VALLEY DIAGNOSTIC, INC.

January 18, 1994

United States Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, DC 20555

License Number: 37-23537-01
Docket Number: 030-28735

SUBJECT: REPLY TO AN NOTICE OF VIOLATION

On December 27, 1993 we were notified of a Severity Level IV violation of 10 CFR 35.32 requiring that the licensee establish and maintain a written Quality Management Program if the licensee administers quantities greater than 30 microcuries of iodine 131.

This license administered 34 microcuries of I131 on April 22 and 41.3 microcuries of I131 on April 29, 1993.

REASON FOR VIOLATION:

At the time of these administrations we were unaware of this NRC requirement. We were first notified of this requirement when contacted by the NRC on May 19, 1993, regarding the recent mandate requiring a Quality Management Program. At that time we self-identified the above two instances and promptly notified the NRC.

Up until April 1993 it was common practice to obtain thyroid uptakes with I123. I131 was listed on the dose chart available to the technologist in the range 10-50 microcuries. This was the dose chart utilized by the previous physicians under this license, prior to our assuming responsibilities for Nuclear Medicine in November 1992. As we were unaware of any Quality Management Program requirement at that time, we elected to keep the dose ranges in effect.

The technologist followed the guidelines listed in the laboratory when the two doses of I131 were administered. He too, was unaware of the NRC requirement for a Quality Management plan.

There was no guideline in effect at Valley Diagnostic at the time which required the use of I123 or prohibited the use of I131 or I125 in doses above 30 uC1 without a Quality Management Program in effect.

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IMMEDIATE CORRECTIVE STEPS

This license took several immediate steps as a result of our self-identified violation of the Quality Management Plan:

1. Imaging protocols were initiated for the use of I123 and I131, and were placed in the protocol book.
2. The requirements of the Quality Management Plan were listed in the protocol book.
3. This license issued a protocol that I131 and I125 are not to be used as a diagnostic agent at Valley Diagnostic until further notice. This eliminates any further possibilities of violations.
4. The Physicians at Valley Diagnostic and the Nuclear Medicine Technologist were instructed regarding the NRC requirement of a Quality Management Plan and our decision not to use I131 and I125.

COLLECTIVE STEPS TO AVOID FURTHER VIOLATIONS

1. I131 and I125 were removed from use at Valley Diagnostic. This eliminates the possibility of future violations.
2. The Physicians at Valley Diagnostic and the Nuclear Medicine Technologist were instructed concerning the removal of I131 and I125 and the requirement of a Quality Management Plan in June 1993.
3. The license held in depth discussions with our Consulting Physicist in October 1993 concerning our activities and emphasizing the need for a close liaison with professional consultants.

As per requirement, the two patients have been sent a written report concerning this violation.

Sincerely,

PAUL SCHAEFER, M.D.
Radiation Safety Officer
Medical Director

PS/kjb
cc: United State Nuclear Regulatory Commission
Regional Administrator Region I
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