



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Facility ID:148056  
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Food and Drug Administration  
Baltimore District Office  
900 Madison Avenue  
Baltimore, MD 21201-2199  
Telephone: (410) 962-3396

01-BLT-29

May 10, 2001

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Paul C. Davis, M.D.  
Women's Imaging Services  
2994 Churchland Boulevard  
Chesapeake, Virginia 23321

Dear Dr. Davis:

A representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA) inspected your facility on April 18, 2001. 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:

- **Your facility failed to document that processor quality control was performed for 20 out of 20 operating days in the month of April 2000;**
- **Your facility failed to document that processor quality control was performed for at least five consecutive days in the month of April 2000;**
- **Your facility failed to document that phantom image testing was performed for 10 weeks in the 12 months prior to the date of your inspection.**

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 a significant MQSA requirement.

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.

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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 findings were listed on the inspection report provided to you at the close of the inspection:

- **During three processing days, your facility processed mammograms when your mammography processor was out of limits;**
- **Corrective action was not documented at least once when your processor exceeded preset operating limits;**
- **Your facility failed to document that [REDACTED] received 40 hours of training in 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 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, to the attention of Nancy L. 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>.

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,



 Lee Bowers  
Director, Baltimore District

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cc: Al Perlas, Radiation Safety Specialist  
Bureau of Radiological Health  
Division of Health Hazards Control  
Department of Health  
Main Street Station  
1500 East Main, Room 240  
Richmond, Virginia 23219

Priscilla F. Butler, M.S.  
Director, Breast Imaging Accreditation Programs  
Standards and Accreditation Department  
American College of Radiology  
1891 Preston White Drive  
Reston, Virginia 22091