NOTICE OF VIOLATION

St. Luke's Medical Center
Milwaukee, Wisconsin

License No. 48-01338-01
Docket No. 030-03419

During an NRC inspection conducted on December 16, 1993, through April 20, 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 35.13(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.

   A. Contrary to the above, as of February 22, 1991, the licensee changed the area where byproduct material is used for cardiovascular stress testing from the Knicely Building, Level One, to the Schroeder Pavilion, Level One, and as of that date, the licensee had not applied for a license amendment authorizing the change.

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

   B. Contrary to the above, as of June 7, 1993, the licensee changed the area where byproduct material is used for in vitro testing for the Immunotherapy "LAK" Program by adding the laboratory located on the first floor of the Medical Center's Galleria, and as of that date had not applied for a license amendment authorizing the additional laboratory.

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

2. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for area surveys are described in the licensee's application dated April 19, 1988, and were approved by License Condition No. 17.

   The licensee's application dated April 19, 1988, states in Item No. 10.12 that the Radiation Safety Officer will review and initial results of dose rate surveys and contamination surveys at least monthly.

   Contrary to the above, as of December 16, 1993, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, the Radiation Safety Officer routinely failed to review the results of dose rate surveys and contamination surveys at least monthly and routinely failed to initial the records to indicate that the reviews were completed.

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

3. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for audit of research laboratories are described in the licensee's letter dated October 6, 1989, and were approved by License Condition No. 17.

   The licensee's letter dated October 6, 1989, states in Item 7.b that the Radiation Safety Officer will perform quarterly confirmatory audits of radiation safety surveys and procedures for research laboratories.

   Contrary to the above, as of December 16, 1993, the licensee, through the Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, the Radiation Safety Officer routinely failed to conduct the quarterly audit of research laboratories as required.

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

Pursuant to the provisions of 10 CFR 2.201, St. Luke's 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.

MAY 0 6 1994

Date

W. J. Holt

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