U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-13998/94001(DRSS)

Docket No. 030-13998

NRC License No. 21-03429-04 Category G Priority 2

Licensee: Gratiot Community Hospital
300 Warwick Drive
Alma, MI 48801

Meeting Conducted: June 1, 1994

Type of Meeting: Enforcement Conference

Inspection Conducted: On site June 8 and 9, 1993,
In-office review of additional material
June 10 to 22, 1993.

Inspector: Frank Mitchell 6/16/94
Mark Mitchell Date
Radiation Specialist

Reviewed By: John A. Grobe 6/16/94
John A. Grobe, Chief Date
Nuclear Materials Inspection
Section 2

Approved by: Roy J. Caniano 6/16/94
Roy J. Caniano, Chief Date
Nuclear Materials Safety Branch

Enforcement Conference Summary

Enforcement Conference on June 1, 1994 (Report No. 030-13998/94001(DRSS))
Areas Discussed: The conference included a review of the apparent violations identified during the special inspection, apparent violations identified as a result of resolution of previously unresolved issues identified during the inspection and the corrective actions taken or planned by the licensee. The enforcement options pertaining to the apparent violations were also discussed.

## DETAILS

1. Persons Present at Conference

Gratiot Community Hospital

Don Pray, Executive Vice President
Dr. Peter Boss, M.D., Radiation Safety Officer
Galen Miller, Radiology Manager
Jim Botti, Physicist, Medical Physics Consultants

U.S. Nuclear Regulatory Commission

Roy Caniano, Chief, Nuclear Materials Safety Branch
Bruce Berson, Regional Counsel
Robert DeFayette, Director, Enforcement and Investigation Coordination Staff
Darrel Wiedeman, Enforcement Specialist
Mark Mitchell, Radiation Specialist
Joseph Delmedico, Enforcement Coordinator
Sally Merchant, Medical Use Specialist

2. Enforcement Conference

The Enforcement Conference was held in the Region III office on June 1, 1994. The conference was the result of the findings from the June 8 to 22, 1993, inspection in which apparent violations of NRC regulations were identified.

The inspection report (No. 030-02132/93001 (DRSS)) was transmitted to the licensee via letter dated July 16, 1993. The inspection report identified four apparent violations and two unresolved items. In a letter dated May 24, 1994, the NRC informed the licensee that escalated enforcement was being considered based on six violations identified during the inspection. The licensee was informed that the number and characterization of the apparent violations may change as a result of further NRC review.

The purpose of this conference was to (1) discuss the apparent violations, causes and the licensee's corrective actions; (2) determine if there were any escalating or mitigating circumstances; and (3) obtain any information which would help determine the appropriate enforcement action.

The licensee representatives presented a written response including corrective actions for the apparent violations being considered for escalated enforcement (enclosed). The licensee agreed with the apparent violations regarding:

(1) Failure to instruct the nuclear medicine technologists in the specifics of the licensee's quality management program (QMP) as required by 10 CFR 35.25(a)(1).

(2) Failure to prepare written directives prior to administering NaI Iodine-131 in quantities greater than 30 microcuries on several occasions.

The licensee contended, that while the documentation of the training is limited, one technologist was trained by the previous nuclear medicine technologist and the other by consultant prior to supervised use of radiopharmaceuticals that required implementation of the QMP.

The licensee's representatives described the events which lead to the violations, including root causes and corrective actions taken. In summary, the corrective actions were:

(1) All nuclear medicine technicians have been retrained in the requirements of the QMP as of June, 1993.

(2) All nuclear medicine technicians have completed a written test in the in the requirements of the QMP as of July, 1993.

(3) The RSO has taken a more hands on approach to the duties of RSO in oversight of the Nuclear Medicine Department and licensed activity.

(4) The consulting medical physicist will review all records and documentation in conducting audits of the department including the details of the annual review of the QMP on a quarterly basis.

The corrective actions for the apparent violations not considered for escalated enforcement and identified in the Inspection Report No. 030-13998/93001 were briefly discussed by the licensee.

The meeting was closed by NRC representatives with a discussion of the NRC Enforcement Policy. The licensee was told that further enforcement action were possible and they would be notified in the near future of the final enforcement action.

Attachment:
Letter from Gratiot Community Hospital to W. L. Axelson dated May 31, 1994.

