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**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

**BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202**

August 7, 1997

WARNING LETTER BUF 97-22

Paul Vervalin
Administrative Director
Guthrie Medical Group
1780 Henshaw Road
Ithaca, NY 14850

Facility ID #115097

Dear Mr. Vervalin:

Your facility was inspected on July 17, 1997 by a representative of the State of New York acting in behalf of the Food and Drug Administration (FDA). This inspection revealed 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:

1. The interpreting physician did not meet the requirement of being licensed by a State to practice medicine: [REDACTED]
2. The interpreting physician did not meet the requirement of being licensed by a State to practice medicine: [REDACTED]
3. The interpreting physician did not meet the requirement of being licensed by a State to practice medicine: [REDACTED]
4. The interpreting physician 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: [REDACTED]

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliances which were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliances are:



5. The interpreting physician 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: [REDACTED]
6. The interpreting physician 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: [REDACTED]
7. The interpreting physician 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: [REDACTED]
8. The interpreting physician 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: [REDACTED]
9. The interpreting physician did not meet the initial training requirement of having 40 hours of continuing medical education in mammography: [REDACTED]
10. The interpreting physician did not meet the initial training requirement of having 40 hours of continuing medical education in mammography: [REDACTED]
11. The interpreting physician did not meet the initial training requirement of having 40 hours of continuing medical education in mammography: [REDACTED]
12. The interpreting physician did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months: [REDACTED]
13. The interpreting physician did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months: [REDACTED]
14. The interpreting physician did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months: [REDACTED]

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:

- 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 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 recordkeeping 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 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 Thomas J. Beras, Consumer Safety Officer, Food and Drug Administration, 599 Delaware Avenue, Buffalo, NY 14202. Also send a copy to the State radiation control office which 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 Thomas J. Beras at (716) 551-4461 ext. 3169.

Sincerely yours,



for Brenda Holman
District Director

cc: Gerald O'Connor
NYS Dept. of Health
2 Univerity Place
Albany, NY 12203-3313

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