

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

October 31, 2000

**WARNING LETTER****CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 01 - 08

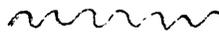
Jeffrey K. Jenkins  
Chief Executive Officer  
St. Michael's Hospital  
2400 W. Villard Avenue  
Milwaukee, Wisconsin 53209

Dear Mr. Jenkins:

On October 12, 2000, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA), inspected your facility (FDA certificate #140194). 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 repeat Level 2 findings were documented at your facility:

**Repeat Level 2 Non-Compliances:**

1. Corrective actions for processor QC failures were not documented at least once for the mammography film processor (  or ; mammography darkroom).
2. Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for your  mammography system (unit #3, room =  ).
3. One of 6 random reports reviewed did not contain a mammography assessment category.

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

Page Two

Jeffrey K. Jenkins  
October 31, 2000

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:

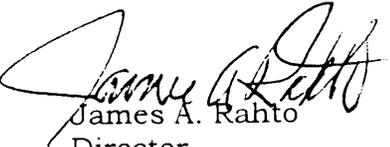
- The specific steps you have taken to correct all of the violations noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- Sample 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.

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, FDA, 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>.

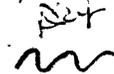
If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

  
James A. Rahto  
Director  
Minneapolis District

TWG/ccl

xc:

  
Lead Interpreting Radiologist  
St. Michael's Hospital  
2400 W. Villard Ave.  
Milwaukee, WI 53209

Paul Schmidt  
Chief, Radiation Protection Unit  
State of Wisconsin  
P.O. Box 2659  
Madison, WI 53701-2659

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