



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

114902n

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

WARNING LETTER NYK 2001-27

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

November 29, 2000

Mary LaRowe, President/CEO  
Westfield Memorial Hospital  
189 East Main Street  
Westfield, NY 14787

Facility ID: 146571

Dear Ms. LaRowe:

Your facility was inspected on November 14, 2000 by a representative of the New York State Department of Health, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

- *Mammograms were processed in [REDACTED] processor, [REDACTED] or [REDACTED], located in the MAMMO room at your facility, when the processor was out of limits on 12 days on January 4, 5 & 6, 2000; July 21, 2000; and November 1, 2, 3, 5, 8, 9, 10 & 13.*

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

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It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 (fifteen) working days from the date you receive this letter:

- *The specific steps you have taken to correct the Level 1 violation noted in this letter; and*
- *Each step your facility is taking to prevent the recurrence of similar violations*

Please submit your response to the attention of Patricia A. Clark, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, NY 14202, Telephone 716-551-4461, ext. 3165.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057, Telephone 1-800-838-7715, or through the internet at <http://www.fda.gov>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'E. W. Thomas', with a long horizontal flourish extending to the right.

Edward W. Thomas  
Acting District Director  
New York District