



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

February 22, 2002

WARNING LETTER NYK 2002-24

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Shirish K. Thanawala, M.D.  
Northeast Bronx Radiology and Mammography  
3117 Buhre Avenue  
Bronx, New York 10461

RE: Facility ID Number 174862

Dear Dr. Thanawala:

Your facility was inspected on January 22, 2002 by a representative of the New York City Department of Health, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed serious regulatory problems 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 and Repeat Level 2 findings at your facility:

- *The system to communicate results is inadequate because there is no system in place to provide timely medical reports and there is no system in place to provide timely lay summaries. (Level 1)*
- *Failure to produce documents verifying the interpreting physician, [REDACTED], met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months. (Repeat Level 2)*
- *Failure to produce documents verifying the interpreting physician, [REDACTED], met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months. (Repeat Level 2)*
- *Failure to produce documents verifying the interpreting physicians, [REDACTED], met the initial experience requirement of having interpreted or multi-read 240 mammograms in 6 months. (Repeat Level 2)*

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. These problems are identified as Level 1 and Repeat Level 2 because they identify a failure to meet significant MQSA requirements and they indicate a failure by your facility to implement permanent correction of problems found during your previous inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent violations 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.

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 these violations and to prevent the recurrence of similar violations. Your response should include documents necessary to demonstrate corrective actions.

In addition, your response should address the Level 2 and Repeat Level 3 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 and Repeat Level 3 findings are:

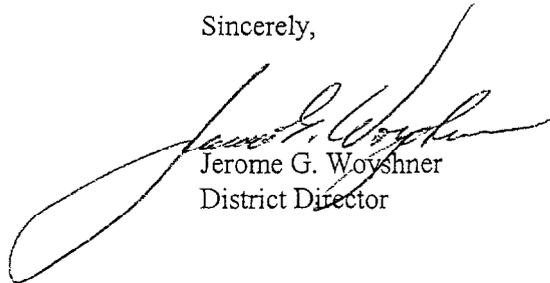
- *Processor QC records in the month of October 2001 were missing for at least 10% but less than 30% of the operating days for processor 1, [REDACTED]*
- *Phantom QC records were missing for the weeks of 9/29/01 and 10/16/01 for unit 1, [REDACTED]*
- *Failure to produce documents verifying the interpreting physician, [REDACTED], met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months.*
- *Failure to produce documents verifying the medical physicist, [REDACTED], met the continuing experience requirement of having surveyed at least 2 mammography facilities and a total of at least 6 mammography units in 24 months.*
- *Failure to conduct a medical audit and outcome analysis for the facility as a whole.*
- *Failure to conduct a medical audit and outcome analysis separately for each individual interpreting physician at the facility.*
- *Failure to conduct a medical audit and outcome analysis annually at the facility.*
- *Failure to enter all positive mammograms into a tracking system.*
- *Failure to have the required personnel qualification documents available during the inspection. (Repeat Level 3)*

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Please submit your response to the above issues 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

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