



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
MTCR

01-PHI-02

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106
Telephone: 215-597-4390

WARNING LETTER

November 30, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Anthony Lombardi
President/CEO
Monongahela Valley Hospital, Inc.
Country Club Road
Monongahela, PA 15063

Re: Inspection ID#: 1552180009

Dear Mr. Lombardi:

We are writing to you because on November 16, 2000, your mammography facility was inspected by a representative from the Commonwealth of Pennsylvania, acting in behalf of the Food and Drug Administration (FDA). 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 women by assuring that a facility can perform quality mammography.

This inspection revealed the following level 1 and level 3 noncompliances:

Level 1 Inspection Finding:

Quality Standards – Personnel: Radiologic Technologists – General Requirements

[21 CFR 900.12(a)(i)]

“All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements.... Be licensed to perform general radiographic procedures in a State; or Have general certification from one of the bodies determined by FDA.....”

OBSERVATION: The radiologic technologist, [REDACTED], did not meet the requirement of being licensed by a State or certified by a FDA approved board.

Ms. West was board certified by the ARRT with an expiration date of 10/31/2000. Ms. West failed to renew her ARRT certification before this expiration date. As such, she no longer met the general requirements stated above. The Commonwealth of Pennsylvania does not license radiologic technologists and therefore they must be certified by a FDA approved board.

Level 3 Inspection Findings:

Quality Standards – Equipment: Semiannual Quality Control Tests - Compression Device Performance

[21 CFR 900.12(e)(4)(iii)(A)]

- Use of Test Results -

[21 CFR 900.12(e)(8)(ii)(A)]

“A compression force of at least 11 newtons (25 pounds) shall be provided.”

“If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:.... Before any further examinations are performed or any films are processed using a component of the mammography system that failed.....”

OBSERVATION: Compression device QC is not adequate for the [REDACTED] mammography unit because corrective action (before further exams) was not documented.

Quality Standards – Personnel: Retention of Personnel Records

[21 CFR 900.12(a)(4)]

“Facilities shall maintain records to document the qualifications of all personnel....These records must be available for review by the MQSA inspectors.”

OBSERVATION: Documentation showing that the radiologic technologist, Catherine West, met all the personnel MQSA requirements were not maintained.

The specific problems noted above appeared on the attached MQSA Facility Inspection Report, which was issued to the facility on November 22, 2000. Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious 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 the Standards,
- suspension or revocation of your facility’s FDA certificate, or obtaining a court injunction against further mammography.

Please note that FDA regulations do not preclude a State from enforcing its own mammography laws and regulations. In some cases, these requirements may be more stringent than FDA’s. When you plan your corrective action, therefore, you should consider the more stringent State requirements, if any.

It is necessary for you to act on this matter immediately. Please address the following items in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- copies of your written standard operating procedures for: assuring all personnel have proper and current

documentation showing that they meet the MQSA personnel requirements, and performance of the compression test, which includes the action limits and instructions not to perform mammography until corrective action is taken.

- copies of records showing corrective action regarding the failed compression test.

Please submit your response to:

Robert E. Davis
Mammography Specialist
U.S. Food & Drug Administration
7 Parkway Center, Rm 390
Pittsburgh, PA 15220

With a copy to:

Robert Scott
PA Dept. of Environmental Protection
Bureau of Radiation Protection
400 Waterfront Drive
Pittsburgh, PA 15222-4745

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 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 more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Robert E. Davis at 412-644-3394.

Sincerely,


for Thomas Gardine
District Director
Philadelphia District

Attachment: MQSA Facility Inspection Report – Inspection ID: 1552180009