



DEPARTMENT OF HEALTH AND HUMAN SERVICES

g3130d

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

February 20, 2002

VIA FEDERAL EXPRESS

FACILITY ID #176370

Craig Watson, C.E.O.
Delta Medical Center
3000 Getwell Road
Memphis, TN 38125

Warning Letter No. 02-NSV-14

Dear Mr. Watson:

Your facility was inspected on January 15, 2002 by a representative of the State of Tennessee on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

The system to communicate results is not adequate for site Delta Medical Center because:
- There is no system in place to provide timely lay summaries.

Level 2

Phantom QC records were missing for at least two weeks but less than four weeks for unit 1, [REDACTED], Room: Mammography.

Failed to produce documents verifying that the interpreting physician [REDACTED] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.

1 of 6 random reports reviewed did not contain an acceptable assessment category for site Delta Medical Center.

Medical audit and outcome analysis was not performed annually at site Delta Medical Center.

There is no designated audit (reviewing) interpreting physician for site Delta Medical Center.

These specific deficiencies appeared on the 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 deficiencies may be symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

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.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards;
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards;
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

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.

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 this letter or MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,



Carl E. Draper
Director, New Orleans District

CED:KRS:man

Cc:

