

NOTICE OF VIOLATION

St. Elizabeth Hospital Medical Center
LaFayette, IN 47903

License No. 13-08615-04
Docket No. 030-11349

During an NRC inspection conducted on January 26-February 3, 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:

1. 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 any brachytherapy radiation dose.

10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration radiation and containing certain information including for brachytherapy, prior to implantation: the radioisotope, number of sources, and source strengths.

Contrary to the above, as of January 26, 1994, the licensee's quality management program for brachytherapy dated October 11, 1993, did not have a procedure for ensuring that written directives contain all of the required information. Consequently, on November 8, 1993, a written directive for a gold-198 permanent implant did not specify the number of sources implanted or the source strengths.

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

2. Condition 10 of License No. 13-08615-04 requires licensed material to be used at a specific location.

Contrary to the above, on February 1, 1993, 8.4 millicuries of iodine-131 was used at a location other than the authorized place of use.

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

3. 10 CFR 35.406(b) requires that a licensee make a record of brachytherapy source use, including: (1) the names of the individuals permitted to handle the sources; (2) the number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of sources in storage after removal, and the initials of the individual who removed the sources from storage; (3) the number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

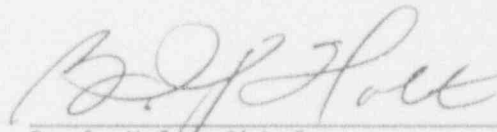
Contrary to the above, the licensee's 1993 record of brachytherapy source usage did not include the number and activity of sources in storage after removal or the number and activity of sources in storage after the return. In addition, on at least eight occasions the record did not include the number and activity of sources removed from storage or the number and activity of sources returned to storage.

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

Pursuant to the provisions of 10 CFR 2.201, St. Elizabeth Hospital Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois, 60532-4351, 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 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.

MAR 8 1994

Dated _____



B. J. Holt, Chief
Nuclear Materials Inspection
Section 1