



May 24, 2001

**VIA FEDERAL EXPRESS**

**FACILITY ID# 179648**

Jim Parks, Operations Manager  
Summit Ancillary Services Center – Cedar Bluff  
9333 Park West Boulevard, Suite 102  
Knoxville, TN 37923

**Warning Letter No. 01-NSV-28**

Dear Mr. Parks:

Your facility was inspected on May 17, 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**

Mammograms were processed in processor 1, [REDACTED] or [REDACTED], Room Darkroom at site Summit Ancillary Services Center – Cedar Bluff, when it was out of limits on at least 5 days.

This specific deficiency appeared on the Post Inspection Report, which was sent to your facility by the state inspector along with instructions on how to respond to this finding. This deficiency 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.

Additionally, it was noted in the “Inspector Remarks” section of your Post Inspection Report that records for continuing experience had to be acquired during the inspection for inspector review. All personnel reading or conducting mammography or mammography department surveys must have continuing experience as required by law. Records of continuing experience should be kept by your department and monitored on an on-going basis to ensure that all personnel do not fall below the minimum requirement.

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.

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,



Howard E. Lewis  
Acting Director, New Orleans District

CED:KRS:man

cc: Darlene Nalepa-Whitmill  
TN Dept. Of Environment and Conservation  
2700 Middlebrook Pike, Suite 220  
Knoxville, TN 37921

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