



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

g1040d RJW

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

March 21, 2001

VIA FEDERAL EXPRESS

Connie R. Keene
Chief Mammographer
Piedmont Imaging, Inc.
750 Highland Oaks Drive
Suite 200
Winston-Salem, NC 27103

Inspection ID: 2209310003

WARNING LETTER

(01-ATL-33)

Dear Ms. Keene:

Your facility was inspected on 3/13/01 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. Two of six randomly selected reports reviewed did not contain an acceptable assessment category.

Level 2 Non-Compliance:

2. 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 problems 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 during the previous inspection of your facility.

Because these conditions 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 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>

You may choose to address both FDA and state requirements in your response. If you have any specific questions regarding this letter or how to ensure you are meeting MQSA standards, please call Thomas Clarida at 704-344-6116.

Sincerely yours,

Handwritten signature of Ballard H. Graham in cursive script, followed by the word "for" written below it.

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