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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  
FACSIMILE: 214-655-8130

**WARNING LETTER**

September 13, 1999  
Certified Mail  
Return Receipt Requested

99-SWR-WL-27/8

Kristi Dixon  
Radiology  
Provenant Medical Center At Summit  
Highway 9 and School Road  
P.O. Box 738  
Fisco, CO 80443

RE: Inspection ID - 2032240006

Dear Kristi Dixon,

We are writing to you because on 08/02/1999, 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 level 1 and level 2 findings at your facility:

Level 2 Repeat: Processor QC records were missing 4 out of 21 days of operation in month 09/1998. Processor QC records missing 19%, for processor (1), Kodak, RP X-OMAT M6.

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.

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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: There is no written procedure for handling consumer complaints.

There is no written procedure for infection control.

Processor QC records were missing 2 consecutive days for processor (1), Kodak, RP X-OMAT M6.

2 of 5 random reports reviewed did not contain an assessment category.

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:

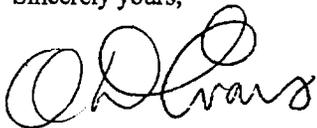
- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample 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,



for Edward R. Esparza  
Regional Food and Drug Director