



g1630d

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

August 16, 2001

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 01 - 70

John Strange  
Facility Administrator, Radiology Department  
St. Luke's Hospital  
915 East First Street  
Duluth, Minnesota 55805

Dear Mr. Strange:

We are writing to you because on August 9, 2001, your facility (Chequamegon Clinic - A St. Luke's Clinic, 514 Ellis Avenue, Ashland, WI 54806) was inspected by a representative of the State of Wisconsin acting on behalf of the Food and Drug Administration (FDA). 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.

The inspection revealed the following Repeat Level 2 finding at your facility:

**Repeat Level 2 Non-Compliance**

1. Your facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required.

The specific problem noted above appeared on your MQSA Facility Inspection Report (copy enclosed) which your facility personnel received at the close of the inspection. This problem is identified as a Repeat Level 2 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent corrective action of this problem found during your previous inspection.

Page Two

John Strange  
August 16, 2001

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to your personnel at the close of the inspection. This Level 2 finding is:

1. The medical physicist's survey for X-ray Unit 2,  , is incomplete because the following tests were inadequate or not done: Numerical results were not given for both targets for AEC performance capability.

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, MQSA 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. (Note: Patient names or identification should be deleted from any submitted copies.)

Please submit your response to Thomas P. Nelson, Compliance Officer, at the address indicated on the letterhead.

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>.

Page Three

John Strange  
August 16, 2001

If you have more specific questions about mammography facility requirements or about the content of this letter please feel free to contact Mr. Nelson at (612) 334-4100 ext. 177.

Sincerely,

  
James A. Rahto  
Director  
Minneapolis District

TPN/ccl  
ES

Enclosure: Facility Inspection Report, 8/9/01

xc: Mark Bunge  
Supervisor, Radiation Protection Unit  
Bureau of Public Health  
Department of Health & Family Services  
P.O. Box 309  
Madison, WI 53701-0309

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