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

September 14, 1994

Bethesda Hospital
ATTN: William Groneman
Senior Vice President
619 Oak Street
Cincinnati, OH 45206

Dear Mr. Groneman:

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT NO. 030-02809/94001)

This refers to the special safety inspection conducted on December 15, 1993 and January 27-28, 1994, to review the incident involving a dislodged brachytherapy cesium-137 source and possible medical misadministration that occurred on December 8-9, 1993 and reported to the NRC on December 10, 1993. It was subsequently determined that this event did not meet the criteria and definition for a misadministration because the prescribed dose did not differ from the administered dose by more than 20 percent. During this inspection we also reviewed the steps your staff took to recover the lost brachytherapy source and evaluated the potential for radiation exposure to hospital staff and members of the public during the nine hour period the source was in an unrestricted area. The report documenting this inspection was mailed to you by letter, dated March 21, 1994. Violations of NRC requirements were identified during the inspection, and on August 31, 1994, an enforcement conference was held in the Region III office. Attending the enforcement conference were you, Mr. Roy Caniano, Chief, Nuclear Materials Safety Branch of Region III, and other members of our respective staffs.

On December 8, 1993, a patient was implanted with four cesium-137 sources to treat a tumor in the nasopharynx area and diseased tissue in the nasal area. This implant was the fourth in a series of brachytherapy treatments for the patient, preceded by three treatments with iridium-192 in an HDR remote afterloading brachytherapy device. The total activity of the cesium-137 sources implanted was 36 mg radium equivalent, approximately 90 millicuries (3.3 GBq), with three sources containing 20 millicuries (0.7 GBq) each and one source containing 30 millicuries (1.1 GBq). The cesium-137 sources and three spacers were loaded into a plastic insert tube. The arrangement was held in place by a plastic rod (plunger) taped to the insert tube. The insert tube was then placed into an endo-tracheal (ET) tube which had been sutured to the patient's nose. Tape was used to secure the insert tube to the ET tube. The written directive specified a dose of 2,000 rads (cGy) at approximately 1.2 centimeters or 24 hours. The treatment plan developed for the source loading indicated a dose rate of 80 cGy/hr at 1.2 cm.

During the course of the treatment, the authorized user verbally changed the treatment time from 24 hours to 23 1/4 hours. Observation of the insert tube at 23 1/4 hours post implant revealed that the plunger and one spacer was gone and one of the 20 millicurie (0.7 GBq) sources was missing. The two remaining 20 millicurie (0.7 GBq) sources had migrated several centimeters from their

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originally loaded position. The 30 millicurie (1.1 GBq) source, however, remained in its original position. After an extensive search by your staff, the missing source was found by the medical physicist inside a trash dumpster near the hospital's loading dock approximately 1.5 hours after the explant procedure. The source was then returned to storage. The time that the source remained in an unrestricted area and not under the immediate control of the licensee was estimated to be 9 hours. We concluded that it was unlikely that hospital staff and members of the public were exposed to significant radiation levels during this period.

The root cause of the violations and the subsequent corrective actions were discussed during the August 31, 1994, enforcement conference. The major factors contributing to the violations appeared to be: (1) the failure of the brachytherapy apparatus to hold the cesium-137 sources in place; and (2) the lack of radiation safety training of two nurses who provided care to the patient. The nurses were not aware of the physical appearance of a brachytherapy source; therefore, they were unable to recognize a dislodged source or other aberration of the implant apparatus.

The NRC entrusts responsibility for radiation safety to the management of the hospital; therefore, the NRC expects effective management oversight of its licensed programs. Incumbent upon each NRC licensee is the responsibility to protect the public health and safety by assuring that all NRC requirements are met and any potential violations or deviations of NRC requirements are identified and expeditiously corrected.

The violations are fully described in the enclosed Notice of Violation (Notice), and represent a failure to control access to licensed materials for radiation safety purposes as specified in 10 CFR 20.207. Therefore, in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, violations listed in Section I. of the Notice are classified as a Severity Level III problem. The enclosed Notice also describes three other violations that are individually classified at Severity Level IV.

Regarding the remaining apparent violations described in our inspection report dated March 21, 1994, we agree with your conclusion that the one nurse who had not received any radiation safety training for a number of years was considered untrained and not a suitable candidate for annual retraining. We have also determined that the use of initials as a signature by an authorized user on a written directive, and the use of other documents (e.g. treatment plan or nursing instructions) as part of the written directive if they are signed and dated by an authorized user, do not constitute violations of 10 CFR 35. In addition, we have decided not to cite, at this time, the apparent violation concerning the failure of the authorized user to sign and date a revised written directive. We have determined, based upon our discussions at the Enforcement Conference, that this matter needs further review. We will provide you with the results of our review at a later date in separate correspondence. Until our review is completed, it is prudent for your staff to have an authorized user sign and date all revisions to written directives prior to implementing the revision. The exception to this is that an authorized user may sign the revised written directive within 48 hours of a

documented oral revision if warranted due to the emergent nature of the patient's condition.

In accordance with the Enforcement Policy, a civil penalty is considered for a Severity Level III problem. However, I have decided not to propose a civil penalty in this case for the following reasons. The base value of a civil penalty for a Severity Level III problem is $2,500. The civil penalty adjustment factors in the Enforcement Policy were considered. The civil penalty was mitigated 25 percent because you identified the violation pertaining to the lost source. The civil penalty was mitigated an additional 50 percent because of your prompt and extensive corrective actions. These included, but are not limited to: (1) policy and procedure changes were immediately reviewed and made to prevent recurrence of this type of event, (2) your staff was trained on the revised procedures, (3) you revised your radiation safety form to account for the implant integrity at specified periods, and (5) this event was reviewed by the Radiation Safety Committee and all members were provided copies of its findings and corrective actions. The civil penalty was also mitigated 100 percent for past performance because our inspections conducted in May 1990 and February 1993 did not identify any violations. The remaining factors in the enforcement policy were also considered and no further adjustment to the base civil penalty was considered appropriate. Therefore, on balance, the civil penalty was fully mitigated. The remaining violations in Section II of the enclosed Notice are each categorized at Severity Level IV.

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, its enclosure, and your response will be placed in the NRC Public Document Room. Accordingly, your response should not, to the extent possible, include any personal privacy, proprietary, or safeguards information so that it can be released to the public and placed in the NRC Public Document Room.

The response 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, Public Law No. 96-511.

Sincerely,

Geoffrey E. Grant for

John B. Martin
Regional Administrator

Docket No. 030-02809
License No. 34-10921-03
EA 94-152

Enclosure:
Notice of Violation

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