MEMORIAL HOSPITAL
OF SOUTH BEND
Excellence

February 14, 1990

U.S. Nuclear Regulatory Commission

Docket No. 030-17335
License No. 13-18881-01

Re: Reply to a notice of violation

Gentlemen:

This reply includes the answer to the following questions for each alleged violation:
1. The reason for the violation.
2. The corrective steps that have been taken.
3. The corrective steps that will be taken to avoid further violations.
4. The date when full compliance will be achieved.

Violation A: Failure to maintain constant surveillance or immediate control over licensed material that was implanted on a patient.

Violation B: Failure to notify the NRC Regional office by telephone after discovering a therapy misadministration.

A1: The patient became unexpectedly incoherent at night. She left her room a number of times, although she was repeatedly told not to. The oncology nurses failed to notify the physician or the radiation safety officer when they first found the patient outside of her room.

A2: a. Oncology nurses were reeducated on radiation safety and it was reiterated that if the radioactive patient attempts to leave the room, that the involved oncologist and RSO be notified immediately.
b. The person who places the sources in the patient now explains the implant to the patient's nurse.
c. Nurses must pass on all the necessary information about the implant patient when they change shift.
d. A photo of the implant may be taken and put in the patient's chart to facilitate checking of implants and

615 North Michigan Street
South Bend, Indiana 46601

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identifying any changes.

e. Nurses must check on implant patient every hour.

f. Before the implant the oncologist evaluate the patient from a mental status viewpoint to determine if the patient is a good candidate for implant.

g. After the performance of implant, if the patient is restless or attempts to leave the room, the physician will decide either to continue or discontinue the implant for medical or safety reasons.

h. The physician and oncology nurses will explain and emphasize the importance of radiation safety to the patient.

To this date we have not had another incident

A3: a. An alarm will be put on implant patient's room door. The alarm will be activated when there is a radioactive patient in the room.

b. A lock will be placed on the bathroom door of the implant patient room. The bathroom door will be locked when there is an implant (Ir-192 or Cs-137) patient in the room. Contents of bedside commode or bedpan will be surveyed on selected cases before disposal. Those cases will be determined by the likelihood of sources being dislodged.

c. Only disposable tray and dishes will be used for all implant patients which then will be placed in a special waste basket. The waste basket remains in the room until surveyed.

d. A new form to document nurses' hourly checks is currently being printed. These will be used for each implant patient.

e. The "Nursing Instructions" sheet has been altered to reflect all applicable changes in A2 and A3.

A4: We believe we are currently in compliance with the completion of all the items under A2 as of Dec. 30,1989. Items c,d, and e under A3 are being currently implemented. The additional items, including the alarms on doors, and the locks on bathrooms, will be implemented in 60 days from the date of this response. Those added items we believe are not essential, but will help give us added assurance in cases of patient non-compliance.

B1: We thought that since the NRC was notified about the incident, and since we had been in constant contact with the NRC during the incident and afterward, that a separate call for therapy misadministration was not necessary.

B2, B3: We reviewed section 35.33 from Title 10, Chapter 1 of the Code of Federal Regulations. If there is any question

as to whether there has been misadministration, the Radiation Safety Officer will contact the NRC office to discuss the matter.

B4: September 26, 1989

If there are any questions concerning this response, please contact our Radiation Safety Officer, Alex Hashemi at 219 284-7461.

Sincerely,

James H. Skogsbergh

James Skogsbergh
Chief Operating Officer
Memorial Hospital of South Bend

Dated: February 14, 1990

cc: Regional Adminst., Region III

UNITED STATES NUCLEAR REGULATORY COMMISSION
ATTN: Document Control Desk
Washington, D.C. 20555