NOTICE OF VIOLATION

Sacred Heart Hospital
Eau Claire, Wisconsin

License No. 48-03116-01
Docket No 030-03435

During an NRC inspection conducted on December 1, 1993 with continuing NRC review through December 20, 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 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

   Contrary to the above, on December 1, 1993, licensed material consisting of sealed sources, generators and radiopharmeceuticals located in the nuclear medicine storage room and hot lab, an unrestricted area, was not secured against unauthorized removal, and was not under constant surveillance and the immediate control of the licensee.

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

2. 10 CFR 35.32(f)(2) requires that the licensee submit to the NRC Region III Office, by January 27, 1993, 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 quantities of greater than 30 microcuries of I-131 for thyroid therapies on July 15, 1992, October 16 and 28, 1992 and January 26, 1993 and, as of April 30, 1993, the licensee had not submitted to the NRC a copy of the licensee's quality management program and a written certification that the program had been implemented.

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

3. 10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct will be administered as directed by the authorized user.

   Pursuant to 10 CFR 35.32(a)(4), the quality management program must include written policies and procedures to meet the specific objective that each administration in accordance with the written directive.

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The licensee's quality management program procedures stipulate that the physician (authorized user) must sign the Quality Management Report Form (written directive) before treatment of a patient.

Contrary to the above, on July 15, 1992, October 16 and 28, 1992, and January 26, 1993 the licensee used quantities of greater than 30 microcuries of sodium iodide I-131 for thyroid therapies and the Quality Management Report Form was not signed by the physician (authorized user).

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

4. 10 CFR 35.51(c) requires, in part, that a licensee check each survey instrument for proper operation with the dedicated check source each day of use.

Contrary to the above, from at least January 1, 1993 to December 1, 1993, the licensee did not check its survey meters with a dedicated check source on days when the instrument was used.

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

This is a repeat violation from the October 12, 1991 inspection.

5. 10 CFR 35.60(b) requires that, to identify its contents, a licensee conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, and that the label show the radiopharmaceutical name or its abbreviation, or the clinical procedure to be performed, or the patient's name.

Contrary to the above, from at least January 1, 1993 to December 1, 1993, the licensee failed to label syringes or syringe shields containing Tc-99m (to show the radiopharmaceutical name, the clinical procedure or the patient's name).

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

6. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within three days after the administration of the dosage.

Contrary to the above, on July 15, 1992, October 16 and 28, 1992, and January 26, 1993, the licensee administered dosages of 122, 100 and 125 millicuries of iodine-131, dosages which require hospitalization for compliance with 10 CFR 35.75, and failed to measure the thyroid burdens of the physician and medical physicist who helped prepare and administer the dosages.

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

This is a repeat violation from the October 12, 1991 inspection.

Pursuant to the provisions of 10 CFR 2.201, Sacred Heart 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 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.

FEB 1 1994

Dated

Roy Caniano, Chief
Nuclear Materials Safety Branch