NOTICE OF VIOLATION

Good Samaritan Hospital
Cincinnati, Ohio

License No. 34-00991-02
Docket No. 030-02665

During an NRC inspection conducted on March 8-9, 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:

A. 10 CFR 35.25(a)(1) requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user to instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material and in the licensee's written quality management program.

Contrary to the above, on October 26, 1993, the licensee permitted the possession and use of byproduct material, in the form of 2.1 millicuries of sodium iodide iodine-131, by an individual under the supervision of an authorized user and the licensee had not instructed the supervised individual in the licensee's written quality management program.

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

B. 10 CFR 35.32(a)(4) requires that a licensee's quality management program (QMP) include written policies and procedures to meet the objective that each administration is in accordance with the written directive.

Item 3 of the licensee's QMP states, in part, that prior to administering a dosage of a radiopharmaceutical containing byproduct material, the person administering the radiopharmaceutical will compare the dosage measured in the dose calibrator with the prescribed dosage in the written directive.

Contrary to the above, on October 26, 1993, a licensee nuclear medicine technologist did not compare the dosage measured in the dose calibrator with the prescribed dosage in the written directive prior to administering a dosage of approximately 2.1 millicuries of sodium iodide iodine-131.

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

C. 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 March 9, 1994, the licensee's Radiation Safety Committee did not review the cause and subsequent actions taken for an incident involving a potential misadministration of sodium iodide iodine-131, which occurred during the fourth quarter of 1993.

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

D. 10 CFR 35.32(a)(1) requires, in part, that a licensee's quality management program (QMP) include written policies and procedures to meet the objective that a written directive be prepared for any therapeutic administration of a radiopharmaceutical, other than sodium iodide iodine-125 or iodine-131, or any administration of quantities greater than 30 microcuries of either sodium iodide iodine-125 or iodine-131.

10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation and containing certain other specific information.

Item 1 of the licensee's QMP states that an authorized user will date and sign a written directive prior to the administration of any therapeutic dose of a radiopharmaceutical or any dosage of quantities greater that 30 microcuries of either sodium iodide iodine-125 or iodine-131.

Contrary to the above, on five separate occasions, the licensee administered either a therapeutic dose of a radiopharmaceutical or a dosage of sodium iodide iodine-131 in excess of 30 microcuries and an authorized user did properly prepare a written directive as required. Specifically, the licensee administered 2 millicuries of sodium iodide iodine-131 to a patient on August 25, 1993 and to another patient on August 30, 1993, and someone other than an authorized user signed and dated the written directive; the licensee administered 205.5 millicuries of sodium iodide iodine-131 to a patient on October 11, 1993, and the written directive was not dated; the licensee administered a therapeutic dose of 3 millicuries of strontium-89 chloride to a patient on October 14, 1993, and the written directive was not signed; and the licensee administered 3 millicuries of strontium-89 chloride to a patient on December 3, 1993, and the written directive was not prepared for a specific patient and was not dated.

This is a repeat violation.

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

E. 10 CFR 35.32(b)(1) requires that, in part, the licensee conduct a review of the quality management program (QMP) including, since the last review, an evaluation of a representative sample of patient administrations.

Contrary to the above, as of March 9, 1994, the licensee did not conduct a review of the QMP to include an evaluation of a representative sample of patient administrations. Specifically, the licensee's February 1994 review of the QMP did not include an evaluation of any of the six patient administrations of strontium-89 chloride performed since the last review conducted in late 1992/early 1993.

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

F. 10 CFR 35.32(b)(3) requires that the licensee retain records of each review of the QMP, including the evaluations and findings of the review, in an auditable form for three years.

Contrary to the above, as of March 9, 1994, the licensee did not retain any records of the review of the QMP conducted in late 1992/early 1993.

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

G. 10 CFR 35.32(f)(2) requires that the licensee submit to the NRC Region III Office, by January 27, 1992, a written certification that the licensee's quality management program has been implemented along with a copy of the program.

Contrary to the above, the licensee used cesium-137 and iridium-192 for brachytherapy on numerous occasions from January 27, 1992 through March 9, 1994, and as of March 9, 1994, the licensee had not submitted to the NRC a copy of the licensee's quality management for that modality. As of January, 1992, however, the licensee had established and implemented a quality management program for brachytherapy.

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

Pursuant to the provisions of 10 CFR 2.201, Good Samaritan 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.

APR 2 1 1994

Dated

Roy J. Caniano, Chief
Nuclear Materials Safety Branch