



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Atlanta District Office

m38dn

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

June 19, 2000

VIA FEDERAL EXPRESS

Kirk Bobbitt  
Chief Technologist  
Carolina Imaging Center, Inc.  
3628 Cape Center Drive  
Fayetteville, NC 28304

Inspection ID: 1055930006

WARNING LETTER  
(00-ATL-51)

Dear Mr. Bobbitt:

Your facility was inspected on 5/26/00 by a representative of the North Carolina Department of Environment & Natural Resources (DENR), 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:

Mammograms were processed in processor #1 located in room P2, when it was out of limits on 5 days.

Phantom QC records were missing for 5 weeks for unit #3, [REDACTED] located in the mammography room.

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. The Level 2 noncompliance items are:

Corrective actions for processor QC failures were not documented at least once for processor #1 described above.

Corrective action for a failing image score (before further exams) was not documented for unit #3 described above.

The interpreting physician, [REDACTED], did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36-month period (0 CME's 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 8<sup>th</sup> St., NE  
Atlanta, GA 30309

With a copy to:

North Carolina DENR  
Division of Radiation Protection  
3825 Barrett Drive  
Raleigh, NC 27609-7221

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 North Carolina DENR, Division of Radiation Protection.)

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 Thomas Clarida at 704-344-6116.

Sincerely yours,

A handwritten signature in cursive script that reads "for Roger E. Kline". The signature is written in black ink and is positioned above the typed name and title.

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

cc: HFA-224  
HFC-230  
HFC-240  
HFI-35 (redacted copy for public display)  
HFZ-240  
TDC, CLT-RP  
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