



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

g1041d RJW
60 Eighth Street, N.E.
Atlanta, Georgia 30309

March 21, 2001

VIA FEDERAL EXPRESS

Tony Taylor
Radiology Manager
Bulloch Memorial Hospital
500 East Grady Street
Statesboro, GA 30459

Inspection ID: 1604160006

WARNING LETTER
(01-ATL-32)

Dear Mr. Taylor:

Your facility was inspected on 3/7/01 by a representative of the Georgia Department of Human Resources, Division of Radiation Protection, 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:

1. Failure to produce documents verifying that the interpreting physicians [REDACTED] met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having 2 months of initial training in the interpretation of mammograms prior to 4/28/99.
2. Failure to produce documents verifying that the following interpreting physicians met the initial requirement of holding a valid state license to practice medicine: [REDACTED]

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be

symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliance items that were listed on the inspection report as follows:

1. Your facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required.
2. Failure to produce documents verifying that the interpreting physicians ([REDACTED] and [REDACTED] met the initial requirement of having 40 hours of medical education in mammography prior to 4/28/99.
3. Failed to produce documents verifying that the interpreting physicians ([REDACTED] and [REDACTED] met the initial requirement of having interpreted or multi-read 240 mammograms in 6 months.
4. Failure to produce documents that the interpreting physician, [REDACTED] met the requirement of having 8 hours of training in the new mammographic modality.
5. Failure to produce documents verifying that the interpreting physicians [REDACTED] and [REDACTED] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.
6. Failure to produce documents verifying that the interpreting physician, [REDACTED] met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months.

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 initiating 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 of 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 requirements, 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 noncompliances 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 corrections will be completed. Please send the original copy of your response to:

Serene A. Kimel, Compliance Officer
U.S. Food and Drug Administration
60 8th St., NE
Atlanta, GA 30309

With a copy to:

Georgia Department of Human Resources
Division of Radiation Protection
2 Peachtree St.
Suite 33-285
Atlanta, GA 30303

and

Thomas Clarida
U.S. Food and Drug Administration
5701 Executive Center Drive, Suite 104
Charlotte, NC 28212

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography/index.html>

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 feel free to call Thomas Clarida at 704-344-6116.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Ballard H. Graham".

Ballard H. Graham, Director
Atlanta District

Cc: Ms. Priscilla F. Butler, M.S., FAAPM, FACR
Director
Breast Imaging Accreditation Programs
1891 Preston White Drive
Reston, Virginia 20191