

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration

d1865b

Refer to: CFN 1124375

Baltimore District  
900 Madison Avenue  
Baltimore, Maryland 21201  
Telephone: (410) 962-4040

June 3, 1998

**WARNING LETTER**

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

Mr. Wilbert Carrington, Radiology Manager  
Maryland General Hospital  
Mobile Mammography Unit  
827 Linden Avenue  
Baltimore, Maryland 21201

Inspection ID #1680130007

Dear Mr. Carrington:

Your facility was inspected on May 11, 1998 by a representative from the State of Maryland's Radiological Health Program acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving mammography performed at your facility.

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

**The number of masses scored in the phantom image, 0.0, did not meet the required number. The minimum number required for masses is 3.**

**The number of speck groups scored in the phantom image, 0.0, did not meet the required number. The minimum number required for speck groups is 3.**

**The number of fibrils scored in the phantom image, 2.0, did not meet the required number. The minimum number required for fibrils is 4.**

**The phototimer in the [REDACTED] mammography unit was malfunctioning at the time of the inspection.**

Mr. Wilbert Carrington  
Page 2  
June 3, 1998

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

Level 1 findings 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.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you at the close of the inspection, as follows:

**The following interpreting physicians 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: Dr. [REDACTED], Dr. [REDACTED], and Dr. [REDACTED].**

If the radiologists listed above have met this requirement, please forward documentation of their mammography readings over the past 24 months. If they have not read 960 patient examinations over the 24-month period prior to the date of the inspection, they cannot legally interpret mammograms independently. Radiologists not meeting this requirement must read either 240 mammograms or the number of mammograms necessary to bring them up to an average of 40 per month for the 24 months preceding the date of the inspection, whichever is less. These readings must be done under the direct supervision of a qualified radiologist. (Direct supervision means that the supervising physician reviews, discusses, and confirms or corrects the diagnosis of the physician under supervision. The supervising physician does not have to be present during the physician under supervision's initial interpretation, but he or she must review and confirm or correct the diagnosis. Furthermore, before the patient is informed of the diagnosis, the supervising physician must be identified on the patient's medical record and mammography report.)

**The following interpreting physicians did not meet the continuing education requirement of having completed a minimum of 15 credits in mammography over a 3-year period (an average of 5 credits/years): Dr. [REDACTED] and Dr. [REDACTED].**

Mr. Wilbert Carrington

Page 3

June 3, 1998

If the above personnel have met this requirement, please forward copies of certificates or letters from the organizations sponsoring the courses. In order to count toward the continuing education requirement, the credits must have been earned after March 31, 1995. If they have not met this requirement, they have 90 days from the date of the inspection to earn enough credits in mammography to meet the required 15 credits. If they fail to earn enough credits to meet this requirement within 90 calendar days from the date of the inspection, they cannot legally practice mammography independently until such time as they have met this requirement.

On May 12, 1998, we received a fax copy of a service ticket for work performed on your mammography unit on May 11, 1998. When responding to the Level 1 and 2 findings listed above, please include two phantom image films taken at a clinical Kvp for a 50% adipose/50% glandular tissue 4.5 cm breast. The images should be taken using two different 8x10" cassettes.

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:

- o the specific steps you have taken to correct all of the violations noted in this letter;
- o each step your facility is taking to prevent the recurrence of similar violations;
- o equipment settings (include technique factors), raw test data, and calculated final results, where appropriate; and
- o 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  
Richmond Resident Post, Suite 424  
Attn: Scott J. MacIntire, Compliance Officer  
10710 Midlothian Turnpike  
Richmond, Virginia 23235

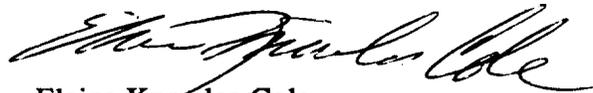
Also send a copy to the state Radiation Control Office that conducted the inspection.

Mr. Wilbert Carrington  
Page 4  
June 3, 1998

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

Should you have specific questions about mammography facility requirements or about the contents of this letter, please feel free to contact Elizabeth A. Laudig at 410-962-3591, extension 159.

Sincerely yours,



Elaine Knowles Cole  
Director, Baltimore District

cc: State of Maryland  
Radiological Health Program  
Maryland Department of the Environment  
2500 Broening Highway  
Baltimore, MD 21224  
Attn: MQSA Monitor

Pamela A. Wilcox-Buchalla, R.N., M.B.A.  
Director, Accreditation Programs  
American College of Radiology  
1891 Preston White Drive  
Reston, VA 22091