



April 23, 2001

VIA FEDERAL EXPRESS

FACILITY ID# 146696

Mark Cain, Administrator
White County Hospital
401 Sewell Road
Sparta, TN 38583

Warning Letter No. 01-NSV-24

Dear Mr. Cain:

Your facility was inspected on April 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 2 (Repeat Finding)

Phantom Quality Control records were missing for at least two weeks for unit 2, [REDACTED] located in the mammography room.

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.

This finding was noted during your inspection of March 30, 2000 and addressed in Warning Letter No. 00-NSV-13 dated April 12, 2000 from this office. In the response from your facility dated April 27, 2000 addressed to Joseph E. Hayes, Compliance Officer, your facility stated that procedures would be put in place as follows: "...to ensure this situation will not occur in the future, the QC will be monitored weekly for 3 months and then monthly thereafter by the Radiologist, Radiology Dept Manager, and submitted to our facility Compliance Officer."

Also noted during your inspection were the following noncompliance items:

Level 3 (Repeat)

The fixer retention QC is not adequate for processor 1, [REDACTED], at site White County Hospital because:
- The fixer retention QC tests were not done at the required frequency.

Level 3 (Repeat – cont.)

The repeat analysis QC is not adequate for site White County Hospital because:
- The QC tests were not done at the required frequency.

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
TN Dept. Of Environment and Conservation
2700 Middlebrook Pike, Suite 220
Knoxville, TN 37921

Missy Wolford
Environmental Assistance Center
540 McCallie Avenue, Suite 550
Chattanooga, TN 37402-2013

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, VA 20191

Director
Government Relations
c/o American College of Radiology
1891 Preston White Drive
Reston, VA 22091