DEPARTMENT OF HEALTH AND HUMAN SERVICES

93138

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

February 20, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 – 10

Ken Archer
Chief Executive Officer
Ortonville Area Health Services
750 Eastvold Avenue
Ortonville, Minnesota 56278

Dear Mr. Archer:

On January 15, 2003, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your mammography facility (FDA certificate #176578). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States law, the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, 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 following Repeat Level 2 finding was documented at your facility:

Repeat Level 2 Non-Compliance:

1. Ten of 10 random reports reviewed did not contain an acceptable mammography assessment category. Title 21, Code of Federal Regulations, Section 900.12(c)(1)(iv) specifies the official wording of mammography assessment categories.

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

The non-compliance is designated as a "repeat" because it was also cited during the previous (1/21/02) inspection. Your facility's Lead Interpreting Physician and

Radiology Manager were also alerted to this issue in a March 11, 2002, letter from FDA. Documentation collected during the inspection indicates that your staff conducted an in-house study entitled "~~~ code Performance Improvement Study for Radiology 2002." This study looked at a limited number of mammography reports each calendar quarter of 2002; it further documents a continuing problem.

FDA acknowledges the January 16, 2003, letter from Radiology Manager Barbara J. Gott.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may result in FDA taking 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 up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the MQSA standards; seeking a suspension or revocation of your facility's FDA certificate; or seeking a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

- 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; and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records. Patient names and 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 Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 No. 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,

W. Charles Becoat

W. Charles Becoat
Director
Minneapolis District

TWG/ccl

xc:

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