APPENDIX A

NOTICE OF VIOLATION

Mercy Hospital
Springfield, Massachusetts

Docket No. 030-01804
License No. 20-00096-02

As a result of the inspection conducted on May 5, 1994, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1993), the following violations were identified:

A. 10 CFR 35.13(e) requires that a licensee apply for and must receive a license amendment before it adds to or changes the areas of use or address or addresses of use identified in the application or on the license.

Contrary to the above, as of November 1993, the licensee added an area where byproduct material is used for cardiac stress testing, and, as of that date, the licensee had not applied for nor received a license amendment authorizing the addition.

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

B. 10 CFR 35.50(b)(4) requires, in part, that a licensee test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used.

Contrary to the above, the licensee did not test its dose calibrator for geometry dependence at the time of installation, which occurred on February 2, 1993.

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

C. 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 from November 1993 until May 1994, the licensee did not survey with a radiation detection instrument at the end of the day areas where radiopharmaceuticals were routinely administered. For example, no such survey was performed of the pulmonary suite used for cardiac stress testing.

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

D. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.



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Contrary to the above, on numerous occasions from October 19, 1991 to March 10, 1994, the licensee did not survey for removable contamination once each week in the nuclear medicine department, an area where radiopharmaceuticals were routinely prepared, administered and stored.

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

E. 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 a nuclear medicine scan room and did not measure the ventilation rates, therein, from June 1991 to May 1994. Specifically, the licensee measured the airflow out of the room, but did not measure the airflow into the room to assure that the room was at negative pressure.

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

F. 10 CFR 35.32(d) requires, for each administration of a radiopharmaceutical or radiation for which a written directive is required under 10 CFR 35.32(a)(1), that the licensee retain, for three years after the date of the administration, the written directive and a record of the radiation dose or radiopharmaceutical dosage administered.

10 CFR 35.32(a)(1) requires that a written directive be prepared for any dosage of iodine-131 greater than 30 microcuries.

Contrary to the above, the licensee used iodine-131 for hyperthyroid treatments from July 1993 to December 1993, and, as of May 1994, the licensee did not maintain the written directive for the administration.

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

G. 10 CFR 20.2108 requires that each licensee maintain records of the disposal of licensed materials made under Paragraphs 20.2002, 20.2003, 20.2004, 20.2005, Part 61, and disposal by burial in soil, including burials authorized before January 28, 1981.

Contrary to the above, as of May 5, 1994, the licensee disposed of microcurie quantities of technetium-99m by sink disposal, and the licensee did not maintain a record of these disposals.

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

Pursuant to the provisions of 10 CFR 2.201, Mercy Hospital 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 I, 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.