DEPARTMENT OF HEALTH AND HUMAN SERVICES

53175A

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

August 13, 2002

VIA FEDERAL EXPRESS—Next Day

FACILITY ID #187377

Doug Jones, Administrator
Thomasville Infirmary
33700 Highway 43
Thomasville, AL 36784

Warning Letter No. 02-NSV-35

Dear Mr. Jones:

Your facility was inspected on July 26, 2002 by a representative of the State of Alabama, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed serious regulatory problems involving 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 findings:

Level 1

Processor QC records failed to document a processor performance test on each day that clinical films were processed, before any clinical films were processed that day, in violation of 21 CFR 900.12(e)(1), and failed to document a weekly image quality evaluation test, using an FDA-approved phantom, in violation of 21 CFR 900.12(e)(2), because:
--In the month of 07/2002, processor QC records were missing for at least 30% of operating days, for processor 1, [redacted], Room Main Darkroom at site Thomasville Infirmary.
--Processor QC records were missing at least 5 consecutive days for processor 1, [redacted], Room Main Darkroom at site Thomasville Infirmary.

The system to communicate results is not adequate for site Thomasville Infirmary because:
- There is no system in place to provide timely medical reports – 21 CFR 900.12(c)(3)(i),(ii)
- There is no system in place to provide timely lay summaries – 21 CFR 900.12(c)(2)(i),(ii)

These specific deficiencies noted above appeared on your MQSA Post Inspection Report which was sent to your facility by the state inspector, along with instructions on how to respond to these findings.

These conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, and represent violations of the law which may result in FDA taking regulatory action. Possible 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, seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to comply with, MQSA standards, seeking suspension or revocation of your facility's FDA certificate, or seeking a court injunction against further mammography. [See 42 U.S.C. §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 actions.

It is necessary for you to act on this matter immediately. Within 15 working days after receiving this letter, you must 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 violations as 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,

Carl E. Draper

Carl E. Draper
Director, New Orleans District

CED:KRS:sjs

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