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

March 30, 2001

**WARNING LETTER**

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

Refer to MIN 01 - 46

Ronald Harman  
Administrator  
Albert Lea Medical Center—Mayo Health System  
404 Fountain Street  
Albert Lea, Minnesota 56007

Dear Mr. Harman:

On March 5, 2001, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your facility (FDA Certificate #166231). 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 non-compliances were documented at your facility:

**Repeat Level 2 Non-compliance:**

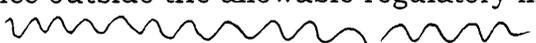
1. One of six random mammography reports reviewed did not contain an acceptable assessment category. A listing of the official and approved alternate wording for assessment categories is enclosed.

~~~~~ R.T. (R)(M), former Radiology Manager, indicated in a May 2, 2000, letter to FDA that this issue had been resolved. It appears that conclusion was inaccurate. Because of the repeat nature of this non-compliance, your corrective action should include a check and balance system to prevent further recurrence of this issue.

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Level 2 Non-compliance:

2. Failure to document corrective action(s) before conducting further clinical exams, for a failing phantom image score, or a phantom background optical density, or density difference outside the allowable regulatory limits.  
Mammography system = , Room = 3;  
ACR unit designation = 2.

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 No. 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 ext. 12.

Sincerely,

  
Cheryl A. Bigham  
Acting Director  
Minneapolis District

TWG/ccl

  
Enclosure

xc:   
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