DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

July 26, 2002

VIA FEDERAL EXPRESS

FACILITY ID #187005

Mike Bruce
Administrator
Elmore Community Hospital
500 Hospital Drive
Wetumpka, AL 36092

Warning Letter No. 02-NSV-32

Dear Mr. Bruce:

Your facility was inspected on July 12, 2002 by a representative of the State of Alabama acting on behalf of 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 and 2 findings:

Level 1

Phantom QC records were missing for at least 4 weeks for unit 2, [redacted], in the Mammo Suite [21 CFR §900.12(e)(2)]

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.

Level 2

The phantom image score (using an FDA-approved mammography phantom) is at least 2 but is less than 3 speck groups for unit 2, [redacted], in the Mammo Suite [21 CFR § 900.12(e)(2)(iii)]

The facility has not specified adequate procedures to be followed for infection control or did not follow them when required at site Elmore Community Hospital [21 CFR § 900.12(e)(13)(i), (ii), (iii)]

Corrective actions for processor QC failures were not documented at least once for processor 1, [redacted], MAIN darkroom at site Elmore Community Hospital [21 CFR 900.12(e)(8)(i) and (ii)(A)(B)]

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], in the Mammo Suite [21 CFR 900.12(e)(8)(i) and (ii)(A)(B)]

Because these deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation of the law which may result in FDA imposing statutory sanctions without further notice to you. These sanctions include, but are not limited to, placing your facility under a Direct Plan of Correction and charging your facility for the cost of on-site monitoring. Failure to correct these violations promptly could also cause FDA to seek 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. [See 42 USC § 263b(h)-(j)]

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