DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Telephone: 615-781-5380
Facsimile: 615-781-5391

August 29, 2003

VIA FEDERAL EXPRESS
NEXT DAY DELIVERY

FACILITY ID #182303
Thomas Bland, Administrator
Montfort Jones Memorial Hospital
Highway 12 West
P.O. Box 887
Kosciusko, MS 39090

Warning Letter No. 03-NSV-27

Dear Mr. Bland:

An inspection of your facility was conducted on July 31, 2003 by a representative of the State of Mississippi acting on behalf of the U.S. Food and Drug Administration (FDA). This inspection revealed serious problems involving the conduct of mammography services offered at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 236b, your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following violations of the MQSA at your facility:

Level 1

Processor QC records in the month of February 2003 were missing for at least 30% (and at least 5 consecutive days) of operating days for processor 1, [redacted], Darkroom at site Montfort Jones Memorial Hospital.

- *21 CFR 900.12(e)(1)(i),(ii),(iii)*

Level 2

Failed to produce documents verifying that the medical physicist [redacted] M.S. (0 CME's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months.

- *21 CFR 900.12(a)(3)(iii)(A)*

Failed to produce documents verifying that the medical physicist [redacted] M.S. met the continuing experience requirement of having surveyed at least 2 mammography facilities and a total of at least 6 mammography units in 24 months.

- ***21 CFR 900.12(a)(3)(iii)(B)***

It is your responsibility to ensure adherence to each requirement of 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.

These violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility. FDA may take additional actions, which may include, but are not limited to the following:

- Requiring your facility to undergo an Additional Mammography Review;
- Placing your facility under a Directed 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 substantially comply with, MQSA standards,
- Seeking to suspend or revoke your facility's FDA certificate; and,
- Seeking a court injunction enjoining further mammography.

See 42 USC 263b(h)-(j) and CFR 900.12(j)

Within 15 working days after receiving this letter, please 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, or will take, to correct the violations as outlined in this letter, including projected timeframes for implementing those steps;
- The specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps; and,
- Sample records that demonstrate proper record-keeping procedures relating to quality control or any other records that are appropriate to the noncompliance finding (NOTE: Patient names or other information that would likely reveal the patient's identity 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.

Please submit your reply 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 Mississippi. 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.

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection of your facility and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

Sincerely,

Patricia K. Schafer

Patricia K Schafer
Acting District Director
New Orleans District

cc: State of Mississippi
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cc: Priscilla F. Butler, MS
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