# NOTICE OF VIOLATION

Fairview Health System
Cleveland, Ohio

License No. 34-01869-01
Docket No. 030-02690

During an NRC inspection conducted on February 24-25, 1997 with continued in-office review through March 14, 1997, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600 (60 FR 34381, dated June 30, 1995), 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 administration of quantities greater than 30 microcuries of either sodium iodine I-125 or I-131.

   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 information including, for any administration of quantities greater than 30 microcuries of either sodium iodine I-125 or I-131, the dosage.

   Contrary to the above, the licensee failed to prepare written directives that included all of the required information prior to administering greater than 30 microcuries of either sodium iodine I-125 or I-131. Specifically, on March 2, 1994, the licensee administered 97 microcuries of sodium iodide I-131 and the written directive did not include the radiopharmaceutical and dosage. In addition, the licensee indicated that on several occasions between 1994 and 1996, chart orders which serve as the written directive for inpatient diagnostic studies involving the administration of greater than 30 microcuries of I-131, have failed to indicate the specific radiopharmaceutical and dosage.

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

2. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 30 microcuries.

   Contrary to the above, the licensee's quarterly dose calibrator linearity tests performed in 1996 covered only a maximum range of 30 millicuries, while the highest dosage that the licensee administered to a patient on July 10, 1996 and October 11, 1996 was in excess of 100 millicuries.

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

Pursuant to the provisions of 10 CFR 2.201, Fairview Health System 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 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. Your response may reference or include previous docketed correspondence, if the correspondence adequately 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.

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. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

Dated at Lisle, Illinois
this 4th day of April 1997