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January 19, 1990

Docket No. 030-17335 License No. 13-18881-01 EA 89-249

Memorial Hospital ATTN: Mr. James Skogsbergh Chief Executive Officer 615 North Michigan Street South Bend, IN 46601

Gentlemen:

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT NO. 030-17335/8900 (DRSS))

This refers to the inspection conducted on September 8, 1989, at Memorial Hospital of activities authorized by License No. 13-18881-01. The report of this inspection was sent to you on December 20, 1989. During the inspection, violations of NRC requirements were identified. On December 22, 1989, a telephone enforcement conference was conducted with Patrick Miller and other members of your staff and Mr. C. E. Norelius and other members of the NRC Region III staff. During the conference, we discussed the violations, their causes, and your corrective actions.

The violations that are described in the enclosed Notice of Violation include: (a) failure to maintain constant surveillance or immediate control over licensed material that was implanted on a patient who, on at least four occasions, was found wandering in hospital hallways and (b) failure to make a telephone notification to the NRC Regional Office within 24 hours after your siaff concluded that a therapy misadministration had occurred. These violations, particularly Violation A, demonstrate a need for improvement in the ration safety program. We acknowledge it is sometimes difficult to contro: : behavior of a patient; however, it is a licensee's responsibility to maintan total and continuous control over licensed material. In this instance, that lack of control resulted in the temporary loss of approximately 6 millicuries of iridium-192 in an unrestricted area and it is fortuitous that the licensed material was recovered at the hospital 22 hours later. In addition, the temporary loss resulted in a therapy misadministration since the patient received only 63 percent of the prescribed dose. We acknowledge that, as soon as the misadministration was discovered, the patient received the balance of the prescribed dose.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Action," 10 CFR Part 2, Appendix C (1989) (Enforcement Policy), Violation A described in the enclosed Notice has been classified at Severity Level III and Violation B has been classified at Severity Level IV. Normally,

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a civil penalty is considered for a Severity Level III violation. However, after consultation with the Director, Office of Enforcement and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, I have decided that a civil penalty will not be imposed in this case because of: (1) your identification and prompt reporting of the event and (2) your good past performance. Nonetheless, we emphasize that any similar violations in the future may result in additional enforcement action.

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 Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Sincerely,

Original stened by

A. Bert Davis Regional Administrator

Enclosures:

1. Notice of Violation

Inspection Report

No. 030-17335/89002(DRSS)

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