



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

PHILADELPHIA DISTRICT  
M5130n

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

01-PHI-07

**WARNING LETTER**

**January 31, 2001**

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Richard Freeman, CEO  
Medical College of Pennsylvania Hospital  
3300 Henry Avenue  
Philadelphia, PA 19106

Re: Inspection ID: 1583370009

Dear Mr. Freeman

We are writing to you because on January 5, 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 repeat level 2, level 2, and level 3 noncompliances:

**Repeat Level 2 Inspection Finding:**

**Quality Standards – Medical Records and Mammography Reports: Contents and Terminology**  
**[21 CFR 900.12(c)(1)(iv)]**

“Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:....Overall final assessment of findings, classified in one of the following categories.....”

**OBSERVATION:** [redacted] of [redacted] random reports reviewed did not contain an assessment category.

Review of [redacted] of [redacted] medical reports found that [redacted] exam with a designation of "ACR Category 4, but it did not have the required assessment category wording of "Suspicious" on the report.

During the annual inspection performed on December 9, 1999, of random reports did not have an assessment category. Your facility responded to this noncompliance on January 4, 2000 and January 13, 2000. The current finding above shows that the corrective action taken last year was not sufficient to assure that each and every medical report will have a properly worded assessment category as required by 21 CFR 900.12(c)(1)(iv).

**Level 2 Inspection Finding:**

**Quality Assurance – 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 two weeks but less than four weeks for the mammography unit.

The inspector observed three weeks where phantom image data was not recorded. Upon further investigation, the inspector found that a temporary technologist who worked at your facility for a short time did take phantom images during the three weeks missing on the chart. The phantom images were not recorded because the data did not pass. This data should be recorded on the phantom image chart and corrective action taken before any additional patients were examined. This problem highlights the failure to have a properly trained individual perform the phantom QC test and the failure of the Quality Control Technologist to review the test results and respond appropriately to the errors that occurred.

**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 Dr. Geraldine Hamilton.

The specific problems noted above appeared on the attached MQSA Facility Inspection Report, which was issued to the facility on January 24, 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 standard operating procedure for assuring a properly worded assessment category is present on every medical report..
- provide a copy of your written standard operating procedure for performing the phantom QC test, which includes the requirement to perform test weekly.
- provide a copy of your written standard operating procedure to assure that personnel qualification documents are obtained prior to individual performing or interpreting mammography exams and are available during the inspection

Please submit your response to:

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

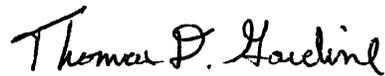
With a copy to:

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,



Thomas Gardine  
District Director  
Philadelphia District

Attachment: MQSA Facility Inspection Report – Inspection ID: 1583370009

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

Joseph Koshy  
PA Dept. of Environmental Protection  
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