



M3732n

May 5, 2000

**CERTIFIED MAIL - RETURN RECEIPT REQUESTED**

**WARNING LETTER-00-NSV-16**

*Overstuffed  
5/5/00  
JH*

**FACILITY ID# 109595**

Teresa Skiles, Center Manager  
Chattanooga Diagnostic Imaging  
440 N. Holtzclaw Avenue  
Chattanooga, TN 37606

Dear Ms. Skiles:

Your facility was inspected on April 26, 2000 by a representative of the State of Tennessee, on 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 13 consecutive days out of 22 days of operation in the month of 06/1999. This accounts for 59% of processor QC records missing for processor 1, [REDACTED], darkroom 1 at site Chattanooga Diagnostic Imaging.

**NOTE:** this item refers to the first 3 items listed under the Level 1 heading of the post inspection report left with your facility at the close of the inspection.

Phantom QC records were missing for 9 weeks for unit 2: [REDACTED], OTH, room mammo.

**Level 2**

The medical physicist's survey for x-ray unit 2, [REDACTED] OTH, room mammo is incomplete because the following tests were not done:

- **No artifact evaluation**

The interpreting physician did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period: [REDACTED]

**Chattanooga Diagnostic Imaging**  
**Teresa Skiles, Center Manager**

These specific deficiencies appear on the Post Inspection Report, which was given to your facility at the close 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 identifies 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:

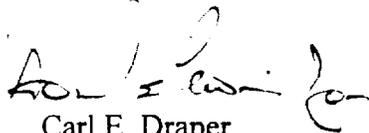
- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit 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 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 within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,



Carl E. Draper  
Director  
New Orleans District Office

CED/krs