



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

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

April 23, 2002

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

02-SWR-WL-38/7

Sandy Tarpley  
Manager  
Lakeland Medical Associates  
117 Medical Circle  
Athens, TX 75751

Dear Ms. Tarpley:

Re: Inspection ID - 1825830007

We are writing to you because on March 25, 2002, 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. Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), 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 violation of Section 354(f) of the Act, 42 USC 263b(f), at your facility:

**Medical Records and Mammography Reports – *Communication of Mammography Results to the Patients* – (21 CFR 900.12(c)(2))**

Level 1: The system to communicate results is not adequate for site because:  
There is no system in place to provide timely lay summaries.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. A Level 1 finding indicates that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents 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 (see Sections 354(h) through (j) of the Act, 42 U.S.C. 263b(h), (j)).

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:

1. The specific steps you have taken to **correct** all of the violations noted in this letter;
2. Each step your facility is taking to **prevent the recurrence** of similar violations;
3. Equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
4. 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

In addition, your response should address the Level 2 findings listed on the inspection report provided to you at the close of the inspection. In the absence of a Level 1 finding, a Level 2 finding indicates that the facility's performance is generally acceptable. However, the inspector found one or more deviations from MQSA standards that may compromise the quality of mammography services offered by the facility. The inspection revealed the following level 2 findings:

**Quality Assurance – Equipment – *Semiannual Quality Control Tests. Darkroom Fog* – (21 CFR 900.12(e)(4)(i))**

Level 2: The measured optical density attributable to darkroom fog is equal to 0.14.

**Medical Records and Mammography Reports – *Contents and Terminology* – (21 CFR 900.12(c)(1)(vi))**

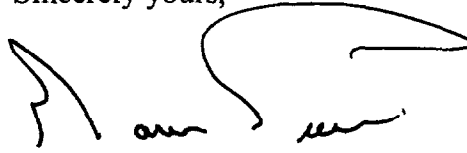
Level 2: 4 of 10 random reports reviewed did not contain an acceptable final assessment of findings category.

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/cdrh/mammography/index.html>.

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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 extension 138.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary L. Pierce". The signature is stylized with a large, sweeping initial "G" and a long, horizontal flourish extending to the right.

Gary L. Pierce  
Regional Food and Drug Director