



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
New Orleans District Office  
Nashville Branch  
297 Plus Park Blvd.  
Nashville, TN 37217

December 9, 1999

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*12/13/99*  
*JEN*

**CERTIFIED MAIL- RETURN RECEIPT REQUESTED**

**WARNING LETTER-00-NSV-05**

**FACILITY ID #178269**

Douglas Beverly, Administrator  
St. Clair Regional Hospital  
2805 Hospital Drive  
Pell City, AL 35125

Dear Mr. Beverly:

Your facility was inspected on December 3, 1999 by a representative of the State of Alabama on contract to the Food and Drug Administration. 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 1**

Mammograms were processed in processor 1, [REDACTED], Room : Main Darkroom, at site St. Clair Regional Hospital, when it was out of limits for 5 days.

**Level 2**

Corrective actions for processor QC failures were not documented at least once for processor 1, [REDACTED], Room: Main Darkroom, at site St. Clair Regional Hospital.

Corrective action for a failing image score (before further exams) was not documented for unit 1, [REDACTED], Room: Mammo Room 1.

These specific deficiencies appear on the Post Inspection Report, which was sent to your facility by the State of Alabama on December 7, 1999. These deficiencies are symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

**St. Clair Regional Hospital  
Douglas Beverly, Administrator**

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 that the inspection identifies 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 similar violations.

If your facility is unable to complete the 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, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,



James E. Gamet  
Director  
New Orleans District

JEG/krs

cc: State of Alabama