DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

May 31, 2002

VIA FEDERAL EXPRESS

FACILITY ID #223626

Philip Dotson
Administrator
Athens Limestone Hospital
Outpatient Diagnostic Center
1005 West Market Street
Athens, AL 35612

Warning Letter No. 02-NSV-24

Dear Mr. Dotson:

Your facility was inspected on April 26, 2002 by a representative of the State of Alabama on contract to the Food and Drug Administration (FDA). This inspection revealed a serious compromise in the quality of the mammography services offered by your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 236b, 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 recent inspection at your facility revealed the following Level 1 finding:

Level 1

Failed to produce documents verifying that the interpreting physician [redacted] met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having 2 months of initial training in the interpretation of mammograms prior to 4/28/99.

This specific deficiency noted above appeared on your MQSA Post Inspection Report which was given to your facility by the state inspector at the close of your inspection, along with instructions on how to respond to these findings.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a 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 Direct 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

MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.
In addition, you should also address the following deficiencies that were listed on the inspection report:

Level 2

Failed to produce documents verifying that the interpreting physician [redacted] met the initial experience requirement of having interpreted or multi-read 240 mammograms in 6 months

Failed to produce documents verifying that the interpreting physician [redacted] met the initial requirement of having 40 hours of medical education in mammography prior to 4/28/99

Failed to produce documents verifying that the radiologic technologist [redacted] met the continuing experience requirement of having performed 200 mammography examinations in 24 months

1 of 8 random reports reviewed did not contain an acceptable assessment category for site Athens Limestone Hospital-Outpatient Diagnostic Center

Medical audit and outcome analysis was not done for the facility as a whole at site Athens Limestone Hospital-Outpatient Diagnostic Center

Medical audit and outcome analysis was not done separately for each individual at site Athens Limestone Hospital-Outpatient Diagnostic Center

Medical audit and outcome analysis was not performed annually at site Athens Limestone Hospital-Outpatient Diagnostic Center

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 action.

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. Your response should include:

- The specific steps you have taken to correct the Level 1 and Level 2 violations outlined in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Sample records that demonstrate proper record-keeping procedures relating to quality control or any other records that are appropriate to the noncompliance findings (NOTE: Patient names or identification should be deleted from any copies submitted).

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 the technical aspects of this letter or concerning MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,

Howard E. Lewis
Acting Director, New Orleans District

CED:KRS:man

cc: Richard Glass
Alabama Dept. of Public Health
Office of Radiation Control
P.O. Box 303017
Montgomery, AL 36130-3017

Priscilla F. Butler, MS
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, VA 22091

Director, Government Relations
C/o American College of Radiology
1891 Preston White Drive
Reston, VA 22091