



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
New Orleans District Office
Nashville Branch
297 Plus Park Blvd.
Nashville, TN 37217

February 22, 2000

*Completed
2/28/00
JMN*

Certified Mail—Return Receipt Requested

FACILITY ID #222458

Gordon Hixson, MD
Women's Health Services, Chattanooga, P.C.
1751 Gunbarrel Road, Suite 101-A
Chattanooga, TN 37421

Warning Letter No. 00-NSV-08

Dear Dr. Hixson:

Your facility was inspected on February 11, 2000, by a representative of the State of Tennessee under contract to the Food and Drug Administration. 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

Processor QC records were missing 17 consecutive days for processor 1, [REDACTED] or [REDACTED], room Dark Room at site Women's Health Services, Chattanooga, P.C.

Processor QC records were missing 20 out of 21 days of operation in June 1999. Processor QC records missing 95%, for processor 1, [REDACTED] or [REDACTED], room Dark Room at site Women's Health Services, Chattanooga, P.C.

Phantom QC records were missing for 5 weeks for unit 1, [REDACTED], room Mammography Suite.

Level 2

3 of 5 random reports reviewed did not contain an assessment category for site Women's Health Services, Chattanooga, P.C.

These specific deficiencies appear on the Post Inspection Report, which was left with you upon the closeout of the inspection. These deficiencies are 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 that the inspection 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; and/or
- Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within fifteen (15) working days of receipt of this letter you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations. If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time frame 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, TN 37217. Should you have any questions regarding this letter or how to ensure that you are meeting MQSA standards, please contact Karen Smallwood, Radiation Specialist, at telephone 615/781-5380 ext. 144.

Sincerely,



Alonza E. Cruse

Acting Director, New Orleans District

AEC:KRS:man