Close file


May 31, 1994

United States
Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

License No. 21-03429-04
Docket No. 030-13998
EA No. 93-281

Dear Mr. Axelson:

SUBJECT: NRC INSPECTION REPORT NO. 030-13998/93001(DRSS)

This document is in reference to your findings from the special safety inspection conducted at our facility June 8 and 9, 1993. Please find below our responses to the concerns raised.

1. FAILURE TO INSTRUCT THE NUCLEAR MEDICINE TECHNOLOGIST IN THE SPECIFICS OF THE LICENSEE'S QMP AS REQUIRED BY 10 CFR 35.25 (a)(1).

   The previous Nuclear Medicine technologist (Steven Homan) did not understand the activity level correctly. He understood the QMP was required with activity greater than 30 mci (millicuries) when in fact the QMP is required over 30 uci (microcuries). Steve in turn told our medical physicist and RSO that we did not do therapy requiring the QMP which perpetuated the problem.

   The Quality Management Program document was relatively new and unfamiliar to the staff and RSO. (January 27, 1992)

   The loss of continuity as a result of multiple staff position changes contributed to the problem. The department manager left in May of 1992, the Nuclear Medicine technologist left in August of 1992, the back-up Nuclear Medicine technologist left in January of 1992. Medical Physics Consultants assigned a new physicist to Gratiot Community Hospital in July of 1992.

   Thomas Abraham reviewed the QMP and was aware of the requirements. Minutes from the Fourth Quarter Radiation Safety Committee meeting indicate that he raised the question concerning administration of the QMP at that time. The assumption was made by the RSO and physicist that we were not exceeding the trigger level for using the QMP and mis-communication between Mr. Abraham and the physicist further delayed the resolution.



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Upon being made aware of our error, we promptly took appropriate corrective action. The most significant responses to this issue are as follows: 1. A technologist training document was instituted that must be read and signed prior to assuming duties at Gratiot Community Hospital. 2. A written test must be taken that assures understanding of the QMP. 3. A redesigned QMP checklist and Written Directives form were instituted. 4. Our physicist stepped up reviews from annually to quarterly. 5. RSO directed that the technologist/physicist provide quarterly reviews of each therapy case.

2. FAILURE TO PREPARE A WRITTEN DIRECTIVE SIGNED AND DATED BY THE AUTHORIZED USER PRIOR TO THE ADMINISTRATION OF QUANTITIES GREATER THAN 30 MICROCURIES OF I-131 AS REQUIRED BY 10 CFR 35.32 (a)(1).

This omission stems from item 1 and corrective actions listed for item 1 are specific to this issue.

3. FAILURE TO DATE WRITTEN DIRECTIVES PREPARED BY THE AUTHORIZED USER PRIOR TO THE ADMINISTRATIONS OF QUANTITIES GREATER THAN 30 MICROCURIES OF I-131 AS REQUIRED BY 10 CFR 35.32 (a)(1) and 35.2.

The omission of the date is the result of item 1 as well. A training checklist and test has been instituted to assure full understanding and compliance with each of the requirements of the QMP.

## SUMMARY

Gratiot Community Hospital responded quickly and appropriately to each of the concerns found as a result of the NRC inspection of June, 1993. Also Gratiot Community's record with the NRC shows that we have not knowingly violated NRC regulations in the past and have responded quickly and appropriately when concerns have been brought forward.

The record shows that during a routine NRC inspection in February of 1992, there were no violations found.

Findings from the June 8-9, 1993 NRC inspection were immediately responded to as a result of the exit conference conducted by Mr. Mitchell on June 9, 1993. A compliance plan was drafted on June 10, 1993 which addressed every item voiced by Mr. Mitchell.

Before receiving the July 16, 1993 documentation from the NRC inspection (in which some of the items did not even appear), every item had been appropriately dealt with. Most items were corrected by June 17, and the entire list was completed by June 22, 1993.

When making your determination with regard to escalated enforcement, we ask that you take into account our past record, our prompt response to concerns and the fact that the QMP is working very well with the changes put in place which includes a new Nuclear Medicine technologist certified by NMTCB and possessing a B.S. degree in Nuclear Medicine Technology. We feel we are operating a well managed Nuclear Medicine department and are confident that, if you were to visit us again, would find we are operating within NRC parameters.

Sincerely,

Don Pray
Executive Vice President

DP:GM:ra

cc: Bob Baker, President
Peter Boss, M.D., RSO
Galen Miller, Radiology Manager