

NOTICE OF VIOLATION

St. Mary's Hospital
Huntington, West Virginia

Docket No. 030-09717
License No. 47-09576-02

During an NRC inspection conducted September 14, 15 and 16, 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:

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 teletherapy radiation dose.

1. 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 of a radiopharmaceutical or radiation and containing certain information including for teletherapy, the total dose, dose per fraction, treatment site, and overall treatment period.

Contrary to the above, on March 16, 1993, a written directive was prepared prior to administering a teletherapy dose and did not contain the required information. Specifically, the written directive was not signed by the authorized user and did not contain the overall treatment period.

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

2. Footnote 1 to 10 CFR 35.32 (a)(1) requires, in part, that a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by the authorized user prior to the administration of the teletherapy dose.

Contrary to the above, on April 19, 1993 and March 22, 1994, written revisions to an existing written directive were made for a therapeutic procedure and the revision was not signed by the authorized user.

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

Pursuant to the provisions of 10 CFR 2.201, St. Mary's Hospital 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, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that

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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 30th day of September 1994

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