



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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

April 11, 2002

VIA FEDERAL EXPRESS

Cindy Beaver
Radiology Department Manager
Piedmont HealthCare
208 Old Mocksville Road
Statesville, NC 28625

Inspection ID: 1407070010

WARNING LETTER

(02-ATL-24)

Dear Ms. Beaver:

Your facility was inspected on 3/20/02 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 the Mammography Quality Standards Act of 1992 (MQSA) and 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:

- 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, [REDACTED] located in the mammography room.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as repeat Level 2 because it identifies a failure to meet a significant MQSA requirement in Title 21 Code of Federal Regulations section 900.12(e)(8). This was a repeat finding from the previous inspection of your facility on 1/18/01.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may

result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction (DPC), charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. The Level 2 finding is:

- One out of six random reports reviewed did not contain an acceptable assessment category. This is a violation of Title 21 Code of Federal Regulations section 900.12(c)(1).

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days after receiving this letter:

- 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:

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

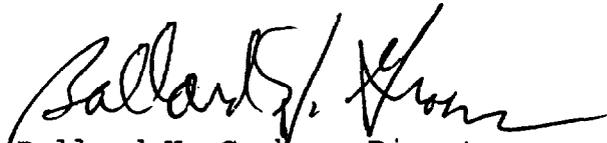
and

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>

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,



Ballard H. Graham, Director
Atlanta District

Cc:

