



WARNING LETTER

Cin WL -4806-0
October 11, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Barbara L. Demyan, B.A., R.T
Associate Administrator of Radiology
University Hospitals Health System and SWGHC
18181 Pearl Road
Strongsville, OH 44136

Facility I.D.#: 223731

Dear Ms. Demyan:

We are writing to you because on October 3, 2000, your facility was inspected by a representative of the State of Ohio, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

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. The inspection revealed the following Level 1 finding at your facility:

Your records revealed that your facility processed mammograms when the processor quality control records were missing for 18 days in the month of June 2000. Also, the inspection found that your facility failed to perform the processor quality control test for 25 days covering May 25 through July 6, 2000.

21 CFR 900.12 (e)(1)(i)-(iii)

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, this condition represents 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.

The other item listed in your October 3, 2000 inspection report identified, as Level 3 should also be corrected. We will verify correction of this item during our next inspection. You are not required to address the Level 3 item in your written response.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the violation noted in this letter; and
- each step your facility is taking to prevent the recurrence of similar violation.

Please include sample records with an explanation that demonstrate proper record keeping procedures that are now being followed. (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food and Drug Administration
6751 Steger Dr.
Cincinnati, OH 45237-3097

Also, please send a copy to the State radiation control office:

Mr. Dwight W. Leeseberg
Ohio Department of Health
Radiologic Technology Section
161 South High St., Suite 400
Akron, OH 44308

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 all other obligations you may 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 any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Mr. R. Terry Bolen at (513) 679-2700, extension 138.

Sincerely yours,



Carol A. Heppe
Acting District Director
Cincinnati District Office

c.

OH/DWLeeseberg

Priscilla F. Butler, M.S.
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Reston, VA 20191