



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-09

WARNING LETTER

March 30, 2001

FEDERAL EXPRESS

Sister Jean Coughlin
President/CEO
Marian Community Hospital
100 Lincoln Avenue
Carbondale, PA 18407

Re: Inspection ID: 1220100007

Dear Sister Coughlin:

We are writing to you because on March 21, 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 repeat level 3 noncompliances:

Level 1 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 four weeks for the [REDACTED] mammography unit.

The inspector found that the phantom image test was not performed for four weeks during the twelve-week time period of August, 2000 through October, 2000. These weeks were 8/13, 8/27, 9/17, and 10/29/2000. Additionally, the phantom image test was not performed during the weeks of 4/23/2000, 5/28/2000, 1/7/2001, and 2/11/2001.

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 facility 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 and did not include directions on how to provide the consumer with adequate directions for filing unresolved serious complaints with their accreditation body (ACR).

Quality Standards – Personnel: Interpreting Physicians – Initial Qualifications

Interim Regulations [21 CFR 900.12(a)(1)(iii)(A)]

"Interpreting physicians shall meet the following requirements (i)...(ii)...(iii) have the following initial experience: (A) Have read and interpreted the mammograms from the examinations of at least 240 patients in the 6 months...".

OBSERVATION: The facility failed to produce documents verifying that the interpreting physician, [REDACTED] met the initial experience requirement of having interpreted or multi-read 240 mammograms in 6 months.

[REDACTED] has been reading mammograms since October , 1994, and thus must meet the interim requirements stated above. The interim requirements were in effect from 10/1/1994 to April 27, 1999. Interpreting physicians who were qualified under FDA's interim regulations are considered to have met the requirements of the final

regulations, which were effective as of April 28, 1999, as stated in 21 CFR 900.12(a)(1)(iii).

Quality Standards – Personnel: Interpreting Physicians – Initial Qualifications

Interim Regulations [21 CFR 900.12(a)(1)(ii)(C)]

"Interpreting physicians shall meet the following requirements: (i)... (ii) Have the following training: (A)... (B)... (C) Have 40 hours of documented continuing medical education in mammography....".

OBSERVATION: The facility failed to produce documents verifying that the interpreting physician, [REDACTED] met the initial requirement of having 40 hours of medical education in mammography prior to 4/28/99.

[REDACTED] has been reading mammograms since October 1994, and thus must meet the interim requirements stated above. The interim requirements were in effect from 10/1/1994 to 4/27/1999. Interpreting physicians who were qualified under FDA's interim regulations are considered to have met the requirements of the final regulations, which were effective as of April 28, 1999, as stated in 21 CFR 900.12(a)(1)(iii).

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

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

"All interpreting physicians shall maintain their qualifications by meeting the following requirements: (A)..... (B).....the interpreting physician shall have taught or completed at least 15 category I continuing medical education units in mammography during the 36 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 education requirement of having completed a minimum of [REDACTED] credits in mammography in a 36-month period.

Repeat 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, as discussed above, were not available for [REDACTED] and [REDACTED]. The previous annual MQSA inspection performed on February 23, 2000 also found that complete personnel qualification documents were not available.

The specific problems noted above appeared on the attached revised MQSA Facility Inspection Report. The original report issued to the facility on March 28, 2001 was modified to remove one level 1 noncompliance that was resolved with adequate documentation after the original report was finalized. 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 phantom QC test, which includes the requirement to perform the test weekly ;
- provide a copy of your modified written procedure for infection control;
- provide a copy of your modified written procedure for handling consumer complaints;
- provide documentation to show that [REDACTED] met the initial experience and training requirements under the interim regulations;
- provide documentation to show that [REDACTED] has met the continuing education requirement or steps taken to remove Dr. Fan from independent reading of mammograms;
- provide of a copy of your written procedure for ensuring that all personnel have met the applicable MQSA personnel requirements under the Interim or 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:

David Gaisior
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

Attachment: MQSA Facility Inspection Report – Inspection ID: 1220100007

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

David Gaisior
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Lee Park, Suite 6010
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