



October 3, 2001

VIA FEDERAL EXPRESS

FACILITY ID# 216408

Ruby Kirby, Interim Administrator
Bolivar General Hospital
650 Nuckolls Road
P.O. Box 509
Bolivar, TN 38009

Warning Letter No. 02-NSV-01

Dear Ms. Kirby:

Your facility was inspected on September 27, 2001 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

Failed to produce documents verifying that the interpreting physician [REDACTED] met the initial requirement of holding a valid state license to practice medicine.

Failed to produce documents verifying that the interpreting physician [REDACTED] met the initial requirement of holding a valid state license to practice medicine.

Failed to produce documents verifying that the interpreting physician [REDACTED] met the initial requirement of holding a valid state license to practice medicine.

The system to communicate results is not adequate for site Bolivar General Hospital because:

- There is no system in place to provide timely medical reports.
- There is no system in place to communicate serious or presumptive cases as soon as possible.

Level 2

Corrective actions for processor QC failures were not documented at least once for processor 1, [REDACTED] Room mammo, at site Bolivar General Hospital.

The medical physicist's survey for x-ray unit 1, [REDACTED] Room mammo, is incomplete because:

:

- The phantom image test was not done at the kVp normally used clinically.

Failed to produce documents verifying that the interpreting physician [REDACTED] (0 CMEs 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.

Failed to produce documents verifying that the radiologic technologist [REDACTED] met the initial requirement of having training specific to mammography under the interim regulations.

Failed to produce documents verifying that the radiologic technologist [REDACTED] met the initial requirement of having training specific to mammography under the interim regulations.

Failed to produce documents verifying that the medical physicist [REDACTED] 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.

Not all positive mammograms were entered in the tracking system for site Bolivar General Hospital.

There is no designated audit (reviewing) interpreting physician for site Bolivar General Hospital.

These specific deficiencies appeared on the Post Inspection Report, given to your facility at the close of the inspection, with instructions on how to respond. 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: Darlene Nalepa-Whitmill
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