



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Southwest Region  
7920 Elmbrook Drive  
Suite 102  
Dallas, TX 75247-4982

Telephone: 214-655-8100  
FAX: 214-655-8130

December 13, 2001

## WARNING LETTER

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

02-SWR-WL-17/7

Leon Fuqua  
Assistant Administrator for Radiology  
Wise Regional Health  
2000 South FM 51  
Decatur, TX 76234

RE: Inspection ID – 2157230005

Dear Mr. Fuqua,

On 12/12/2001, a representative of the State of Texas, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility.

The Mammography Quality Standards Act of 1992 requires that your facility meet specific standards. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 finding at your facility:

- Level 1: The system to communicate results is not adequate for site Wise Regional Health because:
- There is no system in place to provide timely medical reports
- There is no system in place to provide timely lay summaries

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

Level 1 findings 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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It is necessary for you to act on this matter immediately. You are required to respond to this office in writing within fifteen (15) working days from receipt of this letter. Please address the following:

- 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.
- 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).

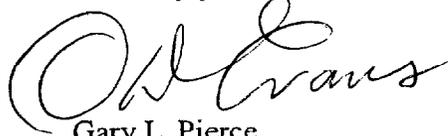
Please submit your response to:

Angela T. Moak, Radiation Specialist  
Food and Drug Administration  
7920 Elmbrook Drive, Suite 102  
Dallas, Texas 75247-4982

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/cdrh/mammography/index.html>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Angela Moak at (214) 655-8100 ext. 135.

Sincerely yours,



for Gary L. Pierce  
Regional Food and Drug Director