

Refer to: CFN: 1125452
ID #215160

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

October 8, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Inspection ID #2151600003

Dr. Leslie Griffin, Medical Director
Griffin Radiology, Cherry Hill
631 Cherry Hill Road
Baltimore, Maryland 21225

Dear Dr. Griffin:

Your facility was inspected on April 6, 1998, by a representative from the Food and Drug Administration (FDA). This inspection revealed serious regulatory problems involving mammography performed at your facility. Because your facility failed to respond by letter to these deficiencies, an unannounced inspection was conducted on September 11, 1998, and revealed the following:

Level 2 Repeat Violations:

1. Phantom image test results were not recorded for 3 months.
2. Processor QC: 33% of the data points for either medium density, density difference, or base plus fog were missing (month of September).
3. The interpreting physician did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months: [REDACTED]
4. The radiologic technologist did not meet the continuing education requirement of having earned 15 Continuing Education Units in mammography in a 3-year period: [REDACTED]

Level 2 Violations:

5. The number of fibrils scored in the phantom image (3.0) did not meet the required number (4).

Because these violations may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent violations 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; 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.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive 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 (include technique factors), raw test data, and calculated final results, where appropriate;
- ◆ Sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

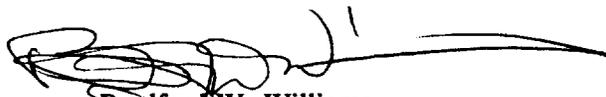
Please submit your response to:

Food and Drug Administration
900 Madison Avenue
Baltimore, Maryland 21201
Attn: Wiley T. Williamson, III
Compliance Officer

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to deficiencies noted during our inspections and does not necessarily address other obligations you may 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, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

If you have any specific questions about mammography facility requirements or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, Ext. 159.

Sincerely yours,



Bradford W. Williams
Acting District Director