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In Reply Refer To:

662/131

February 14, 1994

Docket No.: 030-01214 License No.: 04-00421-05

United States Nuclear Regulatory Commission Region V 1450 Maria Lane Walnut Creek, California 94596-5368

Attention: Gregory P. Yuhas, Chief

Radioactive Materials Safety Branch

Subject: Response to Notice of Violation

This is in response to the Notice of Violation resulting from the NRC inspection of January 10-12, 1994. In the notice we were cited for two severity level IV violations. The federal regulations found to be violated and our response to the findings are listed below.

A. 10CFR35.205(b) requires that a licensee administer radioactive gases only in rooms that are at negative pressure compared to surrounding rooms.

Due to poor communication between Engineering Service, Nuclear Medicine Service and Radiation Safety, radioactive xenon-133 gas was administered between October 1993 and January 1994 in Building 203, Room GB-54 of the Nuclear Medicine Clinic, which was not at negative pressure compared to surrounding rooms. On January 11, the same day this violation was discovered, the air supply was adjusted to create a negative pressure environment in the room and a clearance time was calculated and posted in the room. To prevent further recurrence, each imaging room acceptable for xenon-133 studies will be clearly labeled as such with emergency procedures and clearance times posted. All future xenon-133 studies will be performed in a room at negative pressure with respect to surrounding areas. All Nuclear Medicine personnel have been made aware of the importance of observing this rule. Continued compliance will be assessed by the Radiation Safety Officer at least quarterly.

B. 10CFR35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are performed in accordance with approved procedures. This licensee's procedures for ordering radioactive materials are described in the application dated October 11, 1990, and were approved by License Condition No. 24.B., which refers to Appendix K of Regulatory Guide 10.8, Revision 2. Paragraph 1 states that the Radiation Safety Officer or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

During the inspection it was discovered that the existing procedure for ordering and release of packages does not adequately satisfy these requirements. Although an elaborate inventory system is in place, designed to prevent receipt by authorized users of unauthorized orders of radioactive materials, orders have routinely been made without authorization of the Radiation Safety Officer or his designee. In the future, no orders of radioactive material will be released unless prior written approval by the Radiation Safety Officer or his designee in the laboratory has been granted. We will begin enforcing this rule without exception no later than March 1, 1994.

Sincerely yours,

Medical Center Director

cc: Nuclear Medicine Service
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