



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

July 7, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 42

Dr. Terence R. Pladson
Administrator
CentraCare Clinic
1200 North Sixth Avenue
St. Cloud, Minnesota 56303

Dear Dr. Pladson:

On June 1, 2000, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your facility, CentraCare Clinic—Women and Children's Health Center, at 1520 Northway Drive, St. Cloud, MN 56303. This inspection (ID # 1474050005) revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, 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 1 finding was documented at your facility:

Level 1 Non-Compliance:

The system to communicate results was not adequate for the CentraCare Clinic—Women and Children's Health Center because there was no system in place to provide timely lay summaries to all mammography patients. Note: This is a federal requirement specifically mandated by the Mammography Quality Standards Reauthorization Act (MQSRA).

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

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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 which may result in FDA taking regulatory action without further notice to you. 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, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

FDA acknowledges that Nancy Williams, RTM, from your site responded to the Level 1 non-compliance via a letter dated June 27, 2000. Her letter and supporting attachments have been reviewed. Based on her letter, patients with assessment levels of "Incomplete—Needs additional imaging evaluation," or "Suspicious," or "Highly Suspicious" are "...given a copy of the incomplete/abnormal letter when they come in for their additional imaging at the Breast Center." This is acceptable if the patient receives the letter within 30 days of the original mammogram; it is unclear if this is your policy. Further, her letter did not address the situation where the patient's assessment category is one of the three she references (see above), and then the patient chooses either not to have additional follow-up done, or chooses to have the follow-up at a site other than your Breast Center.

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;
- include a copy of your written policy (SOP) if one exists for patient notification.

Please submit your response to Radiological Health Specialist Thomas W. Garvin, FDA, 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>.

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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 x 12.

Sincerely,



James A. Rahto
Director
Minneapolis District

TGP/ccl

xc: Nancy Williams, RTM
CentraCare Clinic—Women's and Children's
Health Center
1520 Northway Drive
St. Cloud, MN 56303

Sue McClanahan
Supervisor, Section of Radiation Control
Minnesota Department of Health
P.O. Box 64975
St. Paul, MN 55164-0975

Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
Standards/Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, VA 20191