NOTICE OF VIOLATION

Mercy Memorial Medical Center
St. Joseph, MI 49085

License No. 21-04177-01
Docket No. 030-02049

During an NRC inspection conducted on April 4, 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) requires, in part, that a 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. The quality management program must include, in part, written policies and procedures to meet the specific objectives that: (1) prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, or any therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131, (2) final plans of treatment are in accordance with the written directive, (3) each administration is in accordance with the written directive, and (4) any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken. The licensee's written quality management program to address the specific objectives was submitted to the NRC on January 2, 1992 and May 25, 1993.

   Item 3 of the licensee's Quality Management Program, dated January 27, 1992, requires, in part, that prior to administration, a written directive be prepared for any administration of a therapeutic radiopharmaceutical.

   Contrary to the above, the licensee administered strontium-89, a therapeutic radiopharmaceutical, to patients without preparing a written directive on January 19, 1994 and February 2, 1994.

   This is a Severity IV violation (Supplement VI).

2. 10 CFR 35.205(e) requires, in part, that a licensee check each month the operation of reusable collection systems for radioactive gases.

   Contrary to the above, the licensee used a reusable collection system for radioactive xenon-133 gas and did not check the operation of the collection system during the months of September 1993, October 1993, January 1994, and February 1994.

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

3. Condition 20 of License No. 21-04177-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated January 19, 1989, and other specified documents.

Item 10.4 in the letter dated January 19, 1989 requires, in part, that no food be stored in areas where radioactive material is used or stored.

Contrary to the above, on April 4, 1994, food was stored in a refrigerator located in the nuclear medicine injection room, an area where radioactive material is used.

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

Pursuant to the provisions of 10 CFR 2.201, Mercy Memorial 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.

APR 22 1994

Dated

John D. Jones, Acting Chief
Nuclear Materials Inspection
Section 2