NOTICE OF VIOLATION

Trumbull Memorial Hospital
Warren, Ohio

License No. 34-02400-02
Docket No. 030-02705

During an NRC inspection conducted on December 16, 1993, 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 (1993), 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 iodide-125 or I-131.

   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. For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, the written directive must include the dosage.

   Item 1 of the licensee's quality management program dated December 18, 1991, states, in part, that a written prescription from an authorized user must be present for all patient doses of I-125 or I-131 in excess of 30 microcuries. The directive must state the patient name, pharmaceutical name, dosage and route of administration.

   Contrary to the above, written directives have not always included all required information. Specifically, on June 7, 1993, a patient was administered 3.08 millicuries of sodium iodide I-131, and the associated written directive failed to include the dosage.

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

2. 10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

   Pursuant to 10 CFR 35.32(a)(2), the quality management program must include written policies and procedures to meet the specific objective that, prior to each administration, the patient's identify is verified by more than one method.

   Pursuant to 10 CFR 35.32(a)(4), the quality management program must include written policies and procedures to meet the specific objective that each administration is in accordance with a written directive.

Pursuant to 10 CFR 35.32(a)(5), the quality management program must include written policies and procedures to meet the specific objective that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

Item 2 of the licensee's quality management program dated December 18, 1991, states, in part, that the Quality Management Monitor form must be filled out before administering in excess of 30 microcuries of I-125 or I-131. The Quality Management Monitor form is used to ensure that the above listed objectives are met.

Contrary to the above, the Quality Management Monitor form has not always been completed before radiopharmaceutical administration. Specifically, on June 7, 1993, a patient was administered 3.08 millicuries of sodium iodide I-131, and the Quality Management Monitor form was not completed.

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

3. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, in 1993 until the day of this inspection, the licensee did not survey with a radiation detection instrument at the end of the day all areas were radiopharmaceuticals were routinely administered. Specifically, weekly rather than daily surveys have been performed in the Nuclear Medicine Department's stress lab, an area were licensed material is administered on a daily basis.

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

Pursuant to the provisions of 10 CFR 2.201, Trumbull Memorial Hospital 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.

FEB 1 8 1994

Dated

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