



WARNING LETTER

Cin WL -9821-01
August 29, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

David M. Kushner, M.D.
Lead Interpreting Physician
UHHS-Saint Michael Hospital, Inc.
Radiology Dept.
5163 Broadway Ave.
Cleveland, OH 44127

Facility I.D.#: 137802

Dear Dr. Kushner:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on August 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 **repeat** Level 2 finding at your facility:

Quality Assurance – Equipment - 21 CFR 900.12(e)(8)(i)&(ii)(A) as further required in 21 CFR 900.12 (e)(2)(iv)

Your records revealed that your facility failed to document corrective actions before further mammography examinations, for failing image score, or a phantom background optical density or density difference found outside the regulatory limits.

During the inspection, the inspector observed the weekly phantom quality control results, specifically the density differences were outside of the allowable regulatory limits on January 29, 31 and February 1, 2001 and there was no documentation of corrective action taken.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received at the close of the inspection. The problem is identified as **repeat** Level 2 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement **permanent** correction of the problem found during your previous inspection.

Also, 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 – Equipment – Infection control -21 CFR 900.12(e)(13)

Your facility failed to specify adequate procedures to be followed for infection control or your facility did not follow them when required.

During the inspection, the inspector observed your policy did not describe the proper use of “TOR HB” when the equipment comes in contact with blood or other potentially infectious agents. In addition, the inspector observed your facility did not make available for review the infectious control logs or charts as required.

2. Personnel – Interpreting Physicians 21 CFR 900.12(a)(1)(ii)(A)

Your facility failed to produce documents demonstrating that [REDACTED], an interpreting physician meets the continuing experience requirement of having interpreted or multi-read a minimum of 960 mammograms in a twenty four month period.

During the inspection, the inspector observed your facility’s personnel records and found that [REDACTED] had read a total of 922 mammography examinations in a twenty four month period prior to the date of the inspection.

3. 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 individually and collectively for all interpreting physicians at your facility only.

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

Your staff failed to designate a reviewing interpreting physician for the purpose of evaluating your facility medical outcome audit to follow-up positive mammography cases.

In addition, your response should address the **repeat** Level 3 noncompliance item that was listed on the inspection report provided to you at the close of the inspection. This **repeat** Level 3 noncompliance item is:

Retention of Personnel Records - 21 CFR 900.12 (a)(4)

During the inspection at your facility and upon request by the inspector, your staff was unable to provide the required personnel qualification documentation for review by the inspector.

Because these conditions may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, these represent 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.

It is necessary for you to 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 findings 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:

Mr. Dwight W. Leeseberg
Ohio Department of Health
Radiologic Technology Section
161 South High St., Suite 400
Akron, OH 44308-1616

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