



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

g1422d

New Orleans District Office  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127

June 20, 2001

**VIA FEDERAL EXPRESS**

**FACILITY ID# 115089**

Gary Gore, Administrator  
Marshall Medical Center North  
8000 Highway 69  
Guntersville, AL 35976

**Warning Letter No. 01-NSV-34**

Dear Mr. Gore:

Your facility was inspected on June 13, 2001 by a representative of the State of Alabama on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

**Level 2 (Repeat finding)**

Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 2, [REDACTED], Room: Mammography

This particular deficiency was noted during your June 28, 2000 inspection as follows:

Corrective action for a failing image score (before further exams) was not documented for unit 2, [REDACTED], Room: Mammography

**Note:** The wording of this noncompliance was changed in the software to incorporate several other similar noncompliance issues. The finding is specific to corrective action for a failing image score not being documented.

Your facility responded to this noncompliance in a letter to this office dated September 1, 2000. This response indicated that the reason for this noncompliance finding was that the department was using outdated charts with invalid data. This response did not indicate that corrective actions would be documented before mammograms were performed on this unit, but that any deviation outside the acceptable range would result in cessation of mammography exams until corrected.

To correct this noncompliance issue, it will be necessary that your facility take any necessary steps in ensuring that any Quality Control test that results in data outside an acceptable range will have appropriate documentation of corrective action.

Additionally, the following noncompliance was identified:

**Level 2**

Corrective actions for processor QC failures were not documented at least once for processor Mammography, [REDACTED] or [REDACTED], Room: One, at site Marshall Medical Center North

These specific deficiencies appeared on the Post Inspection Report which was sent to your facility by the state inspector along with instructions on how to respond to these findings. These deficiencies may be symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies as identified and to promptly initiate permanent corrective actions.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violations.

If your facility is unable to complete these corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Alabama. Should you have questions regarding this letter or MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,

  
Michael R. Duran  
Acting Director, New Orleans District

MRD:KRS:man

cc:

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