Medical Center

3001 Greenbay Road
North Chicago, IL 60064-3096

Department Of
Veterans Affairs

JUN 0 4 1991

In Reply Refer To 556/112

John A. Grobe
Chief, Nuclear Materials Safety Branch
U. S. Nuclear Regulatory Commission Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

SUBJ: License No. 12-10057-04
Docket No. 030-15269

Gentlemen:

On May 20, 1991, our medical center received a Nuclear Regulatory Commission Notice of Violation regarding a diagnostic misadministration which occured on September 27, 1989 in our Nuclear Medicine Service

Enclosed, please find our written response.

Sincerely,

Hugh Doran

A. S. Pate for
Medical Center Director

Enclosure: 1

cc: Director/Chief, Nuclear Medicine Service, VACO (115B-JC)
Regional Director (132)

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RESPONSE TO THE NOTICE OF VIOLATION OF MAY 10, 1991

1. Statement of the Problem

a. On May 20, 1991 we received a "Notice of Violation" from the Nuclear Regulatory Commission (NRC), Region III, regarding our failure to notify the NRC Office and the referring physician within 15 days, of a diagnostic misadministration, which occured on September 27, 1989 in our Nuclear Medicine Service.

b. On the same day, May 20, 1991, the Radiation Safety Officer (RSO), Dr. S. Loga, posted the Notice of Violation in the Nuclear Medicine Service on the bulletin board.

2. Sequence of Events

a. On September 27, 1989, a diagnostic misadministration took place in Nuclear Medicine Service.

The Nuclear Medicine supervisor, Mr. J. Dowell, informed his Chief, Nuclear Medicine Service, Dr. G. Gergans, immediately that a misadministration may have occured.

b. One week later, on October 3, 1989, Mr. J. Dowell informed the RSO in writing, of the misadministration.

c. On October 4, 1989, the RSO started to investigate the incident, after informing the former Medical Center Director, Mr. L. Rogers, through the former Chief of Staff, Dr. G. Almy.

d. After the RSO completed her investigation, she concluded that indeed a misadministration had occured on September 27, 1989, and felt obligated to report it to the NRC.

e. Because both Nuclear Medicine physicians, Dr. G. Gergans and Dr. T. Balachandra, did not believe that a diagnostic misadministration had taken place, the RSO reported it as an "alleged misadministration" and specified in her report to the NRC, that the referring physician was not informed.

f. On October 10, 1989, still within the 15 days reporting period required by law, a diagnostic misadministration report, NRC Form 473, together with a written report of the incident, were completed by the RSO and hand-carried by her to the Director's Office, at which time she indicated that the time limit for reporting was almost up.

g. However, the immediate supervisor of the RSO, the former Chief of Continuous Quality Improvement Center, Mrs. J. Gunn, informed the RSO that this incident should not be reported to the NRC.

The RSO disagreed and insisted that the report be sent to NRC.

h. This further delayed the report, with the result that the NRC Office received the misadministration report only on October 30, 1989.

i. The referring physician was informed of the incident by Dr. G. Gergans on November 16, 1989, only after he received a memo from the RSO, dated November 6, 1989, relating a phone conversation, on this subject, with Mrs. R. Pankratz from NRC, Region III.

3. Reason for the Violation

a. The main reason for the delay in reporting to NRC and the referring physician, was the disagreement regarding whether or not a diagnostic misadministration had occured.

b. Another reason was the lack of communication between the different members of the Nuclear Medicine Service, as described in paragraphs 2 a and b.

4. Corrective Actions

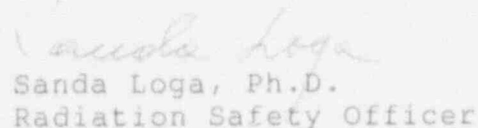
a. On April 24, 1991, the RSO, Dr. Loga, met with the new Medical Center Director, Mr. A. Pate, in the presence of the new Acting Chief of Continuous Quality Improvement Center, Mrs. S. Pusateri, for the annual Radiation Safety Management briefing. In this meeting, the Director emphasized his wholehearted support in abiding by the rules and regulations of NRC, specifically in prompt reporting of misadministrations.

b. On April 25, 1991, at the request of the RSO, a Nuclear Medicine staff meeting took place in which the NRC investigation of April 16, 1991 was discussed. The RSO stressed the need of an immediate reporting of any misadministration and the support of our medical center director in expediting it.

A copy of 10 CFR, Part 35.33 was handed out, by the RSO, to each member of the Nuclear Medicine staff.

5. Completed Corrective Actions

We are confident that the Nuclear Medicine staff is aware of all of the implications which a delay in reporting a misadminsitration might produce and this will surely prevent a violation of this kind of the NRC rules and regulations.



Sanda Loga, Ph.D.
Radiation Safety Officer