



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

Food & Drug Administration  
Olympic Towers, Suite 100  
300 Pearl Street  
Buffalo, NY 14202

June 26, 1998

**WARNING LETTER BUF 98-9**

**PROPERTY OF THE UNITED STATES FOOD & DRUG ADMINISTRATION**

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Anthony Marmo, CEO  
Kingston Hospital  
Medical Arts Building  
368 Broadway  
Kingston, New York 12401

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Re: Facility I. D. Number 119503

Dear Mr. Marmo:

Your facility was inspected on June 15, 1998 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:

*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] [21 CFR 900.12(a)(1)(ii)]*

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued to your facility 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.

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 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;

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- **suspend or revoke a facility's FDA's 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 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.

You should submit documentation demonstrating the interpreting physician either certified by one of the bodies approved by FDA, or has had at least two months of documented training in the interpretation of mammograms.

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:

Lillian C. Aveta, Compliance Officer  
Food and Drug Administration  
850 Third Avenue  
Brooklyn, New York 11232-1593.

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.

Sincerely,



Brenda J. Holman  
District Director

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bcc: Facility file (1319902)  
HFR-NE140 (L. Aveta)  
HFR-NE1500 (M. Kurzman)  
HFR-NE19 (R. Bernacki)  
HFA-224  
HFC-230  
HFC-240  
HFI-35 (redacted copy for public display)  
HFZ-240  
HFZ-322

Mr. Gerald O'Connor  
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