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February 28, 2001

VIA FEDERAL EXPRESS

FACILITY ID# 167163

Sandra Hullett, C.E.O.
Medical Director
Cooper Green Hospital
1515 6th Avenue South
Birmingham, AL 34233

Warning Letter No. 01-NSV-14

Dear Dr. Hullett:

Your facility was inspected on February 22, 2001, by a representative of the State of Alabama on contract to the Food and Drug Administration (FDA). Records were reviewed for the last inspectional year, and the equipment was tested. 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 22 consecutive days out of 22 days of operation in month 10/2000 for Processor [REDACTED], or [REDACTED] located in the Mammo darkroom, at site Cooper Green Hospital

Phantom QC records were missing for 12 weeks for unit 2, [REDACTED] OTH, Room Mammo Room

Level 2

4 of 8 random reports reviewed did not contain an assessment category for site Cooper Green Hospital

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 identified deficiencies and to promptly initiate permanent corrective actions.

Cooper Green Hospital
Sandra Hullett, CEO
Medical Director

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 Richard Glass of 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

cc: State of Alabama
Dept. of Public Health
Office of Radiation Control
P.O. Box 303017
Montgomery, AL 36130-3017
ATTN: Richard Glass