991, and in the documents in support of that application.

Item 8 of the license application states that the licensee will establish and implement the model training program in Appendix A to Regulatory Guide 10.8, Revision 2. Appendix A states, in part, that personnel who work in or frequent restricted areas will be given annual refresher training to include applicable regulations and license conditions, potential hazards associated with radioactive material in each area where the employees will work, appropriate radiation safety procedures and licensee's in-house work rules.

Contrary to the above, in 1991, the licensee did not give annual refresher training covering the required topics to operating room technicians who worked in or frequented the Operating Room No. 2 area, a restricted area when the strontium-90 eye applicator was in use.

This is a Severity Level IV violation (Supplement VI).

- C. 10 CFR 20.105(b) requires that, except as authorized by the Commission in 10 CFR 20.105(a), no licensee allow the creation of radiation levels in unrestricted areas which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days.

Contrary to the above, on February 11, 1992, the licensee allowed the creation of radiation levels measuring 3.8 mR/hr in the storage room located between Operating Room Nos. 1 and 2 that contained a strontium-90 eye applicator, an unrestricted area, such that if an individual were continuously present in the area, he could have received a dose in excess of 100 millirems in any seven consecutive days.

This is a Severity Level IV violation (Supplement VII).

- D. 10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of Part 19, Part 20, documents incorporated into the license, license amendments and operating procedures, or that a licensee post a notice describing these documents and where they may be examined.

Contrary to the above, on February 11, 1992, the licensee did not post any of the required documents in the ophthalmology department area of the clinic to include current copies of Part 19, Part 20, documents incorporated into the license, license amendments, and operating procedures.

This is a repeat Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Luis A. Vazquez, M.D. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region II, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the

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violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated at Atlanta, Georgia  
this 23<sup>rd</sup> day of March 1992