



DEPARTMENT OF HEALTH AND HUMAN SERVICES

1438d

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

June 20, 2001

VIA FEDERAL EXPRESS

Lori McClure  
Radiology Director  
Angel Medical Center  
120 Riverview Street  
Franklin, NC 28734

Inspection ID: 1607390006

WARNING LETTER

(01-ATL-50)

Dear Ms. McClure:

Your facility was inspected on 5/17/01 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:

Repeat Level 2 Non-Compliance:

1. One of five random reports reviewed did not contain an acceptable assessment category.

Level 2 Non-Compliance:

2. Your facility has not specified adequate written procedures for collecting and resolving consumer complaints.
3. The medical physicist's survey for x-ray unit #2, [REDACTED], located in Room #2, is incomplete because the following tests were inadequate or not done:
  - No artifact evaluation
  - No uniformity of screen speed (numerical results were not given).

4. Your facility failed to produce documents verifying that the radiologic technologist, [REDACTED] met the initial requirement of having 40 contact hours training specific to mammography.
5. Medical audit and outcome analysis was not done for the facility as a whole (Angel Medical Center).
6. Medical audit and outcome analysis was not done for the facility as a whole ([REDACTED]).
7. Medical audit and outcome analysis was not performed annually at sites Angel Medical Center and [REDACTED].

The specific deficiencies noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection. Item #1 was also cited in a previous inspection of your facility.

Because the above deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent serious violation of the law which may result in FDA taking regulatory action without further notice to you. 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.

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.

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

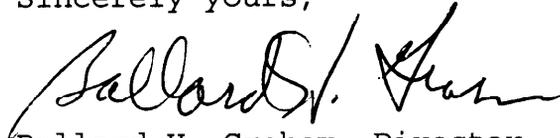
and

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

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 call Thomas Clarida at 704-344-6116.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a large initial "B" and "G".

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