DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

July 11, 2002

VIA FEDERAL EXPRESS

FACILITY ID # 184184

Scott Tongate, Administrator
Carthage General Hospital
130 Lebanon Highway
Carthage, TN 37030

Warning Letter No. 02-NSV-30

Dear Mr. Tongate:

Your facility was inspected on June 26, 2002 by a representative of the State of Tennessee on contract to the Food and Drug Administration (FDA). This inspection revealed serious compromises 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 findings:

Level 1

Processor QC records in the month of 09/2001 were missing for at least 30% of operating days, for processor 1, [redacted] or [redacted], Room 1 at site Carthage General Hospital [21 C.F.R. § 900.12(e)(1)]

Processor QC records were missing at for least 5 consecutive days for processor 1, [redacted] or [redacted], Room 1 at site Carthage General Hospital [21 C.F.R. § 900.12(e)(1)]

Phantom QC records were missing for at least 4 weeks for unit 2, [redacted], Room Mammography Hospital [21 C.F.R. § 900.12(e)(2)]

These specific deficiencies 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. These conditions are Level 1 because they identify failures to meet significant MQSA requirements.

Because these conditions 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 initiating regulatory action without further informal 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, 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)].

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 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 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.

Sincerely,

Howard E. Lewis
Acting Director, New Orleans District

CED:KRS:man

Cc: Darlene Nalepa-Whitmill
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