NOTICE OF VIOLATION

St. Mary Hospital
Milwaukee, WI

License No. 48-01828-01
Docket No. 030-03422

During an NRC inspection conducted on November 15, 1993, through January 28, 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 35.22(a)(3) requires that to establish a quorum and conduct business, at least one half of the Radiation Safety Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

   Contrary to the above, on eight occasions during the period of 1991 through 1993, the licensee's Radiation Safety Committee met and conducted business and the management representative was not present.

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

2. 10 CFR 35.22(b)(5) requires that, to oversee the use of licensed material, the Radiation Safety Committee must review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving byproduct material with respect to cause and subsequent actions taken.

   Contrary to the above, as of December 9, 1991, the licensee's Radiation Safety Committee did not review, with the assistance of the Radiation Safety Officer, the cause and subsequent actions taken for an incident involving patient intervention with the brachytherapy treatment, which occurred during the third quarter of 1991.

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

3. 10 CFR 35.315(a)(7) requires that, for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, a licensee survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters.

   Contrary to the above, on nine occasions from September 1991 to September 1993, the licensee did not conduct a survey for removable contamination before assigning another patient to the room where the patient had received radiopharmaceutical therapy and had been hospitalized for compliance with 10 CFR 35.75.

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

4. 10 CFR 35.205(b) requires that a licensee administer radioactive gases only in rooms that are at negative pressure compared to surrounding rooms.

Contrary to the above, on August 19 and September 10, 1992, the licensee administered radioactive xenon-133 gas in Imaging Room Nos. 1 and 2 of the Nuclear Medicine Department, which were not at negative pressure compared to surrounding rooms.

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

5. 10 CFR 35.205(e) requires, in part, that a licensee measure each six months the ventilation rates available in areas of use of radioactive gas.

Contrary to the above, the licensee used radioactive xenon-133 gas in the Nuclear Medicine Department Imaging Room Nos. 1 and 2, and did not measure the ventilation rates therein from March 8 to December 20, 1993.

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

6. 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, on numerous occasions in 1991, 1992, and 1993, the licensee did not survey with a radiation detection instrument at the end of the day areas in the Nuclear Medicine Department where radiopharmaceuticals were routinely prepared for use or administered. Specifically, the licensee routinely performed the surveys at 6:00 a.m., a time that is not at the end of the day.

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

7. Conditions 6, 7, and 8 of License No. 48-01828-01 limit the byproduct material that may be possessed, the chemical and/or physical form, and the maximum amount that the licensee may possess at any one time under this license.

Contrary to the above, as of November 15, 1993, the licensee possessed byproduct material that was not authorized by Conditions 6, 7, and 8 of License No. 48-01828-01. Specifically, the licensee routinely received and used iodine-125 labeled protein, liquid form, nominal activity 77 microcuries, for clinical in vitro testing.

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

8. 10 CFR 31.11(c)(1) requires, in part, that the general licensee shall not possess at any one time, pursuant to the general license in 10 CFR 31.11(a), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75 and/or iron-59 in excess of 200 microcuries.

Contrary to the above, on December 2, 1993, at the RIA Laboratory, the licensee possessed about 668 microcuries of iodine-125 under the general license, an amount in excess of 200 microcuries.

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

Pursuant to the provisions of 10 CFR 2.201, St. Mary 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 3 1994

Dated

W. L. Axelson, Director
Division of Radiation Safety
and Safeguards