



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

PUNGED *PK*

December 4, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 14

Robert E. Drisner
President
Community Memorial Hospital
W180 N8085 Town Hall Road
Menomonee Falls, Wisconsin 53051

Dear Mr. Drisner:

On November 14, 2000, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA), inspected your facility (FDA certificate #107623). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), 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. Based on the documentation your site presented at the time of the inspection, the following Level 2 findings were documented at your facility. One item was a Repeat Non-Compliance.

Repeat Level 2 Non-Compliance:

1. Four of 6 randomly selected mammography medical reports lacked an approved "Assessment Category."

Level 2 Non-Compliances:

2. The written procedure for handling mammography consumer complaints was inadequate since it lacked all of the required elements.
3. Film processor QC records were missing three consecutive days of operation. (Processor =  = Darkroom)

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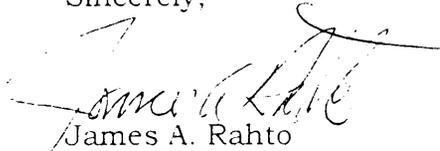
Robert E. Drisner
December 4, 2000

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

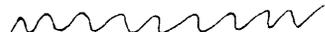
Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography 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/index.html>.

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,



James A. Rahto
Director
Minneapolis District

xc: 
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