

APPENDIX

NOTICE OF VIOLATION

Department of Veterans Affairs
Oklahoma City, Oklahoma 73104

Docket: 030-02873
License: 35-00526-04

During an NRC inspection conducted on August 11-12, and 17, 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 20.1906(b) and (c) require that each licensee monitor the external surfaces of a package labeled with a Radioactive White I, Yellow II, or Yellow III label for radioactive contamination and radiation levels not later than 3 hours after receipt of the package during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

Contrary to the above, from January 1 to August 12, 1994, the licensee had received packages labeled with a Radioactive White I and Yellow II labels, and the licensee had not monitored the packages for radioactive contamination.

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

- B. 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 administration of sodium iodide I-125 or I-131 in quantities greater than 30 microcuries.

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 administrations of sodium iodide I-125 or I-131 in quantities greater than 30 microcuries, the dosage.

Contrary to the above, on June 26, 1994, a written directive was prepared for administration of sodium iodide I-131 to a patient and the dosage was not specified in the written directive. Also, four other written directives prepared between August 4, 1993, and April 19, 1994, did not indicate the activity unit of the specified dosage.

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

- C. 10 CFR 35.32(b)(3) requires, in part, that the licensee retain records of each 12-month review of the quality management program, including the evaluations and findings of the review, in an auditable form for three years.

Contrary to the above, as of August 12, 1994, the licensee had failed to maintain a record of quality management program reviews, including the evaluations and findings, for reviews conducted during 1992 and 1993, a period of less than three years.

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

- D. 10 CFR 35.51(c) requires, in part, that a licensee check each survey instrument for proper operation with a dedicated check source each day of use.

Contrary to the above, prior to August 12, 1994, the licensee had not checked its survey instrument for proper operation with a dedicated check source on days when the instrument was used.

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

Pursuant to the provisions of 10 CFR 2.201, Department of Veterans Affairs, V.A. Medical Center, 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 IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, 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 to show cause 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 Arlington, Texas
this 2nd day of September 1994