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M 353N, PdA

DEPARTMENT OF HEALTH & HUMAN SERVICES

10/29/97
Public Health Service
Food and Drug Administration

Refer to: CFN# 1124407

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

October 16, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mount Vernon Medical Group
9502 Richmond Highway
Lorton, Virginia 22079
Attn: Cortney Dumas Bradshaw

Inspection ID #1732450004

Dear Ms. Bradshaw:

Your facility was inspected on September 29, 1997, by a representative from the Commonwealth of Virginia, Bureau of Radiological Health, 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:

Technologist [REDACTED] did not meet the requirement of being licensed by a state or board certified by either the American Registry of Radiologic Technologists (ARRT), or the America Registry of Clinical Radiography Technologists (ARCRT). An ARRT card was faxed to the State inspector on October 7, 1997, but the card had expired March 1997.

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.

There were also several Level 2 findings which will need to be addressed in your response. They are as follows:

- 1. Records for repeat analysis were not present.**
Repeat analysis was not performed for a period of 1 year.
- 2. Processor QC; 62 percent of the data points for either medium density (MD), density difference (DD), or base plus fog (BF) were missing (month of June)....**

3. Radiologist Technologist [REDACTED] did not meet the requirement for specific training in mammography.

There was no documentation presented which proved that Technologist [REDACTED] received training in mammography.

The Level 3 observation listed on your report does not need to be addressed in writing, but correction needs to be made as soon as possible.

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.
- 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.
- Sample records that demonstrate proper record keeping procedures. (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 Office. 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

cc: Bureau of Radiological Health
Division of Health Hazards Control
Department of Health
Main Street Station
1500 East Main, Room 104A
Richmond, VA 23219