



DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN: 1124048
Facility ID: 113811
Inspection ID #1138110005

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Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396

May 22, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Janice K. Parker, Chief Mammographer
George Washington University Hospital
GWU Ambulatory Care Center
2150 Pennsylvania Avenue, NW
Washington, DC 20037

Dear Ms. Parker:

A representative from the District of Columbia under contract to the Food and Drug Administration (FDA) inspected your facility on April 17, 2000. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings:

- **Breast Phantom QC records were missing for 5 weeks for the [REDACTED] Mammographic Machine located in room 1.**
- **Breast Phantom QC records were missing for 4 weeks for the [REDACTED] Mammographic Machine located in room 2.**
- **Breast Phantom QC records were missing for 4 weeks for the [REDACTED] Mammographic Machine located in room 3.**

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1 findings because they identify a failure to comply with significant MQSA requirements.

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Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent a violation of the law that 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.

In addition, the following Level 2 finding was listed on the inspection report provided to you at the close of the inspection:

- **Radiologic Technologist [REDACTED] failed to meet the continuing education requirement of having completed a minimum of 15 continuing education credits in mammography in a 36 month period. [REDACTED] may not perform unsupervised mammography examinations until the continuing education requirements have been met.**

It is necessary for you to act on these matters immediately. Please address the Level 1 and Level 2 findings in a response to this office in writing within fifteen (15) working days from the date you receive this letter. Your response must describe:

- The specific steps you have taken to correct the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to:

Food and Drug Administration
900 Madison Avenue
Baltimore, Maryland 21201
Attn: Nancy Rose
Compliance Officer

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 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, MD 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

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

Sincerely;

A handwritten signature in black ink, appearing to read 'L. Bowers', with a stylized flourish at the end.

Lee Bowers
Director, Baltimore District

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cc: Phillip Sumner, Program Manager
Department of Health
Environment Health Administration
Bureau of Food, Drug and Radiation Protection
51 N Street NE, Room 6025
Washington D.C. 20002

Priscilla F. Butler, M.S.
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