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

April 12, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 51

Steve Nockerts
Chief Executive Officer
Adams County Memorial Hospital
402 West Lake Street
Friendship, Wisconsin 53934

Dear Mr. Nockerts:

On March 30, 2001, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA), inspected your facility (FDA Certificate #176594). 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, this non-compliance was documented at your facility:

Repeat Level 2 Non-Compliance:

1. 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.

Note: In a letter postmarked April 2, 2001, [redacted] of your staff indicated that the failing phantom QC tests were due to a malfunctioning [redacted] x-ray system. In a service report dated September 27, 2000, [redacted] recommended a [redacted]. On November 20, 2000, your medical

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physicist evaluated the system's exposure control. Your site continued to use the system until it was replaced in February 2001.

This non-compliance was also cited during the previous inspection on February 28, 2000.

The evaluation of the phantom's quality is a mandatory weekly test. If the test indicates that the system is not within regulatory limits, mammography must cease until the problem is corrected. The corrective action(s) need(s) to be documented.

The cited non-compliance is not due to the fact that your mammography system exceeded control limits. Rather, it is due to the fact that your site's QC testing indicated that control limits were exceeded and your site continued to perform mammography.

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

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents 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.

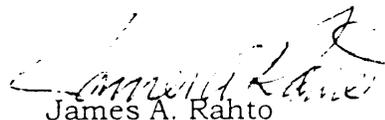
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Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general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



xc:



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