



PURGED R7K

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

December 21, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 17

Susan M. Henkel
Executive Vice President
St. Mary's Center for Women's Health
2315 North Lake Drive, Suite 909
Milwaukee, Wisconsin 53211

Dear Ms. Henkel:

On December 7, 2000, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA), inspected your facility (FDA certificate no. 154765). 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, 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 and Repeat Level 2 findings were documented at your facility:

Repeat Level 2 Non-Compliance:

1. Two of 9 randomly selected mammography reports reviewed did not contain an approved assessment category.

The mammography regulation mandates specific wording for the mammography assessments. FDA, by policy, has approved some additional variants of the official wording. The approved wording was discussed with your site and is also available on the Internet site referenced below. This was also cited during the 1999 inspection.

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Level 2 Non-Compliances:

2. Based on the documentation supplied by your site, Interpreting Physicians  and  do not meet the continuing education requirement of having earned 15 mammography-related CME in the past 36 months.

Individuals failing to meet either the "Initial" and/or "Continuing" MQSA requirements must immediately cease performing mammography independently. Requirements for re-qualification are listed in the Final Regulation that became effective on April 28, 1999. Conditions for Direct Supervision of unqualified personnel are specified in regulation and formal FDA policy. Policy references may be found at the Internet address below.

The specific problems 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 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.

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;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

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.

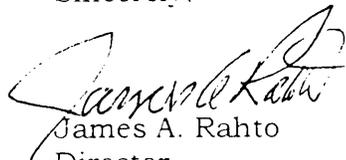
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Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general 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

TWG/ccl

PS
xc:


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