

ENCLOSURE 1

NOTICE OF VIOLATION

Hospital Metropolitano
San Juan, Puerto Rico

Docket No. 030-11155
License No. 52-16033-01
EA 94-065

During an NRC inspection conducted on December 15 and 17, 1993, and as a result of an NRC medical consultant's report dated February 16 and April 19, 1994, 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, the violations are listed below:

- A. 10 CFR 35.21 requires, in part, that the Radiation Safety Officer (RSO) establish and implement procedures for using byproduct material safely and taking emergency action if control of byproduct material is lost.

License Condition 15 requires, in part, that the licensee conduct its program in accordance with the statements and procedures contained in its license application dated July 11, 1989.

Item 10.15 of Attachment 10 and Attachment 10.15 of the application specify the radiation safety procedures for the use of byproduct material for implant therapy. Attachment 10.15 specifies the instructions to doctors, nurses and visitors for use of byproduct material during implant therapy. The instructions require, in part, that the nurses call the physician, RSO and the medical physicist in case of an emergency.

Contrary to the above, on December 11, 1993, the licensee failed to implement procedures for emergency action when control of byproduct material was lost. Specifically, two nurses failed to notify the required individuals upon discovering an emergency where Cs-137 brachytherapy sources were dislodged by a patient.

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

- B. 10 CFR 35.33(a)(2) requires, in part, that the licensee submit to the appropriate NRC Regional Office, a written report of a misadministration within 15 days of the discovery of the misadministration.

10 CFR 35.33(a)(4) requires, in part, that the licensee also submit to the patient a written report of a misadministration within 15 days of the discovery of the misadministration.

Contrary to the above, on December 11, 1993, a misadministration occurred when the licensee discovered a patient had removed three Cs-137 sources from the treatment sight yet failed to remove them from the patient's thigh. The licensee did not submit the required written report to the NRC until January 5, 1994 and did not submit the required written report to the patient until January 13, 1994, both intervals in excess of 15 days from the date of discovery of the misadministration.

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

Pursuant to the provisions of 10 CFR 2.201, Hospital Metropolitano is hereby required to submit a written statement or explanation to the Regional Administrator, Region II, with a copy to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, 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 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 the 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 13th day of June 1994

ENCLOSURE 2

PARTICIPANTS IN ENFORCEMENT CONFERENCE HELD
ON MAY 20, 1994 IN SAN JUAN, PUERTO RICO

Nuclear Regulatory Commission

- B. Mallett, Deputy Director,
Division of Radiation Safety and Safeguards (DRSS)
- B. Uryc, Director, Enforcement and Investigation Coordination Staff
- H. Bermudez, Senior Radiation Specialist, DRSS

Licensee

- M. Maldonado, Executive Administrator
- V. Marrero, Administrator
- A. Miranda, M.D., Medical Director
- J. Ubiñas, M.D., Authorized User
- J. Díaz, M.D., Radiation Safety Officer
- M. Acevedo, Dosimetrist
- L. Ortiz, Director of Nursing
- C. Weigle, Quality Assurance Coordinator
- S. Gomez, Consultant