



August 21, 2001

VIA FEDERAL EXPRESS

FACILITY ID# 206177

Sylvia Sumners, Vice President
Ambulatory Services
Shelby Baptist Medical Center
1004 First Street North, Suite 100
P.O. Box 488
Alabaster, AL 35007

Warning Letter No. 01-NSV-38

Dear Ms. Sumners:

Your facility was inspected on August 7, 2001 by a representative of the State of Alabama 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)

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 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 3, [REDACTED] Room 3

A finding concerning the failure to document a failing image score for unit 2, [REDACTED], MAMMO Room 1 was also noted during your facility's August 10, 2000 inspection. Your facility responded to this finding with a letter to this office dated September 18, 2000 and again with a facsimile dated January 17, 2001 as a result of the follow-up letter from this office dated September 28, 2000 stating that your initial response was inadequate in that it did not include a plan of action to ensure that a similar noncompliance would not recur. Your faxed document included a policy statement assuring FDA that your facility would comply with all conditions to meet health and safety requirements.

NOTE: It was observed and documented at the time of the August 7, 2001 inspection that all phantom image charts for Unit #2 room 1 were missing from August 15, 2000 through December 8, 2000. These

records had been checked in the annual physicist report and corrective actions completed before this inspection.

These specific deficiencies appeared on the Post Inspection Report that was given 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 this 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:

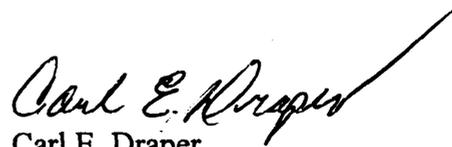
- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards
- seek an injunction in federal court to prohibit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