NOTICE OF VIOLATION

Good Samaritan Hospital
Zanesville, Ohio

License No. 34-16725-02
Docket No. 030-30954
EA 94-023

During an NRC inspection conducted on January 19, 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 use of byproduct material by an individual under the supervision of an authorized user shall instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material.

Contrary to the above, on November 10, 1993, the licensee permitted the use of byproduct material, namely iridium-192 brachytherapy seeds contained in nylon ribbon, by individuals under the supervision of an authorized user, and the licensee failed to instruct the supervised individuals in the principles of radiation safety appropriate to the individuals' use of the byproduct material. Specifically, the licensee failed to instruct a radiation therapy technologist and a medical physicist in the principles of radiation safety appropriate to the implantation of iridium-192 ribbons, including, but not limited to, procedures used to ensure the proper implantation of source ribbons. (01013)

This is a Severity Level III 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 6 of the licensee's QMP states, in part, that the licensed user or designee will use radiographs as a basis of verifying the position of temporary implant brachytherapy sources.

Item 8 of the licensee's QMP states, in part, that after insertion of temporary implant brachytherapy sources, an authorized user will promptly record the actual loading sequence of the radioactive sources implanted and sign or initial the patient's chart or other appropriate record.

Contrary to the above, on November 10, 1993, an authorized user did not promptly review a radiograph to verify the position of temporary implant brachytherapy sources. Specifically, the authorized user reviewed the radiograph approximately three hours post-implant. (02014)

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

C. 10 CFR 35.410(a) requires, in part, that a licensee provide radiation safety instruction to all personnel caring for a patient undergoing implant therapy.

10 CFR 35.410(b) requires, in part, that a licensee retain a record of individuals who have received the instruction required by 10 CFR 35.410(a).

Contrary to the above, as of January 19, 1994, the licensee had not provided radiation safety instruction to all personnel caring for the patient undergoing implant therapy and did not retain a record of individuals who had received the instruction required by 10 CFR 35.410(a). Specifically, the licensee did not provide instruction to three individuals who provided care to an implant patient on November 11 through 13, 1993. In addition, the licensee's records of instruction did not indicate that two individuals who provided care to implant patients had been provided the required instruction. (03014)

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

D. 10 CFR 19.11(a) and (b) require, in part, that a licensee post current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures; or that the licensee post a notice describing these documents and where they may be examined. 10 CFR 19.11(c) requires that a licensee post Form NRC-3, "Notice to Employees." 10 CFR 19.11(d) requires that the documents, notices, or forms posted must appear in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies.

Contrary to the above, on January 19, 1994, the licensee did not post any of the required documents or notices in areas observable to individuals who provided care to patients undergoing implant therapy. (04014)

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, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, 801 Warrenville Road, Lisle, Illinois 60532, 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 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 Lisle, Illinois
this 28 day of February, 1994