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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
T1397M

Refer to: CFN 1124228
af-BLT-33

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4099

January 21, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Julie Trueman, Administrator
The Washington Clinic
5401 Western Avenue, N.W.
Washington, DC 20015

RE: Inspection ID #1430650003

Dear Ms. Trueman:

Your facility was inspected on November 19, 1997, by a representative from the District of Columbia's Radiological Health Program under contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards), as specified in Title 21, Code of Federal Regulations, Part 900.12, as follows:

The interpreting physician, [REDACTED] did not 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. Please submit documentation of [REDACTED] board certification or two months training. If [REDACTED] does not have documentation of either of these requirements, he must cease performing mammography immediately.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility. Also, the following Level 2 findings should be addressed in your response to this letter:

The interpreting physicians, [REDACTED] did not meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a 3-year period (an average of 5 credits/year) . Please submit documentation of each physicians' continuing education credits earned from the period of October 1994 to

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November 1997. If the radiologists have not accumulated 15 credits in mammography over the last three years, please inform us of this. Radiologists not meeting this requirement have three months after the close of the inspection to meet this requirement before further regulatory action is taken.

The interpreting physician, [REDACTED], did not meet the initial training requirement of having 40 hours of continuing medical education in mammography. Please submit documentation of this training to us with your response. If [REDACTED] did receive such training prior to October 1, 1994, he can attest to the training. If the training was received after October 1, 1994, he must submit documentation (e.g. certificates or letters) of the training.

The interpreting physician, [REDACTED], did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months. There was no evidence present at the time of your MQSA inspection sufficient to prove that [REDACTED] met this requirement. If he did read the required mammograms prior to October 1, 1994, he can attest to meeting the requirement. If the films were read after October 1, 1994, he must submit a letter from the radiologist who directly supervised the reading or from the residency program in which he participated.

The radiologic technologist, [REDACTED], did not meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a 3 year period (an average of 5 credits/year). Please submit documentation of continuing education credits earned from the period of October 1994 to November 1997 by [REDACTED]. If she has not accumulated 15 credits in mammography over the last three years, please inform us of this. Technologists not meeting this requirement have three months after the close of the inspection to meet this requirement before further regulatory action is taken.

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 identified, and promptly initiating permanent corrective actions.

If you fail to promptly correct the 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, 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
- Sample records that demonstrate proper record keeping procedures, if the noncompliances 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 the Food and Drug Administration, Richmond Resident Post, Suite 424, 10710 Midlothian Turnpike, Richmond, Virginia 23235, Attn: Scott J. MacIntire, Compliance Officer. 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 Elizabeth Laudig at (410) 962-3591.

Sincerely yours,


Elaine Knowles Cole
District Director