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

April 14, 12003

VIA FEDERAL EXPRESS
OVERNIGHT DELIVERY

FACILITY ID #218255

Theresa Lucas, C.E.O.
Baptist Women's Pavilion Hospital
Breast Services
300 20th Avenue North, Suite 401
Nashville, TN 37203

Warning Letter No. 03-NSV-14

Dear Ms. Lucas:

An inspection of your facility was conducted on March 25, 2003 by a representative of the State of Tennessee acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious deficiency in the quality of the mammography services offered by this 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 this facility revealed the following Level 1 finding:

Level 1

- Mammograms were processed in processor 1, [redacted] Mammo room at site Baptist Women's Pavilion Hospital Breast Services when it was out of limits on at least 5 days
  - ***21 CFR 900.12(e)(1)(i),(ii),(iii)***

This specific deficiency noted above appeared on the MQSA Post Inspection Report which was sent to this facility by the state inspector along with instructions on how to respond to this finding. This condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at this facility, and it represents a violation of the law that may result in FDA taking regulatory action. 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, seeking civil money penalties up to $10,000 for each failure to substantially 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)]

Additionally, you should also address the following deficiencies that were also listed on the inspection report:

Level 2

- Corrective actions for processor QC failures were not documented at least once for processor 1, [redacted] Mammo room at site Baptist Women's Pavilion Hospital Breast Services
  - ***21 CFR 900.12(d)(2); see also 21 CFR 900.12(b)***

- Failed to produce documents verifying that the interpreting physician [redacted], (5 CME's in 36 months) met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months
  - ***21 CFR 900(a)(4); see also 21 CFR 900(a)(1)(ii)(B)***

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.

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 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 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.

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 Tennessee. 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,

Carl E. Draper

Carl E. Draper
Director, New Orleans District