APPENDIX

NOTICE OF VIOLATION

Sacred Heart Hospital
Yankton, South Dakota

Docket No. 30-03235/90-01
License No. 40-01683-01

During an NRC inspection conducted on October 24, 1990, 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 (1990), the violations are listed below:

1. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity at least quarterly over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

   Contrary to the above, the licensee had failed to: (1) test the dose calibrator for linearity during the third quarter of 1988 and first quarter of 1990, and (2) conduct the test over a range of activity as low as 10 microcuries for each of the linearity tests completed during the period September 1987 through September 1990.

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

2. 10 CFR 35.51(a)(2) and (b) require, in part, that a licensee: (1) calibrate survey instruments using two separate readings on each scale that must be calibrated, and (2) consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

   Contrary to the above, the licensee had failed to: (1) calibrate the Victoreen Model 592B and Nuclear Chicago Model 2612 survey instruments using two separate readings on each scale of use during calibrations conducted in October 1988 and November 1989 for the Victoreen instrument, and July 1989 for the Nuclear Chicago instrument; and (2) calibrate the Nuclear Chicago instrument such that the indicated exposure rate differed from the calculated exposure rate by less than 20 percent or to attach a correction chart or graph to the instrument when indicated exposure rates varied as much as 10 percent from the calculated value for calibrations done in June 1988 and July 1989.

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

3. 10 CFR 35.70(h) requires, in part, that a licensee retain a record of each (radiation) survey which must include a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in millirem per hour (mr/hr), and the instrument used to make the survey.

Contrary to the above, records of (radiation) surveys conducted during the period September 1987 to October 1990 did not include the items noted above. Rather than recording the detected dose rate in units of mr/hr for each area surveyed, the licensee had instead recorded "background."

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

4. 10 CFR 35.92(b) requires, in part, that records of disposals permitted under 10 CFR 35.92(a) include identification of the survey instrument used (to conduct radiation surveys prior to disposal), the background dose rate (measured at the time of disposal), and the dose rate measured at the surface of each waste container.

   Contrary to the above, records of disposals during the period September 1987 to October 1990 did not include: (1) notation of the survey instrument used for disposal surveys, and (2) background or waste container surface dose rate at the time of disposal. The licensee had instead recorded "background."

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

5. 10 CFR 35.200(b) requires, in part, that a licensee prepare reagent kits in accordance with the manufacturer's instructions. Section 35.200(c)(1) specifies, in part, that a licensee may depart from the manufacturer's instructions for preparing reagent kits provided that the licensee has a written directive made by an authorized user physician that directs a specific departure for a particular patient or for a radiopharmaceutical.

   The manufacturer's instructions for the macroaggregated albumin reagent (MAA) used by the licensee specifies that each vial be reconstituted with 20-50 millicuries of technetium-99m and that the recommended number of particles per single injection be 200,000-700,000.

   Contrary to the above, during the period August through October 1990, the licensee had reconstituted the reagent kit using less than 20 millicuries of technetium-99m and had injected as many as 2 million particles per single injection.

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

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, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region IV, and if applicable, a copy to the NRC Resident Inspector, 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. Under the authority of Section 182 of the Act. 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Arlington, Texas
this 27 day of Nov. 1990