



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

HFI-35 049701

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

December 5, 2000

VIA FEDERAL EXPRESS

Roland Gardner
Executive Director
Port Royal Medical Center
Radiology Department
1320 S. Ribaut Rd.
Port Royal, SC 29935

Inspection ID: 2198650003

WARNING LETTER

(01-ATL-14)

Dear Mr. Gardner:

Your facility was inspected on 11/16/00 by a representative of the South Carolina Department of Health, Environmental Control (DHEC), Radiological Health Branch, 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:

- Phantom QC records were missing for 4 weeks for unit #1, [REDACTED] located in the mammography room.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued 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, your response should address the Level 2 noncompliance items that were listed on the inspection report. The Level 2 noncompliance items are:

- The phantom image score (using an FDA-approved mammography phantom) is at least 2 masses but is less than 3 masses for unit #1 described above.
- 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.

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:

South Carolina DHEC
Radiological Health Branch
2600 Bull Street
Columbia, SC 29201

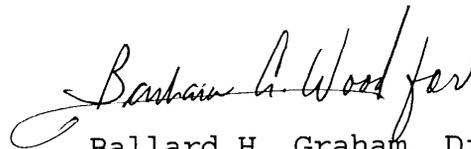
and

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

(NOTE: If phantom image is required for corrective action, please submit original to South Carolina DHEC, Radiological Health Branch.)

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 contact Thomas Clarida at 704-344-6116.

Sincerely yours,



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