



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

PHILADELPHIA DISTRICT
 M5104n

01-PHI-04

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

Telephone: 215-597-4390

WARNING LETTER

December 4, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Martin McElroy, CEO
 Mercy Community Hospital
 2000 Old West Chester Pike
 Havertown, PA 19083

Re: Inspection ID#: 1243130008

Dear Mr. McElroy:

We are writing to you because on November 20, 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 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

Lay summary letters to those patients that have an exam diagnosed as “Suspicious” or “Highly suggestive of malignancy” are not sent until 10 – 14 days after the exam. This is not considered communicating the results as soon as possible.

The specific problems noted above appeared on the attached MQSA Facility Inspection Report, which was issued to the facility on November 30, 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.

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>.

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: 1243130008

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

Barry Siskind, M.D.
Medical Director of Mercy Community
Radiology Department
Mercy Community Hospital
2000 Old West Chester Pike
Havertown, PA 19083

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