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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN: 1124485  
Facility ID: 198598  
Inspection ID #1985980005



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

March 22, 2000

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Vincent J. Mascatello, M.D.  
Chief Radiologist  
Fair Oaks Imaging Center  
4001 Fair Ridge Drive  
Suite 103  
Fairfax, Virginia 22033

Dear Dr. Mascatello:

A representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA) inspected your facility on December 22, 1999. 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 finding:

- **Twenty-one weeks of Breast Phantom Images and related QC records for the [REDACTED] Mammography Unit were not available for review.**

The specific problem noted above appeared on the MQSA Facility Inspection Report issued to your facility at the close of the inspection. This problem is identified as a Level 1 finding because it identifies a failure to comply with a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, it represents 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, your response should address the following Level 2 findings that were listed on the inspection report:

- **One Radiologic Technologist did not meet the continuing education requirement of having completed 15 continuing education units (CEU) in mammography during the prior 36-month period. Records indicate the technologist has completed 9 CEUs during the prior 36 months. The technologist may not perform unsupervised mammography examinations until the continuing education requirements have been met.**
- **There was no written procedure for handling consumer complaints.**

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  
Attn: David J. Gallant,  
Compliance Officer

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of the 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