DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

g3495d

September 6, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 42

Terry Hoff
Chief Executive Officer
Trinity Breast Imaging Center - MAC Clinic
400 Burdick Expressway East
Minot, North Dakota 58701

Dear Mr. Hoff:

On July 25, 2002, a representative of the State of North Dakota, acting on behalf of the Food and Drug Administration (FDA), inspected your facility (FDA certificate #195008). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, and the Quality Standards for Mammography set forth in Title 21, Code of Federal Regulations, Part 900 (21 CFR 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.

Level 1 Non-Compliance:

Processor QC records in the month of December 2001 were missing for at least 30% of operating days for processor 0000000001, Other, Mammosuite room, at Trinity Breast Imaging Center—MAC Clinic site.

21 CFR 900.12(e)(1) states: Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and

density difference, using the mammography film used clinically at the facility.

Note: Your site was unable to document compliance with the processor QC regulations for the period July 2001 – December 2001. Reportedly Quality Control Charts and supporting test films were discarded at the end of the calendar year. Because your site lacks the appropriate documentation, it cannot be verified that this test was conducted (or if it was conducted, that the test results were acted upon accordingly).

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

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law that may result in FDA imposing regulatory sanctions. These sanctions include, but are not limited to, placing your facility under a Directed Plan of Correction and/or charging your facility for the cost of on-site monitoring. Failure to correct these violations promptly may also cause FDA to seek 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, suspension or revocation of your facility's FDA certificate, or a court injunction against performing further mammography [see 42 U.S.C. §§ 263b(h) through (j) of the MQSA].

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;
- please provide sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records (patient names or identification should be deleted from any copies submitted).

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,

David R. Yost
Acting Director
Minneapolis District

TWG/ccl

xc: M.D.
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