



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

October 27, 2000

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

01-SWR-WL-04/7

Yolanda Cervantes  
Administrator  
Osteopathic Medical Center  
Dba Diagnostic Imaging Center  
3825 Camp Bowie Blvd.  
Fort Worth, TX 76107

RE: Inspection ID - 1097360006

Dear Yolanda Cervantes,

On October 16, 2000, a representative of the State of Texas acting in 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 your facility to 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: Processor QC records were missing 7 out of 23 days of operation in month 08/2000. Processor QC records missing 30%, for processor 1, Kodak, RP X-OMAT.

The specific problem 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.

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. The inspection revealed the following Level 2 findings:

Level 2: 1 of 10 random reports did not contain an assessment category.

Level 2: Processor QC records were missing 3 consecutive days for processor 1, Kodak, RP X-OMAT.

Level 2: The interpreting physician did not meet the continuing education requirement of having completed a minimum of 14 CME credits in mammography in a 36 month period: [REDACTED] (0 CME's in 36 months).

Level 2: The interpreting physician did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period: [REDACTED]

Level 2: There were no examples of nor attempts to get biopsy results.

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:  
Deborah M. McGee, Radiation Specialist  
Food and Drug Administration  
7920 Elmbrook Drive, Suite 102  
Dallas, TX 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

Page 3

October 27, 2000

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.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary L. Pierce". The signature is fluid and cursive, with a long, sweeping horizontal stroke at the end.

Gary L. Pierce  
Regional Food and Drug Director