



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35
M2177M
Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE

6751 Steger Drive
Cincinnati, OH 45237-3097

WARNING LETTER

November 4, 1998

Cin WL-99-32

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert C. Erwin
Medical Director
Med Center One - Streetsboro
9424 State Route 14 at Market Square
Streetsboro, OH 44241

Inspection I.D.#:2131990002

Dear Mr. Erwin:

Your facility was inspected on October 20, 1998 by a representative from the State of Ohio radiation control program under contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Your records lack the required information that the following interpreting physician is qualified to interpret mammograms: [REDACTED].. Your records did not demonstrate that [REDACTED] is licensed in Ohio to practice medicine.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliance that was listed on the inspection report provided to you at the close of the inspection. This Level 2 noncompliance is:

The darkroom fog was measured at the fog level of 0.14 which exceeded the maximum allowable fog limit of 0.05.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

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If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- **impose civil money penalties** on a facility of up to \$10,000 **for each failure** to substantially comply with, **or each day** of failure to substantially comply with, the Standards.
- **suspend or revoke a facility's FDA certificate** for failure to comply with the Standards.
- **seek an injunction in federal court** to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- 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;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the noncompliances that were found relate to quality control or other records (**Note: Patient names or identification should be deleted from any copies submitted**).

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

Mr. R. Terry Bolen
MQSA Radiological Health Officer
Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097.

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

Ms. Neann Manubay
Ohio Department of Health
Northeast District Office
Oliver R. Ocasek Government Office Building
Suite 400
161 S. High St.
Akron, OH 44308-1616

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

Sincerely yours,



R. Duane Satzger, Ph.D.
Acting District Director
Cincinnati District Office

c.
OH/NManubay