



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
mstorn

HFE-35 (redacted)

01-PHI-05

900 U.S. Customhouse
2nd and Chestnut Streets,
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

December 28, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert C. Young, CEO
Fox Chase Cancer Center
7701 Burholme Avenue
Philadelphia, Pa 19111

Re: Inspection ID#: 1506560007

Dear Mr. Young:

We are writing to you because on December 8, 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, level 2, and level 3 noncompliances:

Level 1 Inspection Finding:

Quality Standards – Medical Records and Mammography Reports: Communication of Mammography Results to the Patient [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 communicate serious or highly suggestive cases ASAP

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: There is no written procedure for infection control.

Your facility had a written procedure for infection control, however it was not complete because 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 – Equipment: Daily Quality Control Tests
- Use of Test Results -**

[21 CFR 900.12(e)(1)]

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

".....A processor performance test shall be performed on each day that clinical films are processed for that day...(ii) The mid-density shall be within +/- 0.15 of the established operating level....(iii) The density difference shall be within +/- 0.15 of 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 actions for processor QC failures were not documented at least once for the [redacted] processor and

Mammograms were processed in the [redacted] processor when it was out of limits on 2 days.

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.

Level 3 Inspection Findings:

**Quality Assurance – Equipment: Annual Quality Control Tests – X-ray field/light field/image
receptor/compression paddle alignment**

[21 CFR 900.112(e)(5)(vii)(A)]

"All systems shall have beam-limiting devices that.....provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID"

OBSERVATION: The nipple side of the x-ray field extends beyond the nipple edge of the image receptor by more than 2 % of the SID for the [REDACTED] unit in Room [REDACTED]

Quality Assurance – Equipment: Semiannual Quality Control Tests – Compression Device Performance
[21 CFR 900.12(e)(4)(iii)]

"Facilities with screen-film systems shall perform the following quality control tests at least semiannually
....Compression device performance..."

OBSERVATION: Compression device QC is not adequate for the [REDACTED] unit in Room [REDACTED] because the QC records were not done at the required frequency.

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: The required personnel qualification documents were unavailable during the inspection.

The specific problems noted above appeared on the attached MQSA Facility Inspection Report, which was issued to the facility on December 13, 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;
- provide a copy of your written standard operating procedure for providing written lay summaries to all patients and timeframes for sending these lay summaries to the patients.
- provide copies of your written standard operating procedures daily processor QC, phantom QC, compression QC, and retention of personnel qualification documents and
- provide copies of service records for correction nipple edge alignment problem for the [REDACTED] unit in Room [REDACTED]

Please submit your response to:

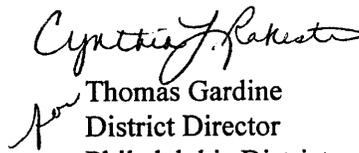
Robert E. Davis
Mammography Specialist
U.S. Food & Drug Administration
7 Parkway Center, Rm 390
Pittsburgh, PA 15220

With a copy to:

Joseph Pryber
PA Dept. of Environmental Protection
Bureau of Radiation Protection
Lee Park, Suite 6010
555 North Lane
Conshohocken, PA 19428

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: 1506560007

cc: Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191

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PA Dept. of Environmental Protection
Bureau of Radiation Protection
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