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

February 15, 1994

Docket No. 030-02003
License No. 21-01103-04
EA 94-014

Genesys Regional Medical Center
ATTN: Homer W. Read
Assistant to the President
302 Kensington Avenue
Flint, MI 48502

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $3,750 (NRC INSPECTION REPORT NO. 030-02003/93001(DRSS))

Dear Mr. Read:

This refers to the NRC inspection of St. Joseph Hospital (now d.b.a. Genesys Regional Medical Center, St. Joseph Campus) from April 26 through May 4, 1993. A copy of the report documenting this inspection was mailed to you on May 28, 1993. Significant violations of NRC requirements were identified during the inspection, and on February 3, 1994, an open enforcement conference was held with you and members of your staff to discuss the violations, their causes, and your corrective actions. A copy of the Enforcement Conference Report was mailed to you on February 8, 1994.

The violations are fully described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). Briefly, they include failures to (1) instruct nurses in the size and appearance of brachytherapy sources, (2) provide initial and annual radiation safety training to nuclear medicine technologists, (3) measure the thyroid burden of each individual who helped prepare or administer therapy dosages of iodine-131 (repeat violation), (4) repair or replace a dose calibrator when the accuracy error exceeded ten percent, and (5) failures to survey the cardiac stress room. The first violation is the most significant. Here, a brachytherapy patient apparently removed a tandem containing three cesium-137 sources from her body and handed it to a nurse. Because the nurse did not recognize the tandem or the cesium-137 sources, she placed the tandem on a window sill where it remained for the next eight hours until it was discovered and subsequently removed by an oncologist. This resulted in a misadministration in that the patient received an estimated 333 centigray of the 2000 centigray intended. Moreover, it was extremely fortuitous that neither the nurse, nor anyone else, received any significant exposure to the unattended sources.

These violations, taken collectively, represent a significant breakdown in the control of NRC licensed activities. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations are being classified in the aggregate as a Severity Level III problem.

The root cause of the violations was discussed during the enforcement

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conference, where you stated that the Radiation Safety Officer and higher management were not providing sufficient attention to the entire radiation safety program. You indicated that, when the Radiation Safety Officer was hired in 1991, he was given responsibility over the Radiation Oncology radiation safety program, whereas the responsibility for the Nuclear Medicine radiation safety program was delegated to an outside medical physics consultant. As you reported during the conference, this division of responsibilities no longer exists; the Radiation Safety Officer is responsible for the radiation safety of all activities conducted under the authority of your NRC license.

The NRC license issued to Genesys Regional Medical Center entrusts responsibility for radiation safety to the management of the medical center, 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 indicate a significant breakdown in the process by which management, and in particular, the Radiation Safety Committee and the Radiation Safety Officer, ensure that the radiation safety program is properly implemented.

The NRC recognizes that subsequent to the NRC inspection, prompt and effective actions were taken by you to correct the violations. However, to emphasize the NRC's concern with the lack of adequate oversight of your program, I have been authorized to issue the enclosed Notice in the amount of $3,750 for the Severity Level III problem.

The escalation and mitigation factors in the NRC Enforcement Policy were considered in the calculation of this amount. The base value of a civil penalty for a Severity level III problem is $2,500. This was escalated 50% because all the violations were identified by the NRC. The base civil penalty was escalated another 50% for your performance during the previous two NRC inspections, in which three Severity Level IV violations were identified in 1990, and five Severity Level IV violations were identified in 1987. The base civil penalty was also mitigated 50% for your prompt and effective corrective actions. These included (1) increasing the time spent by the Radiation Safety Officer in the nuclear medicine department, and increasing his familiarity with 10 CFR Part 35; (2) appointing a lead nuclear medicine technologist who is also a member of the Radiation Safety Committee; (3) training all oncology nurses in radiation safety principles, especially those relevant to brachytherapy, holding an emergency drill, and instituting policies and procedures whereby annual radiation safety refresher training is mandatory for all oncology nurses; (4) training all nuclear medicine technologists in radiation safety principles and in your quality management program; (5) measuring the thyroid burden of each individual who helped prepare or administer therapy dosages of iodine-131 on the day of the therapy; and (6) conducting and recording daily and weekly surveys of the cardiac stress room. These corrective actions were implemented almost immediately after the 1993 inspection, as was verified during the January, 1994 NRC inspection.

The remaining factors in the Enforcement Policy were also considered and no further adjustment to the base civil penalty was considered appropriate. Therefore, in summary, the base civil penalty was escalated 50%.

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,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalty

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