NOTICE OF VIOLATION

Greene Memorial Hospital, Inc.
Xenia, Ohio

License No. 34-17975-01
Docket No. 030-13774

During an NRC inspection conducted on May 27, 1993 (onsite) with continuing NRC review through July 13, 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 the violations are listed below:

1. 10 CFR 35.32(a)(1)(iv), requires, in part, that the licensee's quality management program include written policies and procedures to insure that 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. A written directive, as defined in 10 CFR 35.2, means an order in writing for a specific patient dated and signed by an authorized user prior to administration of a radiopharmaceutical or radiation.

   Contrary to the above, on March 16, 1993, the licensee administered 3.2 millicuries of iodine-131 and a written directive was not prepared prior to administration of the radiopharmaceutical.

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

2. 10 CFR 35.59(g) and (d) require, in part, that the licensee retain for five years records of quarterly physical inventories and leakage test results of sealed sources and that the record include the signature of the Radiation Safety Officer.

   Contrary to the above, since at least January 1991, the licensee's records of quarterly physical inventories and leakage results for sealed sources did not contain the signature of the Radiation Safety Officer.

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

3. 10 CFR 35.50(e)(2) (3) and (4) require, in part, that a licensee retain records of annual dose calibrator accuracy, quarterly linearity and geometrical dependence tests and that the records include the signature of the Radiation Safety Officer.

   Contrary to the above, since at least January 1991, the licensee's records of annual dose calibrator accuracy, quarterly linearity and geometrical dependence did not include the signature of the Radiation Safety Officer.

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

4. 10 CFR 35.50(4)(d) requires, in part, that a licensee shall mathematically correct dosage readings for any linearity error that exceeds 10 percent.

Contrary to the above, in June 1992, the quarterly linearity readings performed at 48 and 72 hours indicated errors of 12.9 percent and 10.2 percent respectively and the dosage readings were not mathematically corrected for the errors.

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

5. 10 CFR 35.50(e) and 35.50(e)(1) require, in part, that a licensee retain records of daily constancy checks of the dose calibrator for three years unless directed otherwise, and that the records include the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check.

Contrary to the above, as of May 27, 1993, the licensee failed to retain records of daily dose calibrator constancy checks performed on February 1, 2 and 3, 1992 and on March 8, 1993.

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

Pursuant to the provisions of 10 CFR 2.201, Greene Memorial Hospital, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137, 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.

AUG 0 3 1993
Dated

Roy J. Caniano, Chief
Nuclear Materials Safety Branch