DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 29, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 – 02

Ronald J. Volk
Chief Executive Officer
St. Aloisius Medical Center
325 Brewster Street
Harvey, North Dakota 58341

Dear Mr. Volk:

On October 2, 2002, a representative of the State of North Dakota inspected your mammography facility (FDA certificate #185850) on behalf of the Food and Drug Administration (FDA). The inspector found violations of the Mammography Quality Standards Act of 1992 (MQSA), as amended, 42 U.S.C. § 263b, and implementing regulations promulgated by FDA, 21 C.F.R. Part 900. These violations are described in a Facility Inspection Report (FIR), a copy of which the inspector provided to your facility at the end of the inspection.

Level 1 Finding

The inspector found that your facility was unable to provide records demonstrating that your [redacted], located in the x-ray room, had been subjected to the daily quality control testing required by FDA regulations. 21 C.F.R. § 900.12(d)(2), (e)(1). Records were missing for six of the 16 days in July 2002 in which this processor was used to process clinical films.

This is Level 1 finding. Under FDA's three-tiered system for classifying MQSA inspection findings, Level 1 findings are the most serious. They indicate a failure to meet a key MQSA requirement that seriously threatens the quality of mammography services performed at a facility. FDA focuses its enforcement resources on facilities with Level 1 findings.

Level 2 Findings

The inspection also revealed two Level 2 violations, the first of which remains uncorrected since your last inspection. Level 2 findings indicate violations of other significant mammography quality requirements.

1. Your [redacted] mammography unit, located in your mammography room (ACR unit designation = 1) had weekly quality control test scores outside the appropriate action limits, but the inspector found no documentation that corrective action required by FDA regulations, 21 C.F.R. § 900.12(e)(8), was implemented before the unit was used for further exams.

2. Quality control records required by FDA regulations, 21 C.F.R. § 900.12(d)(2), were missing for three consecutive days for your facility's [redacted] mammography film processor, located in the x-ray room.

FDA has legal authority to take action against your facility to assure compliance with the MQSA and FDA's implementing regulations. The MQSA authorizes FDA to impose one or more sanctions on mammography facilities found to be out of compliance. These sanctions include directed plans of correction, payment for the cost of onsite monitoring, patient notification, civil money penalties, suspension or revocation of a facility's mammography certificate and injunctive relief. 42 U.S.C. § 263b(h)-(j). FDA is also authorized to require a mammography facility to provide information for review by an entity designated by the agency to help determine whether the facility is in compliance with Part 900.21 C.F.R. § 900.12(j). This is known as "additional mammography review."

You should immediately address the findings from your facility's October 2, 2002, inspection. Please describe to this office in writing within 15 working days from the date you receive this letter (1) the specific steps you have taken to correct the violations, and (2) each step your facility is taking to prevent the recurrence of these violations. Please include with your response examples of records demonstrating that your facility has corrected the record keeping violations described above. Please assure that the records you submit do not bear patient names or other patient identifiers.

This letter only concerns the findings of your October 2, 2002, inspection. It does not address other obligations you have under the MQSA or any other federal law. Nor does it address state law requirements. Nothing in the MQSA or FDA regulations precludes a State from enforcing its own mammography laws and regulations, which may be more stringent than the MQSA. When you plan your corrective actions, therefore, you should consider not only the MQSA, but also any applicable state requirements. You may choose to address both the MQSA and state requirements in your response.

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

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; *http://www.fda.gov/cdrh/mammography*). If you have any questions regarding this letter or how to ensure that you are meeting MQSA standards, please phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

Annette Byrne
Acting Director
Minneapolis District

TGP
TWG/ccl

xc: [redacted]
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