



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service *JEN*
g1501d
Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

July 10, 2001

VIA FEDERAL EXPRESS

FACILITY ID# 159616

David Baytos, Administrator
Methodist Hospital Germantown
7691 Poplar Avenue
Germantown, TN 38138

Warning Letter No. 01-NSV-36

Dear Mr. Baytos:

Your facility was inspected on June 11, 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 2 (Repeat Finding)

Failed to produce documents verifying that the interpreting physician [REDACTED] met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units (CME) in mammography in 36 months

NOTE: Additional findings reported on the initial Post Inspection Report provided to your facility regarding physicians [REDACTED] and [REDACTED] were dropped after documentation submitted to FDA for review was found to be adequate. A second Post Inspection report was faxed to your facility June 2, 2001 with these findings removed.

A finding concerning the lack of CMEs for physicians [REDACTED] and [REDACTED] was also noted during your facility's June 29, 2000 inspection. Your facility responded to this finding with a letter to this office dated July 17, 2000 which stated that the physicians in question had completed their CMEs and the documentation was sent to this office for review. In light of the repeat finding, it will be necessary that your facility provide to this agency assurance of understanding of the need for ongoing review by your facility of continuing education and experience requirements for personnel associated with the reading or conducting of mammograms, as well as the surveying of the equipment by a medical physicist. A comprehensive quality assurance program at your facility would implement this as part of the standards of your mammography department to assure the intention of the regulations being met.

██████████ cannot lawfully read mammograms independently until he obtains the necessary CME credits to return him to compliance with the regulations.

Level 2

The medical physicist's survey for x-ray unit 2, ██████████, Room Mammo Room B, and x-ray unit 3, ██████████, Room A, is incomplete because the following tests were inadequate or not done:

- No phantom image: Test not done at the kVp normally used clinically
- No kVp Reproducibility: Tests were not done at the kVp normally used clinically
- No beam quality (HVL) measurement: Test not done at the kVp normally used clinically

These specific deficiencies appeared on the Post Inspection Report, which was given to your facility by the state inspector 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,



Patricia K. Schafer
Acting Director, New Orleans District

CED:KRS:man

cc: Darlene Nalepa-Whitmill
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