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DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
SOUTHWEST REGION

Office of the Regional  
Food and Drug Director  
7920 Elmbrook Drive, Suite 102  
Dallas, TX 75247-4982  
TELEPHONE: 214-655-8100  
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WARNING LETTER

October 4, 1999  
Certified Mail  
Return Receipt Requested

99-SWR-WL-29/8

Wayne W. Wenzel, M.D.  
Vail Valley Medical Center  
181 W. Meadow Drive  
Vail, CO 81657

RE: Inspection ID - 1686330017

Dear Wayne W. Wenzel, M.D.,

We are writing to you because on 9/9/1999, your facility was inspected by a representative of the State of CO, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following repeat level 2 findings at your facility:

Level 2 Repeat: The radiologic technologist did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36 month period: [REDACTED]

Level 2 Repeat: The radiologic technologist did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36 month period: [REDACTED]

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as repeat Level 2 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent correction of problem found during your previous inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

Level 2: Processor QC records were missing 5 out of 27 days of operation in month 7/1999. Processor QC records missing 19%, for processor (1), Kodak, RP X-OMAT M6B,6AN,6AW, room Main D.R. at site Vail Valley Medical Center.

Level 2: Processor QC records were missing 2 consecutive days for processor (1), Kodak, RP X-OMAT M6B,6AN,6AW, room Main D.R. at site Vail Valley Medical Center.

Level 2: Mammograms were processed in processor (1), Kodak, RP X-OMAT M6B,6AN,6AW, room Main D.R. at site Vail Valley Medical Center, when it was out of limits on 2 days.

Level 2: Corrective actions for processor QC failures were not documented at least once for processor (1), Kodak, RP X-OMAT M6B,6AN,6AW, room Main D.R. at site Vail Valley Medical Center.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:  
Deborah M. McGee  
Food and Drug Administration  
7920 Elmbrook Drive, Suite 102  
Dallas, TX 75247

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Deborah M. McGee at (214) 655-8100 ext. 138 or fax (214) 655-8130.

Sincerely yours,

  
Edward R. Esparza  
Regional Food and Drug Director