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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 2002-25

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Juan Yamin, M.D.
Medical Director
Diagnostic X-ray & Imaging, Inc.
37-28 75th Street
Jackson Heights, NY 11372

RE: Facility ID Number 175018

Dear Dr. Yamin:

Your facility was inspected on January 24, 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 finding at your facility:

- *Phantom QC records were missing for 4 weeks in December 2001 for unit 3, [REDACTED]*

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 a 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.

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. Your response should include documents necessary to demonstrate corrective actions.

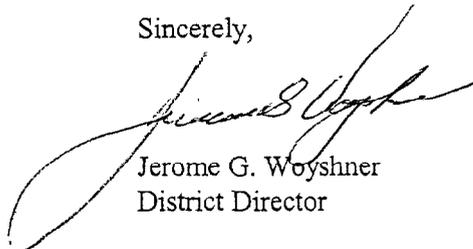
In addition, your response should address the Level 2 and Repeat Level 3 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 and Repeat Level 3 findings are:

- *Failure to specify adequate procedures for infection control or to follow procedures when required.*
- *Failure to conduct a performance verification test after each move for mobile unit 3, [REDACTED]*
- *The time period between the previous and current surveys for x-ray unit 3, [REDACTED] exceeds 14 months.*
- *Failure to produce documents verifying the radiologic technologist, [REDACTED] met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months.*
- *Failure to conduct a medical audit and outcome analysis separately for each individual interpreting physician at the facility.*
- *The chest wall edge of the compression paddle is visible on the test image for unit 3, [REDACTED] (Repeat Level 3)*

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