



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

August 26, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Harrison Trammel, CEO
Roper Hospital, Inc.
316 Calhoun Street
Charleston, SC 29401-1125

WARNING LETTER

Inspection ID: 1344600003

Dear Mr. Trammel:

Your facility was inspected on 7/9/97 by a representative of the South Carolina Department of Health and Environmental Control acting on behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain Quality Standards for Mammography as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

The number of masses scored in the phantom image was 1.0 and did not meet the required number. The minimum number required for masses is 3: [REDACTED]
[REDACTED] Mammo.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was discussed with you at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, you should address the Level 3 noncompliances that were provided to you during the inspection. These noncompliances will be checked on your next inspection. You may be required to respond to the State of South Carolina on these Level 3's. These Level 3 noncompliances are:

Mammograms were processed at least once with the medium density or density difference or base+fog out of control: [REDACTED]
Mammo.

It was discovered during the inspection that the test-films for Darkroom Fog, screen film contact and fixer retention had been discarded. For this reason, it could not be determined if Darkroom Fog had been conducted at the appropriate density. The fixer retention test and screen film contact tests had incomplete data recorded. In the future, please keep all test films from inspection to inspection and record all test result data.

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 causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially 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.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirement, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of the specific steps you have taken to correct all of the violations noted in this letter; each step your facility is taking to prevent the recurrence of similar violations; equipment settings (including technique factors), raw test data, and calculated final results, where appropriate and sample records that demonstrate proper recordkeeping procedures, if the noncompliance that were found relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed. Please send the original copy of your response to:

U.S. Food and Drug Administration
Compliance Enforcement Team
60 8th Street, N.E.
Atlanta, Georgia 30309
Attn: John J. McCall

With a copy to:

South Carolina Department of Environmental Control (DHEC)
2600 Bull Street
Columbia, South Carolina 29201
Attn: Claudia Wheeler

[NOTE: If phantom image is required for corrective action, please submit to S.C. Bureau of Radiological Health.]

You may choose to address both FDA and State requirements in your response. If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call John J. McCall at (404) 347-3162.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District