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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

February 28, 2000

**WARNING LETTER**

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

00-SWR-WL-35/7

R. Wayne East  
Radiology Manager  
St. Michael Health Care Center  
2600 St. Michael Drive  
P.O. Box 2911  
Texarkana, TX 75504

RE: Inspection ID - 1402020005

Dear Mr. East,

On February 15, 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 and level 2 findings at your facility:

Level 1: The system to communicate results is not adequate for site because:

- There is no system in place to provide timely medical reports.
- There is no system in place to provide timely lay summaries.

Level 2: There is no designated reviewing interpreting physician for site.

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 problem 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. 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.

February 28, 2000

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).

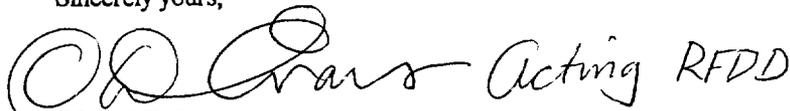
Please submit your response to:

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 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 Ms. McGee at (214) 655-8100, extension 138.

Sincerely yours,

Handwritten signature of Edward R. Esparza in cursive script, followed by the text "Acting RFDD".

Edward R. Esparza

for Regional Food and Drug Director