



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

m4828r

Food and Drug Administration  
New Orleans District Office  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127

November 17, 2000

**VIA FEDERAL EXPRESS**

**FACILITY ID# 216929**

Sharon L. Stocking, M.D.  
Northside Radiology  
1701 North Main Street  
Shelbyville, TN 37160

*Quigley*  
11/20/00  
*[Signature]*

**Warning Letter No. 01-NSV-05**

Dear Dr. Stocking:

Your facility was inspected on October 9, 2000 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**

Processor QC records were missing for the months of November and December 1999 for processor 1, [REDACTED] at site Northside Radiology.

Phantom QC records were missing for 12 weeks for unit 1, [REDACTED], Room 4.

**Level 2**

Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 1, [REDACTED], Room 4.

These specific deficiencies appeared on the Post Inspection Report, which was sent 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.

**Northside Radiology**  
**Sharon Stocking, M.D.**

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 correction 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. 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

CED:krs:man

Cc: State of Tennessee  
Dept. Of Environment and Conservation  
Division of Radiological Health  
L and C Annex, Third Floor  
401 Church Street  
Nashville, TN 37243-1532

Darlene Nalepa-Whitmill  
State of Tennessee  
Dept. Of Environment and Conservation  
2700 Middlebrook Pike, Suite 220  
Knoxville, TN 37921

**Northside Radiology**  
**Sharon Stocking, M.D.**

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