



DEPARTMENT OF HEALTH AND HUMAN SERVICE

maz406n HFI-35
Public Health Service (Pur687)

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Telephone: (410) 962-3461 x122
FAX: (410) 962-2219

Refer to: CFN 1124318
ID #107748

December 23, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Inspection ID #1560670003

Mr. Lansing Holman, Vice President
Yater Medical Group
1780 Massachusetts Avenue
Washington, D.C. 20036

Dear Mr. Holman:

A representative from the Food and Drug Administration (FDA) inspected your facility on December 4, 1998. This inspection revealed serious regulatory problems involving the mammography performed 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 public health by assuring that a facility can perform quality mammography.

The inspection revealed the following Level 1 findings at your facility:

Level 1 Violations:

1. **No processor QC records were present for the months of August and September 1998.**

You stated to the FDA inspector that mammographic examinations were not performed during August and September 1998. However, documentation was discovered for examinations performed on approximately 16 days during these months. No processor QC records were available for the days on which these examinations were performed.

2. **There was no documentation present at the facility to suggest that the medical physicist, [REDACTED], was licensed or approved by a state or certified by any of the approved boards.**

All credentials must be available for the inspector to review and should be kept on file at the facility. Please submit a copy of [REDACTED] state approval or license or board certification within 15 working days from receipt of this letter.

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

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 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, the inspection revealed Level 2 findings, some of which are repeated from previous inspections, and repeated Level 3 findings. Your response should address these Level 2 and repeated Level 3 findings. These violations include:

Repeated Level 2 Violations:

1. [REDACTED] the interpreting physician, did not meet the initial training requirement of having received 40 hours of continuing medical education in mammography.

[REDACTED] must cease independent interpretation of mammograms unless he submits to this office, within 15 working days from receipt of this letter, either a complete FDA attestation or a letter from the facility where he was trained. A physician can submit an FDA attestation form if he met this training requirement before October 1, 1994. The attestation must include the name of the training facility, the date(s) of the training, and the number of hours of training received. If a physician met this training requirement after October 1, 1994, he must submit a letter from the training facility that includes the information mentioned above. In addition, proper documentation must be kept on file at your facility for review during future MQSA inspections.

2. [REDACTED], the radiologic technologist, did not have specific training in mammography.

[REDACTED] must not be allowed to perform mammography independently unless she submits to this office, within 15 working days of receipt of this letter, documentation of specific training in mammography. Acceptable training includes, but is not limited to, passing the mammography certification examination offered by the American Registry of

Radiologic Technologists (ARRT), obtaining 40 hours of documented training in mammography, or attending the 3-day mammography training seminar offered by the Medical Technology Management Institute (MTMI).

- 3. The number of masses and speck groups scored in the phantom image did not meet the required number.**

The phantom image produced fewer than the required minimum of three masses and three speck groups.

Additional Level 2 Violations:

- 1. [REDACTED], the 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.**

The MQSA requires radiologists to maintain a minimum proficiency level by reading at least 960 patient examinations during the two years preceding the date of the inspection. The radiologists listed above must cease independent interpretation of mammograms unless they can submit documentation that they have read the required 960 patient examinations or until they read 240 patient examinations under supervision.

- 2. [REDACTED], the interpreting physicians, and [REDACTED], radiologic technologist, did not meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a 3-year period.**

[REDACTED] and Radiologic Technologist [REDACTED] must not perform mammography unless they submit to this office, within 15 working days of receipt of this letter, copies of documents indicating they have completed, or stating when they will complete, the required continuing education. These individuals have 90 days from the date of the inspection, until March 4, 1999, to complete 15 credits and to forward documentation of such to this office. If these individuals have not completed this training by March 4, 1999, they can no longer perform mammography independently until the training has been completed and the associated documentation reviewed by this office.

Repeated Level 3 Violations:

- 1. Corrective actions for phantom image failure were not documented on at least one occasion.**

Control limits for phantom image charting were exceeded in September, October, and November 1998. There was no documentation to show that any corrective action was taken to correct this deficiency.

2. Personnel responsibilities were missing from the quality assurance program documentation.

Your facility failed to document the names and duties of all personnel involved in mammography functions as required by the MQSA.

It is necessary for you to act on this matter immediately. Please explain to this office in writing, within 15 working days from the date you receive this letter:

- the specific steps you have taken to **correct** all the violations noted in this letter;
- each step your facility is taking to **prevent the recurrence** of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- 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 the Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Thomas C. Knott, Compliance Officer.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter concerns only the findings of your most recent inspection and does not necessarily address all the obligations you have under the law. You may obtain general information about FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

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

Sincerely Yours,



Elaine Knowles Cole
District Director