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

February 2, 1994

Docket No. 030-02101
License No. 21-11494-01
EA 94-009

Oakland General Hospital
ATTN: Mr. Robert Deputat
Vice President Operations
27351 Dequindre Avenue
Madison Heights, MI 48071

Dear Mr. Deputat:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $3,750
(NRC INSPECTION REPORT NO. 030-02101/93001(DRSS))

This refers to the inspection conducted on December 20 and 21, 1993, at Oakland General Hospital. The report documenting this inspection was sent to you by letter dated January 20, 1994. During this inspection violations of NRC requirements were identified. An enforcement conference was held on January 28, 1994.

During this inspection, the inspector identified that the quality management program you submitted to the NRC on December 30, 1991, did not address any of the five objectives of 10 CFR 35.32(a). You provided a second document to the inspector entitled, "Radiological/Nuclear Medicine Quality Assurance Program," which also did not address any of the five objectives. Deficiencies in the quality management program had been previously brought to your attention by your consultant during the Radiation Safety Committee meeting held on June 29, 1993; however, you failed to rectify the deficiencies. Six brachytherapies were performed, two since June 1993, without an acceptable program in place.

On December 22, 1993, a Confirmatory Action Letter was issued confirming your decision that Oakland General Hospital would not perform brachytherapy until a quality management program was submitted that met the specific objectives of 10 CFR 35.32. Subsequently, on December 27, 1993, you submitted a quality management program that adequately addressed brachytherapy.

One violation is described in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involving your failure to establish and maintain a written quality management program for administering brachytherapy radiation doses.

The root cause of the violation appears to be a lack of sufficient knowledge and regulatory awareness on the part of your management, the Radiation Safety Officer, and the Radiation Safety Committee. An upper level manager did not attend Radiation Safety Committee meetings nor was a manager adequately

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involved with the radiation safety program. In addition, managers appeared to be confused about their responsibility for the activities of the radiation oncology contract physicians and physicists.

No brachytherapy misadministrations occurred during the period while the quality management program was not implemented. However, without a program you could not provide the confidence expected pursuant to 10 CFR 35.32 that brachytherapy administrations would be as directed by the authorized user. Therefore, the violation described above represents a substantial failure to implement the quality management program. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violation has been categorized at Severity Level III.

We acknowledge your corrective actions. You submitted a quality management program on December 27, 1993, and plan to strengthen the Radiation Safety Committee by including senior managers as members. You plan to have the Radiation Safety Committee conduct inspections of the radiation safety program in addition to the required annual review. The Radiation Safety Officer committed to take more responsibility for the program. However, we are concerned that your plans were not fully formulated at the time of the conference. For example, you did not present specific plans to ensure that radiation safety responsibilities are clearly delineated for the several individuals involved with the program.

To emphasize the need for implementation of your quality management program for brachytherapy administrations, and the need for adequate management involvement with the radiation safety program, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $3,750 for the Severity Level III violation. The base value of a civil penalty for a Severity Level III violation is $2,500.

The civil penalty adjustment factors in the Enforcement Policy were considered. The base civil penalty was escalated 50 percent because the NRC identified the violation. The base civil penalty was not mitigated for your corrective actions because we have concerns in this area as discussed above. The base civil penalty was escalated 100 percent for prior opportunity to identify because although your consultant initially identified deficiencies in the quality management program during the Radiation Safety Committee meeting on June 29, 1993, you did not submit an adequate quality management program to the NRC until December 27, 1993, after the NRC inspection. The base civil penalty was mitigated 100 percent for your good past performance in that only two violations were identified during the previous two inspections.

The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been increased by 50 percent.

Section II of the Notice describes two violations not assessed a civil penalty involving failure to have a copy of the license that identified a visiting physician as an authorized user, and failure of the Radiation Safety Committee, with the assistance of the Radiation Safety Officer, to review your

radiation safety program.

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.

Your response should also address the following NRC concerns: (1) senior management was not sufficiently involved and did not understand the radiation safety program requirements; (2) radiation safety managers, the Radiation Safety Officer, and the Radiation Safety Committee failed to adequately integrate activities involving radiation therapy into their oversight of the radiation safety program; (3) attendance at Radiation Safety Committee meetings does not reflect the appointed membership; and (4) radiation safety duties were divided among several individuals without cohesive oversight or direction.

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 responses 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, Public Law No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

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