UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

February 28, 1994

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

Good Samaritan Hospital
ATTN: Daniel L. Sylvester
Vice President for
Professional Services
800 Forest Avenue
Zanesville, Ohio 43701

Dear Mr. Sylvester:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 030-30954/94001(DRSS))

This refers to the NRC inspection conducted on January 19, 1994, at Good Samaritan Hospital, Zanesville, Ohio, to review a brachytherapy misadministration. A copy of the report documenting this inspection was mailed to you on February 11, 1994. During the inspection, apparent violations of NRC requirements were identified. On February 17, 1994, an enforcement conference was conducted by telephone with you and members of your staff to discuss the apparent violations, their causes, and your corrective actions. A copy of the enforcement conference report is attached.

On November 11, 1993, you informed us of the misadministration, in which a patient's larynx received an unintended radiation dose of approximately 282 centigray due to a mispositioned iridium-192 ribbon. This was apparently caused by a crimp in the catheter at the level of the patient's larynx, which hindered the ribbon from being fully inserted to its proper location.

The inspection revealed that on the day of the misadministration, the dosimetrist, who had always performed all implants in the past, delegated the task to a radiation therapy technologist and an attending medical physicist without the knowledge and permission of the authorized user physician. Neither the radiation therapy technologist, who actually implanted the iridium-192 ribbon, nor the medical physicist had ever physically implanted an iridium ribbon, and had not received any formal training in this procedure. As a result, they did not know that the ribbon was not properly seated because it was impeded by a crimp in the catheter.

The violation involved the failure to instruct the radiation therapy technologist and the 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. This is classified as a Severity Level III violation in accordance with the "General Statement of Policy and Procedure for NRC Enforcement

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Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C.

The root cause of this violation and the subsequent corrective actions were discussed during the enforcement conference. You stated that the dosimetrist, the individual trained to implant iridium-192 ribbons, did not consult with the authorized user physician prior to delegating the implant procedure to the untrained technologist and physicist. The NRC recognizes that immediate corrective actions were taken following the inspection. These included: (1) providing instruction and hands-on training in source implantation to all radiation therapy technologists and medical physicists; (2) formalizing the procedures regarding comparison of the ribbon and catheter lengths prior to source implantation in order to ensure that the ribbon is properly seated; and (3) requiring that the authorized user physically implant the source ribbons.

The NRC license issued to Good Samaritan Hospital entrusts responsibility for radiation safety to the management of the hospital, the Radiation Safety Committee, and the Radiation Safety Officer. Therefore, the NRC expects effective management control and oversight of this licensed program. Incumbent upon each NRC licensee is the responsibility to protect the public health and safety by ensuring that all requirements of the NRC license are met. The violations described in the enclosed Notice indicates that your radiation safety training program was not sufficiently implemented to ensure adequate safety and preclude events such as the brachytherapy misadministration.

In accordance with the Enforcement Policy, a civil penalty is usually assessed with a Severity Level III violation in order to emphasize the need for lasting remedial action and to deter future violations both by the involved licensee as well as by other licensees conducting similar activities. However, after considering the civil penalty adjustment factors set forth in the Enforcement Policy, I have decided that a civil penalty will not be assessed. Full mitigation of the civil penalty was appropriate because you identified the violation, because of your prompt and comprehensive corrective actions (as described above) and your past good performance.

Three Severity Level IV violations were also identified during the inspection. These violations are indicative of management inattentiveness, as we discussed during the enforcement conference. The first violation, the failure to follow Quality Management Program procedures, refers to the fact that the "stat" radiograph, which is used to check the location of the brachytherapy sources after implantation, was not read promptly, as required. Because this failure appears to be an isolated occurrence, the violation has been categorized at Severity Level IV. Your corrective action for this violation included requiring that the "stat" radiograph be hand carried immediately to the prescribing physician for evaluation. The second violation, the failure to properly instruct individuals who provide care to patients undergoing implant therapy, and the failure to maintain proper training records, refers to the fact that not all patient care staff who provided care to an implant patient from November 10 through 13, 1993, had received the required instruction, and that names of some individuals who had received the training were not listed

in the records. Your corrective actions included training the staff, and implementing policies and procedures whereby training records would be maintained, and untrained individuals would not care for implant patients. The third violation was the failure to post any of the required documents, notices, or forms in the areas frequented by the nurses caring for implant patients. You indicated that this was corrected almost immediately after the inspection.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

JBMuller for

John B. Martin
Regional Administrator

Enclosures:
1. Notice of Violation
2. Enforcement Conference Report

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