

FEB - 9 1994

Docket No. 030-28735

License No. 37-23537-01

Valley Diagnostic, Inc.  
ATTN: Paul Schaefer, M.D.  
Administrator  
Suite 106, Professional Plaza  
625 Lincoln Avenue  
North Charleroi, Pennsylvania 15022

Dear Dr. Schaefer:

Subject: Routine Inspection No. 030-28735/93-001

This letter refers to your January 18, 1994 correspondence, in response to our December 21, 1993 letter.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

No reply to this letter is required. Thank you for your cooperation in this matter.

Sincerely,

Original Signed By:  
Jenny M. Johansen

Jenny M. Johansen, Chief  
Medical Inspection Section  
Division of Radiation Safety  
and Safeguards

9403010020 940209  
PDR ADDCK 03028735  
C PDR

cc:  
Public Document Room (PDR)  
Nuclear Safety Information Center (NSIC)  
Commonwealth of Pennsylvania

280056

OFFICIAL RECORD COPY - S:\PENDING\VALLYDIA.RL - 02/09/94

RETURN ORIGINAL TO  
REGION I

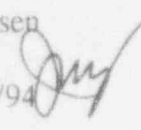
IE-07

Valley Diagnostic, Inc.

-2-

bcc:  
Region I Docket Room (w/concurrences)

DRSS:RI  
Nessen/gc  
PN  
2/9/94

DRSS:RI  
Johansen  
2/9/94 

VALLEY DIAGNOSTIC, INC.

January 18, 1994

United States Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406

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 uCi without a Quality Management Program in effect.

- continued -

Suite 106, Professional Plaza  
North Charleroi, PA 15022  
Phone: (412) 483-6564

JAN 24 1994

~~9401270259~~

# VALLEY DIAGNOSTIC, INC.

## IMMEDIATE CORRECTIVE STEPS

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

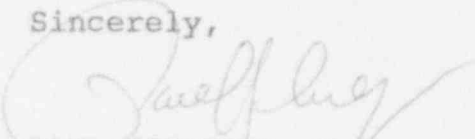
1. Imaging protocols were initiated for the use of I123 and I131, and were placed in the protocol book.
2. The requirements of the Quality Management Plan were listed in the protocol book.
3. This license issued a protocol that I131 and I125 are not to be used as a diagnostic agent at Valley Diagnostic 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  
Document Control Desk  
Washington, PA 20555

Suite 106, Professional Plaza  
North Charleroi, PA 15022  
Phone: (412) 483-6564