DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

53930d

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

March 21, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03-13

Clyde M. Chumbley, M.D.
Chief Executive Officer
Medical Associates Health Center
W180 N7950 Town Hall Road, P.O. Box 427
Menomonee Falls, Wisconsin 53051

Dear Dr. Chumbley:

On February 20, 2003, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA") which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA at your facility. These violations were noted on the MQSA Facility Inspection Report and the document *"Important Information about Your MQSA Inspection"* that the inspector left with your facility at the close of the inspection. The violations are again identified below.

Level 1: Phantom quality control records were missing for at least four weeks for the following back-up processors:

[redacted], Room 2, ACR designation = Unit 2, Processor = Back-up).

[redacted] Room 1, ACR designation = Unit 3, Processor = Back-up).

These processors must be evaluated as part of the phantom image evaluation. See 21 CFR 900.12(e)(2), 900.12(d)(2).

Level 2: Your facility failed to produce documents verifying that the radiologic technologist, [redacted], met the general requirement of having 40 contact hours of training specific to mammography. See 21 CFR 900.12(a)(2)(ii), 900.12(a)(4), 900.12(d)(2).

Level 2: Some mammography reports did not include the required assessment category. See 21 CFR 900.12(c)(1)(iv).

Because the continued failure to resolve these violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- Requiring your facility to undergo an Additional Mammography Review
- Placing your facility under a Directed Plan of Correction
- Charging your facility for the cost of on-site monitoring
- Seeking 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
- Seeking to suspend or revoke your facility's FDA certificate

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

If you choose to respond to the above violations, your response should include:

1. The specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. The specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps; and

3. Sample records that demonstrate proper record keeping procedures. **Note: Patient names or other information that would likely reveal the patient's identity should be deleted from any copies of records you submit.**

Please submit your response to this letter to:

Thomas W. Garvin
Radiological Health Specialist
Food and Drug Administration
2675 N. Mayfair Road
Suite 200
Milwaukee, WI 53226-1305
Tel (414) 771-7167
Fax (414) 771-7512

Please send a copy of your response to:

Paul Schmidt
Chief, Radiation Protection Unit
State of Wisconsin
P.O. Box 2659
Madison, WI 53701-2659

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection of your facility 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/index.html.

If you have additional or more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Garvin at (414) 771-7167.

Sincerely yours,

W. Charles Becoat
Director
Minneapolis District