



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M3186n

**PURGED**

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

November 8, 1999

cc: HFI-35  
DWA

**WARNING LETTER**

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

Refer to MIN 00 - 07

Daniel Will  
Administrator  
Zumbrota Health Care  
383 W. Fifth Street  
Zumbrota, Minnesota 55992

Dear Mr. Will:

On November 2, 1999, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection (ID - 1792910006) 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 Level 1 and Level 2 findings were documented at your facility.

Level 1 Non-Compliance:

1. The system to communicate lay results to patients, in written form, was not adequate. The system did not include letters to all patients within 30 days regardless of the assessment level. This requirement includes the category "Incomplete: Need additional imaging evaluation."

Level 2 Non-Compliance:

1. Five of 5 randomly selected reports did not contain an official assessment category; use of the Bi-Rads number by itself is not sufficient.

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

Page Two

Daniel Will  
November 8, 1999

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, 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>.

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

Sincerely,

  
James A. Rahto  
Director  
Minneapolis District

TWG/ccl

xc:   
Lead Interpreting Physician  
Zumbrota Health Care  
383 W. Fifth Street  
Zumbrota, Minnesota 55992

Pamela A. Wilcox-Buchalla  
Director, Accreditation Programs  
American College of Radiology  
1891 Preston White Drive  
Reston, Virginia 22091

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