OAKLAND GENERAL HOSPITAL
Osteopathic

February 28, 1994

REPLY TO A NOTICE OF VIOLATION

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

Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington D.C. 20555

Dear Sir/Madam:

Pursuant to your letter dated February 2, 1994 concerning NRC Inspection Report No. 030-02101/93001 (DRSS) our responses to the violations are listed below:

I. *10 CFR 35.32(a) requires, in part, that each licensee shall establish and maintain a written Quality Management Program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.*

OGH RESPONSE:

OGH submitted a Quality Assurance Program in December 1991 that failed to address the Brachytherapy Component. (We were inspected in February 1992 by the NRC. The inspector was given a copy of the plan we submitted. No negative comments were received concerning the plan at that time.) In June 1993, following a review of the plan by our contractual physicist, we became aware of deficiencies in the therapy component of the plan. We were working toward resolving these at the time of the December 1993 inspection.[1] *At the Radiation Safety Committee meeting held December 24, 1993 a revised QMP was approved. On December 27, 1993 we submitted the revised QMP that "adequately addressed Brachytherapy". Thus we have reached "full compliance" pursuant to the NRC notice of violation dated February 2, 1994 and signed by Mr. John Martin, Regional Administrator.*

IIA. *10 CFR 35.37(a)(2) provides, in part, that a licensee may permit any visiting user to use licensed material for medical use under the terms and conditions of the licensee's license for sixty days each year if the licensee has a copy of a license issued by the Commission or Agreement State or a permit issued by a Commission or Agreement State board licensee that identifies the visiting authorized user by name as an authorized user for medical use.*

[1] Radiation Safety Committee minutes dated June 29, September 30, 1993.

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Madison Heights, Michigan 48071
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IIA (Continued)

OGH RESPONSE:

OGH did not have a copy of an authorized user license, for the performance of Brachytherapy for Yosh Maruyama, M.D. on file. We did have a copy of the minutes of the Radioisotope Committee meeting, held at Harper Hospital. These minutes showed that Dr. Maruyama is authorized to perform Brachytherapy. The type of license from Harper Hospital, was a broad scope license and specific authorized users are not listed. We are modifying our credentialing process so that any "new user" applying for privileges will pass before the RSO at OGH and Dr. Wayne Court, M.D. from Harper Hospital. We anticipate approval of this change at the next Radiation Safety Committee meeting to be held March 18, 1994.

IIB. 10CFR 35.22(b)(c) requires that, to oversee the use of licensed material, the Radiation Safety Committee must review annually, with the assistance of the Radiation Safety Officer, the licensee's Radiation Safety Program.

OGH RESPONSE:

10 CFR 35.22(b)(c) requires a review to be performed annually by the Radiation Safety Committee. Our review was not performed by the Radiation Safety Officer; it was performed quarterly by our contractual physicist who reported the results to the Radiation Safety Committee. The Radiation Safety Officer would review the submitted quarterly report and sign off on the document.

To correct the deficiency we have performed an audit for 1993 by the RSO for the Nuclear Medicine component. An audit of the Radiation Oncology Brachytherapy Program will be carried out by Wayne Court, M.D. and will be presented at the March 18, 1994 Radiation Safety Committee Meeting (with the assistance of Pat McDermott, PhD.). Further corrective action is planned in the form of a mock inspection which will be carried out by a team represented by local experts in the field of Brachytherapy and Radiation Physics. The report will be directed to the RSO.

The NRC also states several 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.

OGH RESPONSE:

The Radiation Safety Committee has been redesigned in total. The committee will include a representative from senior management as a regular member. The committee will report to the Medical Executive Committee and to the Hospital Executive Committee, both of whom report to the Board of Directors. Responsibilities have been assigned for both Radiation Therapy and Nuclear Medicine. Dr. Patrick McDermott, PhD. has been assigned the responsibility to audit the Brachytherapy activities and to regularly report and to recommend as needed, any changes to the Radiation Safety Committee. Wayne Court, M.D. has been selected to serve on the Radiation Safety Committee in the credentialing of Brachytherapy.

We trust these responses satisfactorily address the cited deficiencies and request that you contact the undersigned at your convenience should further clarification be required.

Sincerely,

Robert A. Deputat
V.P. Operations

RAD/dw

Attachments

pc: Regional Administrator
U.S. Nuclear Regulatory Commission, Region III
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Lisle, Illinois 60532-4351