

NOTICE OF VIOLATION

Sylvia M. Sánchez, M.D.
Fajardo, Puerto Rico

Docket No. 030-33123
License No. 52-21042-02

During an NRC inspection conducted on April 16, 1998, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

- A. 10 CFR 35.32(a)(1) requires, in part, that the licensee establish and maintain a quality management program which must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for brachytherapy.

10 CFR 35.2 defines, in part, a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation.

Contrary to the above, as of April 16, 1998, written directives prepared for brachytherapy did not include the authorized user's signature. Specifically, the licensee administered brachytherapy radiation doses on 615 occasions but failed to sign 609 written directives, between July 1, 1994 and April 16, 1998.

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

- B. 10 CFR 35.32(b) requires, in part, that the licensee develop procedures for and conduct a review to verify compliance with all aspects of the quality management program at intervals no greater than 12 months.

Contrary to the above, the licensee did not conduct a review to verify compliance with the quality management program between July 1, 1994 and April 16, 1998, an interval greater than 12 months.

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

Pursuant to the provisions of 10 CFR 2.201, Sylvia M. Sánchez, 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 violation or severity level, (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. Your response may reference or include previous docketed correspondence, if the correspondence adequately

Enclosure

addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a 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.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Dated at Atlanta, Georgia
this 12th day of May 1998