



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

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December 13, 2001

WARNING LETTER

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

02-SWR-WL-<sup>15<sup>TH</sup></sup>~~1817~~

Argentry Fields  
Site Manager  
Dallas County Hospital District  
9202 Elam Road  
Community Oriented Primary Care/SE  
Dallas Health Center  
Dallas, TX 75217

RE: Inspection ID – 1924270007  
Inspection ID – 2158550006-Mobile

Dear Argentry Fields,

On 12/10/2001, a representative of the State of Texas, acting on behalf of the Food and Drug Administration (FDA) inspected your facilities. These inspections revealed a serious regulatory problem involving the mammography at your facilities.

The Mammography Quality Standards Act of 1992 requires that your facilities 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 findings at both of your facilities:

- Level 1: The system to communicate results is not adequate for site Dallas County Hospital District 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 Reports, which were issued to your facilities at the close of the inspections.

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:

December 13, 2001

Page 2

- Placing your facilities under a Directed Plan of Correction.
- Charging your facilities 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 facilities' FDA certificates, or obtaining a court injunction against further mammography.

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 facilities are 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).

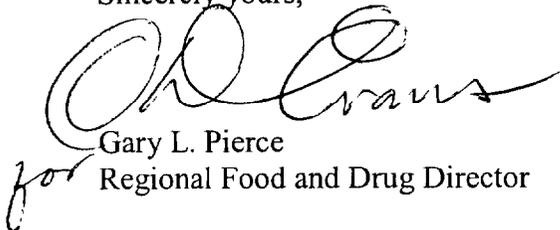
Please submit your response to:

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 inspections 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