DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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 –02-14834

September 17, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gary Halman
Chief Executive Officer
Medina General Hospital
1000 East Washington St.
Medina, OH 44256

Facility I.D.#: 123695

Dear Mr. Halman:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on August 15, 2002. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under the Mammography Quality Standards Act (MQSA) of 1992, 42 U.S.C. § 263b, and the regulations set forth in Title 21, Code of Federal Regulations (C.F.R.), Part 900, 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 (identified on your inspection report):

Medical records and mammography reports – *Communication of mammography results* (21 C.F.R. § 900.12(c)(2))

Your records revealed that your facility failed to provide lay summary letters on the results of each mammography examination to patients when addendum mammography reports were produced based on the interpretation of the past mammography films.

According to your facility's policy, interpretation of mammograms is delayed for up to two weeks pending receipt of previous films. If, after the two weeks, the previous films have not been received, the mammograms are interpreted, and a report and associated lay letters are issued. However, during the inspection, the inspector observed that your facility is not issuing an addendum lay letter to the patients when your facility receives the previous films and an addendum report is generated.

The inspection also revealed the following repeated violation your facility (identified on your inspection report):

Quality Assurance – *Equipment* - 21 CFR 900.12(e)(8)(i)&(ii) & 21 CFR 900.12(e)(2)

Your records revealed that your facility failed to conduct and to document corrective actions on a mammography unit for which density difference optical density readings for the unit were charted outside the regulatory limits before further mammography examinations.

During the inspection, the inspector observed the weekly phantom quality control (density difference) results were out of limits on twenty seven (27) occasions in July 25 & 31; October 5, 12, 19, 26; November 2, 9, 16, 23, 30; December 7, 14, 21, 28, 2001; January 4 & 11; February 1 & 22; March 1 & 29; April 19 & 26; May 3, 10, 17, 24, 2002 for the [redacted] mammography unit located in room 3. Your records showed that mammography examinations were performed with no documentation of corrective actions taken.

In addition, we found other deficiencies that were listed as Level 2 findings on your inspection report:

1. Quality Assurance – *Equipment* - 21 CFR 900.12(e)(13) - *Infection control*

Your facility does not have adequate procedures to be followed for infection control when required.

During the inspection, the inspector observed that your facility's infection control procedure does not describe the proper use of the infection control product when the equipment comes in contact with blood or other potentially infectious agents. Your written policy lacked information regarding the wet standing time before wiping. Your facility's procedure also does not provide for a log or chart indicating that appropriate infection control has been performed.

2. Quality Assurance – *Equipment* - 21 CFR 900.12(e)(9) & 21 CFR 900.12(e)(5)(i)(A)&(B)

The medical physicist's survey for the [redacted] mammography unit is incomplete because automatic exposure control (AEC) performance capability test covering the 2 to 6 cm phantom thickness at typical kVp(s) was not performed.

During the inspection, the inspector reviewed the May 29, 2002 medical physicist survey report for the [redacted] mammography unit. The inspector observed that the report shows the performance capability test covering the 2 to 6 cm phantom thickness at typical kVp(s) was not performed on the 24 x 30 cm bucky system detector.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent serious violations of the law that may result in FDA initiating regulatory action. 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; seeking civil money penalties of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with the MQSA Standards; seeking suspension or revocation of your facility's FDA certificate; or seeking a court injunction against performing further mammography (see 42 USC §§ 263b(h) through (j) of the MQSA).

It is necessary to act on these matters 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 violations noted in this letter; and
- Each step your facility is taking **to prevent the recurrence** of similar violations.

Please also provide the following in answering this letter: (Note: Patient names or patient social security numbers should be deleted from any copies submitted)

- A copy of your corrected written procedure for communication of mammography results. The written procedures shall cover any and all addendum mammography results for patients. Also include a copy of a sample lay summary letter for an addendum report.
- A copy of the your written standard operating procedure covering the phantom control chart operation and a copy of the phantom control chart covering the time period just prior to and after the August 15, 2002 inspection.
- A copy of the corrected written infection control procedures.
- A copy of the amended medical physicist's report demonstrating the AEC automatic exposure control (AEC) performance capability test covering the 2 to 6 cm phantom thickness at typical kVp(s) for the 24 x 30 cm bucky system detector was performed.

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 Leeseberg
Ohio Department of Health
Radiological 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 certain 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 R. Terry Bolen at 513-679-2700, extension 138.

Sincerely yours,

Mr. John W. Thorsky
Acting District Director
Cincinnati District Office

c.
OH/DWLeeseberg

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