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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1124242

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

December 19, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Margaret Wallace, Manager
Ambulatory Radiology Services
Washington Hospital Center
106 Irving Street, N.W.
Washington, DC 20010

Inspection ID #1457710003

Dear Ms. Wallace:

Your facility was inspected on November 17, 1997 by representatives of the Food and Drug Administration (FDA) and the District of Columbia's Radiological Health Program. 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:

Patient films were processed when the processor density difference points were out of specification, for periods of up to two and one-half weeks. Adequate documentation must be provided to ensure that patient films will not be processed when the processor is out of specifications. A standard operating procedure should be implemented so this does not recur.

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 have not been addressed or have been addressed inadequately by your facility:

[REDACTED] did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months. The documentation provided to the inspectors revealed

that [REDACTED] interpreted only 906 patient mammograms over a 24 month period. [REDACTED] must cease doing mammography until either of the following criteria is met:

- 1) Interpret mammograms under the direct supervision of a qualified radiologist to increase to 240 patients in a 6-month period,

or

- 2) Interpret mammograms under the direct supervision of a qualified radiologist so that [REDACTED] average patient exams are at the minimum of 40 per month.

[REDACTED] did not have specific training in mammography. [REDACTED] must immediately cease doing independent mammography. If training was received after October 1, 1994, she must submit documentation of the training from the training facility (e.g., certificates or letters).

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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'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 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.

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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 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. 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 Lori A. Holmquist at (410) 962-3591.

Sincerely yours,



Elaine Knowles Cole
District Director

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cc: Pharmaceutical, Radiological and
Medical Device Control Division
Department of Consumer and Regulatory Affairs
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Washington, DC 20001

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