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August 30, 2000

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CERTIFIED MAIL - RETURN RECEIPT REQUESTED

WARNING LETTER-00-NSV-21

FACILITY ID# 187377

Albert Ban, Administrator
Thomasville Infirmary
33700 Highway 43
Thomasville, AL 36784

Dear Mr. Ban:

Your facility was inspected on August 23, 2000 by a representative of the State of Alabama 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

The system to communicate results is not adequate for site Thomasville Infirmary because:

- ***There is no system in place to provide timely lay summaries***

This specific deficiency appeared on the Post Inspection Report, which was mailed out to your facility by the State inspector, along with instructions on how to respond to this finding. This deficiency 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 deficiency as identified and to promptly initiate permanent corrective action.

If you fail to properly address this deficiency, 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.

Thomasville Infirmary
Albert Ban, Administrator

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,



Howard E. Lewis
Acting Director
New Orleans District Office

CED/krs

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

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