DCS

November 28, 1989

Docket Nos. 030-02623; 030-11781; 070-03042
License Nos. 31-02892-03; 31-02892-05; SNM-1969
EA 89-190

Veterans Administration Medical Center
ATTN: James Farsetta
800 Poly Place
Brooklyn, New York 11209

Gentlemen:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $8,750
(NRC Inspection No. 89-001)

This letter refers to the NRC inspection conducted between July 19-21, 1989 at your facility in Brooklyn, New York, and continued in the Region I office between August 12, 1989 and August 21, 1989 to review additional documentation submitted by you at that time that was unavailable at the time of the inspection. The inspection consisted of a review of activities authorized by NRC License Nos. 31-02892-03, 31-02892-05 and SNM-1969. The inspection report was sent to you on September 27, 1989. During the inspection, violations of NRC requirements were identified. On October 17, 1989, an enforcement conference was conducted with you and other members of your staff to discuss the violations, their causes, and your corrective actions.

One of the violations is set forth in Section I of the enclosed Notice. That violation, which occurred on October 25, 1988, involved the failure of a technician to follow emergency procedures when a teletherapy source did not return to the shielded position while a patient was undergoing treatment. The teletherapy unit timer continued to operate beyond the preset time instead of terminating the prescribed treatment. The technician did not take immediate action to remove the patient from the source beam as required by procedures; rather, he allowed the patient to remain there with the source unshielded for approximately an additional 30 seconds in order to demonstrate the timer malfunction to your consultant. As a result, the dose received by the patient for that specific treatment was about 50 rads more than prescribed.

The NRC recognizes that the patient's cumulative radiation dose for the entire series of prescribed treatments was not exceeded because the dose during the following treatment was reduced to compensate for the additional exposure received on October 25, 1988. Nonetheless, the failure to take immediate action to either remove the patient from the radiation field, or return the teletherapy source assembly to the shielded position, constituted poor judgment by the technician. If the patient had been at, or near, the end of the treatment cycle, or if the source had been of greater strength, a potential would have existed for the patient's total therapeutic radiation dose to have exceeded the cumulative prescribed radiation dose. This failure

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by the technician to follow the emergency procedures is of a significant regulatory concern. The NRC is also concerned that the incident was not brought to the attention of senior Medical Center management and that the Radiation Safety Committee did not take a more immediate active role to ensure that a full evaluation of the incident was performed and appropriate corrective actions were implemented.

The violations described in Section II of the enclosed Notice, include, but are not limited to: (1) failure of the Radiation Safety Officer (RSO) to ensure that radiation safety activities were performed in accordance with approved procedures and regulatory requirements; (2) failure to appoint representatives from the teletherapy and pacemaker departments to the Radiation Safety Committee; (3) failure to instruct two individuals working in a restricted areain the precautions and procedures to minimize exposure; (4) failure to adequately evaluate radiation exposures to the whole body of an individual; (5) failure to adequately evaluate wipe samples of incoming radioactive packages; (6) failure to perform radiation survey measurements of radiopharmaceutical elution, preparation and injection areas; and (7) failure to maintain complete records of the annual full calibration of the teletherapy system and the monthly safety spot check of the system.

These violations are of concern to the NRC because of the number of violations identified, and because Violations H. and I. in Section II of the Notice are repetitive from the previous NRC inspection at your facility in 1987. During that previous inspection (Inspection Report No. 87-001), a violation was identified involving the failure to properly maintain records of the annual full calibrations and monthly safety spot checks of the teletherapy system. Notwithstanding the NRC issuance of a Notice of Violation for this matter on April 6, 1988, your corrective actions were not sufficiently comprehensive to prevent recurrence.

The violations set forth in Section II of the enclosed Notice, if considered individually, would normally be classified at Severity Level IV or V. However, these violations collectively indicate a lack of management oversight of, and attention to, your radiation safety program. If adequate attention and oversight of licensed activities had been provided, these violations would probably not have gone undetected until the NRC inspection.

The violations in Sections I and II of the enclosed Notice demonstrate the need for Medical Center management, the Radiation Safety Committee and the RSO to aggressively monitor and evaluate licensed activities throughout the Medical Center to assure that these activities are conducted safely and in accordance with the terms of your licenses. To emphasize this need, I have been authorized, after consultation with the Director of Enforcement and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $8,750. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (1989), (Enforcement Policy), the violation set forth in Section I of the enclosed Notice has been categorized as a Severity Level III

violation because it created a substantial potential for a significant misadministration at your facility. The violations set forth in Section II of the enclosed Notice have also been classified in the aggregate as a Severity Level III problem to focus on the underlying NRC concern, namely, a lack of management attention to licensed activities.

The base civil penalty for a Severity Level III violation or problem is $2,500. With respect to the violation set forth in Section I of the Notice, the escalation and mitigation factors in the Enforcement Policy were considered and no adjustment to the base civil penalty is warranted because: (1) although the incident was identified by your staff, the malfunctioning timer could reasonably have been repaired sooner if management had promptly investigated and resolved the problem that had been identified by the teletherapy technicians; (2) your corrective actions, which included replacement of the defective timer and installation of a second backup timer, although considered adequate, were not considered comprehensive since the incident was never brought to the attention of senior management and the Radiation Safety Committee did not take an immediate and active role in the evaluation of the incident and correction of the problem; and (3) although your overall past performance is poor, the NRC has considered this factor in escalating the base civil penalty for the violations in Section II by 100%, and, therefore, further escalation on this factor is considered inappropriate.

With respect to the violations set forth in Section II of the Notice, the escalation and mitigation factors in the Enforcement Policy were considered and the base civil penalty has been increased by 150% because: (1) the violations were identified by the NRC and reasonably should have been identified sooner had hospital management and the RSO adequately monitored the program and, therefore, 50% escalation of the base civil penalty is warranted; and (2) your past performance (which includes 16 violations during the previous two inspections, including one violation that recurred during this recent inspection), is not good and therefore, 100% escalation of the base civil penalty on this factor is warranted. Your corrective actions, as set forth in your letter received by the NRC on August 12, 1989, and as presented at the enforcement conference, while adequate, were not considered prompt and comprehensive and therefore, no adjustment to the base civil penalty on this factor was warranted. The other mitigation and escalation factors were considered and no further adjustment was considered appropriate.

You are required to respond to this letter and the enclosed Notice, 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 take to prevent recurrence. Furthermore, you should describe the actions taken or planned to improve the management oversight of your radiation safety program by the Radiation Safety Officer, the Radiation Safety Committee, and the Medical Center Administration. You do not need to include documents previously submitted at or prior to the Enforcement Conference to support the actions taken. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further action is needed to ensure compliance with regulatory requirements.

We emphasize that any recurrence of these violations may result in more significant enforcement action.

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 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, PL No. 96-511.

Sincerely

Original Signed By
WILLIAM T. RUSSELL
William T. Russell
Regional Administrator

Enclosure:
As stated

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