



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-16

**WARNING LETTER**

May 3, 2001

**FEDERAL EXPRESS**

William Milligan  
President/CEO  
Tyler Memorial Hospital  
880 SR 6W  
Tunkhannock, PA 18657

Re: Inspection ID: 1440140006

Dear Mr. Milligan:

We are writing to you because on April 25, 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.....”.

**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”.

**Level 2 Inspection Finding:**

**Quality Standards – Personnel: Interpreting Physicians – Continuing Experience**

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

"All interpreting physicians shall maintain their qualifications by meeting the following requirements: (A) ..... the interpreting physician shall have read 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:** 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.

Your facility was only able to document that [REDACTED] read [REDACTED] mammography exams in a 24 month period. [REDACTED] cannot independently read mammograms unless he meets the continuing experience requirement.

**Level 3 Inspection Finding:**

**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.

Complete personnel qualification documents were not available for [REDACTED]

The specific problems noted above appear on the attached revised MQSA Facility Inspection Report. One level 1 item was removed from the original inspection report that was issued to the facility on April 19, 2001. 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 communicating results of the exam to the patient that includes the requirement to send lay letters to all patients, including those exams which are categorized as "Incomplete: Needs Additional Imaging Evaluation";
- provide a copy of the lay letter to be sent to patients with exams that are categorized as "Incomplete: Needs Additional Imaging Evaluation";
- provide documentation to show that [REDACTED] has met the continuing experience requirement or steps taken to remove [REDACTED] from independent reading of mammograms or procedures to be taken to have [REDACTED] requalify;
- 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:

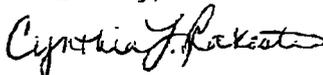
Robert E. Davis  
Mammography Specialist  
U.S. Food & Drug Administration  
7 Parkway Center, Rm 390  
Pittsburgh, PA 15220

With a copy to:

Joseph Koshy  
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,

  
for Thomas Gardine  
District Director  
Philadelphia District