



PURGED *RAX*

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

June 2, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 -34

David Bertrand
Administrator,
Minneapolis Medical Arts Clinic
825 Nicollet Mall, Suite 300
Minneapolis, Minnesota 55402

Dear Mr. Bertrand:

Your mammography facility (MQSA certificate #215640) was inspected on May 7, 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, Part 900.12 (21 CFR 900.12).

It is FDA's expectation that all personnel records will be available at the time of inspection for review. Despite being given an opportunity to supply the missing documentation to the inspector following the close of the inspection, your site submitted none. Consequently the following Level 1 and Level 2 non-compliances are cited:

Level 1

1. Your site lacked documentation that these interpreting physicians meet the requirement of being licensed by a State to practice medicine: ~~_____~~

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- [REDACTED]
2. Your site lacked documentation the these interpreting physicians meet the requirement of being board certified by any of the approved boards or having two months full-time training in the interpretation of mammograms:
[REDACTED]

Level 2

3. Your site lacked documentation that these interpreting physicians meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a three year period (an average of five credits/year): [REDACTED]
4. These interpreting physicians did not meet the initial training requirement of having 40 hours of continuing medical education in mammography:
[REDACTED]
5. These interpreting physicians did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in six months: [REDACTED]

Level 3

Measured darkroom fog exceeded 0.05. (The measured fog level was 0.09.)

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:

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- 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 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 and Level 2 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.

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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

Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Mr. 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
MN Department of Health
P.O. Box 64975
St. Paul, MN 55164-0975