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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

August 19, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 32

Curt Hohman
Interim Administrator
Avera Gregory Healthcare Center
400 Park Avenue
Gregory, South Dakota 57533

Dear Mr. Hohman:

On July 15, 2003, a representative of the State of South Dakota, acting on behalf of the Food and Drug Administration (FDA), inspected your mammography facility (FDA certificate #114892). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States law, the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, 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 finding was documented at your facility:

Level 1 Non-Compliance:

> Radiologic technologist ~~~~ does not meet the initial requirement of holding either a valid state license or a valid certificate from an FDA-approved body.
>
> Title 21, Code of Federal Regulations, § 900.12(a)(2)(i-ii), define the *initial* qualifications for radiologic technologists performing mammography. Individuals failing to meet either the "Initial" and/or "Continuing" MQSA requirements must immediately cease performing 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.

This condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, and it represents a serious violation of the law that may result in FDA taking regulatory action. 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, seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the MQSA standards, seeking a suspension or revocation of your facility's FDA certificate, or seeking 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 N. Mayfair Road, Suite 200, Milwaukee, Wisconsin 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, Maryland 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,

W. Charles Becoat
Director
Minneapolis District