IE-07

PUBLIC

MAR 21 1994

Riverside Methodist Hospital
ATTN: Marian Hamm
Senior Vice President
3535 Olengtangy River Road
Columbus, OH 43214

License No. 34-01055-01
Docket No. 030-02669

Dear Ms. Hamm:

SUBJECT: NOTICE OF VIOLATION DATED JANUARY 7, 1994

This acknowledges receipt of your letter dated February 4, 1994, in response to our letter dated January 4, 1994, transmitting a Notice of Violation. In addition, a telephone conference was held on March 15, 1994, between your staff and NRC Region III staff. The conference was held to verify your agreement that the violations occurred.

We have reviewed your corrective actions, which appear to be adequate, and have no further questions at this time. These corrective actions will be examined during a future inspection.

Sincerely,

Original Signed by Roy J. Caniano

Roy J. Caniano, Chief
Nuclear Materials Safety Branch

cc w/o enclosure:
S. Jayaraman, Ph.D.
Radiation Safety Officer

bcc w/ltr dtd 02/04/94:
PUBLIC

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| RIII | RIII | RIII |
|---|---|---|
| Young | Holt | Caniano |
| 3/16/94 | 3/16/94 | 3/16/94 |

CONVERSATION RECORD TIME 9:00 a.m. DATE 3-15-94

○ VISIT ○ CONFERENCE X TELEPHONE (OUTGOING)

Location of Visit/Conference NMSB Chief Office (Roy Caniano, B. J. Holt, and Thomas Young)

| NAME OF PERSON(S) CONTACTED OR IN CONTACT | ORGANIZATION (OFFICE, DEPT.ETC.) | TELEPHONE NO. |
|---|---|---|
| Stephanie Zembar, Ralph Kennaugh, Mark Crynkovich<br>Marian Hamm, John Niemkiewicz, Paul Lundahl | Riverside Methodist Hospital<br>Columbus, OH | 614/565-5151 |

SUBJECT

Discussion of the licensee's letter dated February 4, 1994, in response to the Notice of Violation dated January 7, 1994, that identified two violations of 10 CFR Part 35.33 (a).

SUMMARY

Mr. Caniano outlined the chronology of events pertaining to the Notice, summarized the key aspects of Information Notice 93-36 that explains NRC expectations for licensee notification of patients in the event of a misadministration that occurs at the licensee's facilities, and characterized the violations in the Notice as Severity Level IV violations. He asked the licensee if they were in agreement that the violations had occurred.

Ms. Zembar replied that the licensee believes their personnel acted properly and notified the referring physician when the misadministration was discovered in February 1993. However, the licensee also recognized the need for education of their personnel and so they prepared their own version of Information Notice 93-36 and issued it to their authorized users and technical and professional staff. The referring physician was unaware of NRC requirements and specific details of the patient notification issues when he was contacted by the NRC inspector in June 1993. That conversation later became the basis for the Notice of Violation.

Mr. Caniano addressed future NRC expectations for the licensee's Radiation Safety Officer to investigate all licensee incidents, including misadministrations. In addition, 10 CFR Part 35.33 does not allow flexibility for notification of the patient or the patient's family. The licensee must notify them within 24 hours of the discovery of the misadministration. If the notification cannot be made, then the licensee should contact Region III. The licensee representatives acknowledged their understanding of these discussion items.

Dr. Crynkovich asked for clarification of a hypothetical case where it is decided not to tell the patient of the misadministration, but then later the decision is reconsidered and the patient is notified.

Again, Mr. Caniano suggested that the licensee notify the NRC of the situation when the patient has no family member that can be notified within 24 hours, and the patient's medical condition prevents notification of the patient. If the patient's condition improves, then the patient should be notified and NRC should be updated regarding the notification process.

In conclusion, Mr. Caniano indicated that a routine letter of acknowledgement would be sent to the licensee. No further action is necessary by the licensee or Region III.

ACTION REQUIRED

Send letter to acknowlege that the licensee's letter dated February 4, 1994, was adequate.

| NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE | DATE |
|---|---|---|
| Thomas Young | Thomas Young | 3-15-94 |

ACTION TAKEN

| SIGNATURE | TITLE | DATE |
|---|---|---|