



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

PHILADELPHIA DISTRICT
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2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

01-PHI-15

WARNING LETTER

May 3, 2001

FEDERAL EXPRESS

Robert Filosa
President/CEO
Lansdale Medical Group, P.C.
1001 South Broad Street
Lansdale, PA 19446-0508

Re: Inspection ID: 1608460006

Dear Mr. Filosa:

We are writing to you because on April 19, 2001, 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, level 2, and level 3 noncompliances:

Level 1 Inspection Finding:

Quality Standards – Medical Records and Mammography Reports: Communication of Mammography Results to the Patients [21 CFR 900.12(c)(2)]

“Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are “Suspicious” or “Highly suggestive of malignancy”, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.”

OBSERVATION: The system to communicate results is not adequate because there is no system in place to provide timely lay summaries.

Your facility does not send a written lay summary to those patients that have an exam with an overall final assessment category of “Incomplete: Needs Additional Imaging Evaluation”.

Quality Standards – Equipment: Weekly Quality Control Tests

[21 CFR 900.12(e)(2)]

"Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

OBSERVATION: Phantom QC records were missing for at least 4 weeks for the [REDACTED] mammography unit.

There was no documentation showing that the weekly phantom QC test was performed during the weeks when mammography exams were performed on 4/7,10,14,18/00.

Level 2 Inspection Findings:

Quality Standards – Infection Control

[21 CFR 900.12(e)(13)]

"Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and"

OBSERVATION: The facility has not specified adequate procedures to be followed for infection control or did not follow them when required.

Your written procedure for infection control was not complete in that it did not provide a procedure for documenting that infection control procedures were implemented when the mammography equipment came in contact with blood or other potentially infectious materials.

Quality Standards – Consumer Complaint Mechanism

[21 CFR 900.12(h)]

"Each facility shall (1) Establish a written and documented system for collecting and resolving consumer complaints; (2) Maintain a record of each serious complaint received by the facility for at least three years from the date the complaint was received; (3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumers satisfaction; (4)....."

OBSERVATION: The facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required.

Your written procedure did not address how long each complaint should be maintained, did not include directions on how to provide the consumer with adequate directions for filing unresolved serious complaints with their accreditation body (ACR), and did not state that the facility will send all unresolved serious complaints to the ACR.

**Quality Standards – Equipment: Weekly Quality Control Tests
- Use of Test Results**

[21 CFR 900.12(e)(2)]
[21 CFR 900.12(e)(8)(ii)(A)]

"Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly. (i)....(ii)....(iii) The phantom image shall achieve at least the minimum score established by the accreditation body.....(iv) The density difference.... shall not vary by more than ± 0.05 from the established operating level."

"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: Corrective action before further exams, for a failing image score, or a phantom background optical density or density outside the allowable regulatory limits was not documented for the [REDACTED] mammography unit.

Review of the phantom QC records for the [REDACTED] mammography unit found that the speck group score failed on 8/24/00, 12/11/00, and 3/20/01 and no corrective action was taken before further mammography exams were performed.

Quality Standards – Equipment: Weekly Quality Control Tests

[21 CFR 900.12(e)(2)(i)]

"Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly... The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition."

OBSERVATION: The phantom QC is not adequate because the image was not taken at the clinical setting for the [REDACTED] mammography unit.

Your facility uses the [REDACTED] on the mammography unit to x-ray clinical patients. The phantom image QC test must be performed using this mode. Your facility was using the [REDACTED] and [REDACTED] density.

Quality Standards – Personnel: Interpreting Physicians – Continuing Experience and Education

[21 CFR 900.12(a)(1)(ii)(A)]

"All interpreting physicians shall maintain their qualifications by meeting the following requirements: (A)..... the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two."

OBSERVATION: The facility failed to produce documents verifying that the interpreting physician, [REDACTED], met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.

Dr. Leviton only interpreted [REDACTED] mammograms in the 24-month period preceding the date of the inspection.

Level 3 Inspection Findings:

Quality Assurance – General

[21 CFR 900.12(d)(1)(i)(iii)(iv)]

Quality Assurance – Mammography Medical Outcomes Audit

[21 CFR 900.12(f)(3)]

“Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility... (1) Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties... (i) Lead interpreting physician... (iii) Medical physicist... (iv) Quality control technologist

“Each facility shall designate at least one interpreting physician to review the medical outcomes audit data...”

OBSERVATION: **The QA program is inadequate because personnel responsibilities is missing or incomplete.**

Your facility did not have a list of assigned responsible personnel that identifies by name; the lead interpreting physician, the audit interpreting physician, the quality control technologist, and the medical physicist, and other individuals assigned various QC tasks.

Quality Assurance – Equipment: Quarterly Quality Control Tests – Repeat Analysis

[21 CFR 900.12(e)(3)(ii)]

“Facilities with screen-film systems shall perform the following quality control tests at least quarterly: (i)... (ii) Repeat Analysis...”

OBSERVATION: **The repeat analysis QC was not adequate because it was not done at the required frequency.**

The repeat analysis QC was not being performed because of low volume of patients. Repeat analysis must be performed at least quarterly regardless of volume.

Quality Assurance – Equipment: Semiannual Quality Control Tests - Screen-Film Contact

[21 CFR 900.12(e)(4)(ii)]

- Use of Test Results

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

“Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.”

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

OBSERVATION: The screen-film contact QC is not adequate because corrective action was not documented at least once.

Review of the screen-film contact films revealed a plus density strip [REDACTED] wide along the chest wall side on several large cassettes. This does not pass the ACR procedure being used by your facility for this test. No corrective action was taken.

The specific problems noted above appeared on the attached revised MQSA Facility Inspection Report that was faxed to the facility on April 11, 2001. The original report issued to the facility on April 4, 2001 was modified to clarify several remarks. 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;
- provide a copy of your written procedure for performing the processor QC test, which includes: the requirement to be performed every day that mammography exams are performed, the pass/fail criteria, and procedures to follow when processor QC is out of limits;
- provide a copy of your modified written procedure for infection control;
- provide a copy of your modified written procedure for handling consumer complaints;
- provide a copy of your written procedure for performing the phantom QC test, which includes: the requirement to be performed every weeks mammography exams are performed, the technique/mode to take the phantom image for each mammography unit; the pass/fail criteria and procedures to follow when the phantom image does not meet the pass/fail criteria;
- provide a copy of your written procedure for performing the screen-film contact test, which includes the pass/fail criteria and procedures to follow if the pass/fail criteria is not met;
- provide a copy of your written procedure to perform the quarterly repeat analysis QC test;
- provide a list of responsible personnel identifying by name: the lead interpreting physician, the audit interpreting physician, the quality control technologist, the medical physicist, and any other individuals assigned any QC tasks;
- provide documentation to show that [REDACTED] has met the continuing experience requirement or steps taken to remove [REDACTED] from independent reading of mammograms;

provide of a copy of your written procedure for ensuring that all personnel have met the applicable MQSA personnel continuing requirements under the Final regulations (as applicable) and documentation to be obtained and maintained for each interpreting physician, radiologic technologist, and medical physicist.

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:

State of Delaware
Div. of Public Health/Office of Radiation Control
Plan Review Permitting & Enforcement
Federal & Water Streets
P.O. Box 637
Dover, DE 19903

Attn: Kevin Charles, Section Chief – Health Systems Protection

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/cdrh/mammography>. 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,



Thomas Gardine
District Director
Philadelphia District

Attachment: MQSA Facility Inspection Report – Inspection ID: 2238510001