



5/17/98
T1756M

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

PURGED BK

cc: HFI-35/FOI Staff
DWA

April 29, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 20

Robert Salmon
Administrator
Canby Community Health Services
112 St. Olaf Avenue South
Canby, Minnesota 56220

Dear Mr. Salmon:

Your mammography facility (MQSA #176768) was inspected on April 14, 1998, by a representative of the State of Minnesota acting on behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows below.

Your staff has been unable to supply the following mandatory documentation regarding your site's mammography personnel:

1. Documentation that interpreting physician [REDACTED] was licensed by a State to practice medicine.
2. Documentation that radiologic technologist [REDACTED] met the requirement of being either licensed by a State, or board-certified by any of the approved boards.

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The above items were listed as Level 1 non-compliances in the "MQSA Facility Inspection Report" which was supplied to your site at the conclusion of the inspection. It is our understanding that neither of the above individuals is currently employed by your site. This highlights the importance of obtaining proper mammography credentials prior to an employee being allowed to practice mammography at your site.

In addition to the above, the following Level 3 non-compliances were observed:

3. Processor QC--corrective actions for processor (QC) failures were not documented on at least one occasion [REDACTED] M35 or M35A-M Room ID=Darkroom).
4. Mammograms were processed at least once with the medium density or density difference or base+fog out of control [REDACTED] M35 or M35A-M Room ID=Darkroom.
5. Documentation was missing to show that corrective action(s) were taken when called for in the medical physicist's survey report.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- * impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- * suspend or revoke a facility's FDA certificate for failure to comply with the Standards.

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* seek an injunction in Federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all of the Level 1 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 non-compliances that were found relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

Tom Garvin
Radiological Health Specialist
Food and Drug Administration
2675 N. Mayfair Road, Suite 200
Milwaukee, WI 53226-1305

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Also, send a copy of your response to the state radiation control office that conducted the inspection (address below).

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Tom Garvin at (414)771-7167, ext. 12.

Sincerely,


James A. Rahto
Director
Minneapolis District

TWG/ccl

xc: Judith A. Ball
Manager, Section of Radiation Control
Minnesota Department of Health
P.O. Box 64975
St. Paul, MN 55164-0975