



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

January 8, 2003

WARNING LETTER NYK 2003-12

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Lynn M. Duttinger  
Director, Radiology Services  
North Medical Family Physicians, P.C.  
5100 West Taft Road, Suite 10  
Liverpool, New York 13088

RE: Facility ID Number 127696

Dear Ms. Duttinger:

A representative of the New York State Department of Health, acting on behalf of the United States Food and Drug Administration (FDA), conducted an inspection of your facility on December 19, 2002. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, 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 the [REDACTED] processor when it was out of limits on at least five days. Mammograms were processed on April 29 and 30 and May 6, 7, 8, and 9, 2002 when the processor was out of limits (see 21 C.F.R. 900.12(e)(8)(ii)(A)).*

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.

This condition 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 fifteen (15) working days from the date that you receive this letter each step your facility is taking to correct this violation and to prevent the recurrence of similar violations.

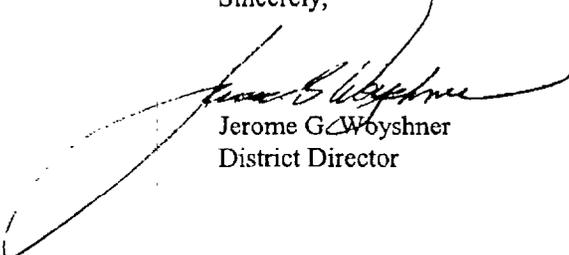
In addition, your response should address the Level 2 observations listed on the inspection report. The Level 2 observations noted include the following:

- *Failure to document corrective actions at least once for processor QC failures for the [REDACTED] processor (see 900.12(e)(8)(ii)).*
- *The time period between the previous and the current survey for the [REDACTED] x-ray unit 2 exceeds 14 months (see 21 CFR 900.12(e)(9)).*

Please submit your response to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, NY 14202, telephone (716) 551-4461 ext. 3117.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your 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, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

Sincerely,



Jerome G. Woyshner  
District Director

cc: Priscilla F. Butler, M.S.  
Director, Breast Imaging Accreditation Programs  
Standards and Accreditation Program  
American College of Radiology  
1891 Preston White Drive  
Reston, VA 22091

cc: Vidya Goyal  
New York State Department of Health  
Central NY Regional Office  
217 South Salina Street  
Syracuse, NY 13202