



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1164B

PURGED

February 5, 1997

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

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-33

John Frobenius
Chief Executive Officer
St. Cloud Hospital
1406 Sixth Avenue North
Saint Cloud, Minnesota 56303

Dear Mr. Frobenius:

Your mammography facilities (fixed site plus 2 mobile vans) bearing FDA certification numbers 206052, 138131, and 138149 were inspected on January 24, 1997. The inspections were conducted by a representative of the State of Minnesota acting on behalf of the Food and Drug Administration (FDA). The inspections 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:

- A x-ray technologist at your site has been performing mammography exams since Autumn 1996. Based on inspectional evidence, she does not meet the minimum personnel requirements for mammography technologists since she is neither state licensed nor Board Certified.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Reports which were issued at the close of the inspections. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

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It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA 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;
- * 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 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 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

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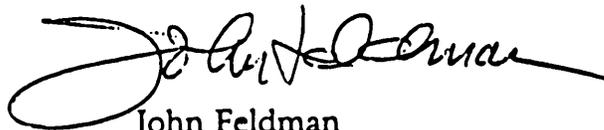
- sample records that demonstrate proper record keeping procedures, if the non-compliances that were found relate to quality control or other records (Note: patient names or identification should be deleted from any copies submitted).

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, Milwaukee, WI 53226-1305. Also, send a copy to the State radiation control office that conducted the inspection (address is referenced at the end of this letter).

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 yours,



John Feldman
Director
Minneapolis District

TPG/ccl

xc: Jean Rogers, R.T.(M)
Mammography Supervisor,
St. Cloud Hospital
1406 Sixth Avenue North
Saint Cloud, MN 56303

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