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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

CFN: 1124218  
Facility ID:141739  
Inspection ID #1417390007

Food and Drug Administration  
Baltimore District Office  
6000 Metro Drive  
Suite 101  
Baltimore, MD 21215-3215  
Telephone: (410) 773-5454

02-BLT-17

May 30, 2002

**WARNING LETTER**

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

Ms. Esther Wolfrey, Radiology Administrator  
Virginia Hospital Center Arlington Health System  
1715 North George Mason Drive  
Suite 403  
Arlington, Virginia 22205

Dear Ms. Wolfrey:

A representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA) inspected your facility on April 30, 2002. This inspection revealed a serious regulatory problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following violations of Section 354(f) of the Act at your facility identified on your inspection report:

- Your facility failed to document that corrective action was taken when phantom image testing results fell outside of pre-set limits for the following machines on the dates indicated: [redacted] unit [redacted] located in room 4 on 9/19/2001; [redacted] unit located in room 3 on 9/6 and 9/13/2001; [redacted] unit located in room 2 on 9/6/2002 [21 CFR 900.12(e)(8)(ii) and 21 CFR 900.12(e)(2)(i through iv)].
- The [redacted] unit located in room 4 does not indicate the focal spot or the target material after exposure when in automatic exposure control mode [21 CFR 900.12(b)(7)(i through iii)].
- The measured fog density in your mammography darkroom is [redacted]. This exceeds the allowed limit of .05 optical density [21 CFR 900.12(e)(4)(i)].
- The time period between the previous and current medical physicist surveys for the [redacted] unit [redacted] located in room 4 exceeded 14 months [21 CFR 900.12(e)(9)(i)].

Page 2 - Ms. Esther Wolfrey, Virginia Hospital Center Arlington Health System  
May 30, 2002

- Your facility failed to provide documentation which verified that Dr. [REDACTED] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months [21 CFR 900.12(a)(1)(ii)(A)].

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 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.

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 (see Sections 354(h) through (j) of the Act).

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, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Steven B. Barber, 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) 779-5441.

Sincerely,



*for* Lee Bowers  
Director, Baltimore District