



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

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

February 8, 2000

WARNING LETTER NYK 2000-33

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Juan Yamin, M.D.
Diagnostic X-ray and Imaging
37-28 75th Street
Jackson Heights, New York 11372

RE: Facility ID Number 175018

Dear Dr. Yamin:

Your facilities located at 37-28 75th Street, Jackson Heights, New York and at Pelham X-ray, 2114 Williamsbridge Road, Bronx, New York were inspected on January 25 and 26, 2000, respectively, by a representative of the New York City Bureau of Radiological Health, acting in behalf of the Food and Drug Administration. These inspections revealed serious regulatory problems involving the mammography at your facilities.

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

- *Phantom QC records were missing for 12 weeks for the [REDACTED] unit at Pelham X-ray.*
- *The medical physicist [REDACTED] did not have a Masters degree or higher in a physical science, with 20 semester hours in physics.*

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued at the close of the inspections on January 27, 2000. These problems are identified as Level 1 because they identify failures to meet significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facilities, 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 facilities under a Directed Plan of Correction; charging your facilities 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; obtaining a court injunction against further mammography.

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

- *The [REDACTED] x-ray system located at Pelham X-ray does not include compression paddles for 2 sizes.*
- *The phantom image score (using an FDA-approved mammography phantom) was 3 fibers on one film and 3.5 fibers on a second film for the [REDACTED] unit at Pelham X-ray. The fiber score must be at least 4.0.*
- *The processing speed (using the STEP procedure) was 76 for standard processing for the [REDACTED] processor located at Pelham X-ray.*
- *Processor QC records were missing 2 out of 11 days of operation, or 18% of the time, in December 1999, for the [REDACTED] processor located at Pelham X-ray.*
- *Corrective action for a failing image score (before further exams) was not documented for the [REDACTED] unit located at Pelham X-ray.*

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

- 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;
- Equipment settings (including technical factors), raw test data, and sample records such as a phantom image film, and service reports, that demonstrate proper record keeping procedures and correction of problems.

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Please submit your response to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Olympic Towers, Suite 100, Buffalo, New York 14202.

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>.

If you have any questions about mammography facility requirements, you may contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely,



Brenda J. Holman
District Director

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