



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFD-35

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL -10941-02
October 31, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William Leister
Imaging Manager
Fairfield Medical Center
Diagnostic Health Services
1159 East Main St.
Lancaster, OH 43130

Facility I.D.#: 112193

Dear Mr. Leister:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on October 22, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) 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:

Quality Assurance – Equipment - 21 CFR 900.12(e)(8)(i)&(ii) as further required in 21 CFR 900.12 (e)(1)

Your records revealed that your facility processed mammograms when the processor quality control parameters (density difference) were found outside the regulatory limits for six days in October, 2001.

The MQSA regulation requires the mammography processor be evaluated by performing daily processor quality evaluation test. The inspection found that your facility failed to demonstrate that the daily quality control tests were performed within regulatory limits on October 8-12 & 15, 2001.

The inspector recognized that the above noncompliance issue was corrected before inspection (CBI). Your staff indicated to the inspector that the backup mammography technologist failed to implement corrective actions when the density difference readings were out of limits. Your staff indicated to the inspector that your facility corrected this deficiency when the primary quality control mammography technologist returned from vacation.

Because this condition may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, this represents 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, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

In addition, your response should address the Level 2 noncompliance items that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliance items are:

1. **Quality Assurance – Mammography Medical Outcomes Audit 21 CFR 900.12(f)(1)& (2)**

Your staff failed to show that an annual medical audit and outcomes analysis was performed collectively for all interpreting physicians at your facility only.

2. **Quality Assurance – Mammography Medical Outcomes Audit 21 CFR 900.12(f)(3)**

Your facility did not designate an interpreting physician to review the medical outcomes audit data at least once every 12 months.

You must act on these matters immediately. Please explain the following elements 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 violations noted in this letter; and
- Each step your facility is taking **to prevent the recurrence of similar violations.**

Please submit sample records that demonstrate proper record keeping procedures, if the finding relate to quality control or other records (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 & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

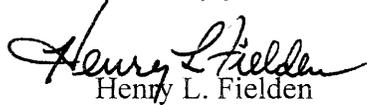
Also, please send a copy to the State radiation control office:

Ms. Stacey Melick
Ohio Department of Health
Radiologic Technology Section
P.O. Box 118
Columbus, OH 43266-0118

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. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,



Henry L. Fielden
District Director
Cincinnati District Office

c.
OH/SMelick

Priscilla F. Butler, M.S.
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