



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

January 4, 2001

REF: NYK-2001-34

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Kristin Johnston
Corporate Manager
Northeast Radiology
3630 Hill Boulevard
Jefferson Valley, NY 10535

Facility ID: 182618

Dear Ms. Johnston:

Your facility was inspected on December 12, 2000 by a representative of the New York State Department of Health, acting in behalf of the Food and Drug Administration. 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 findings at your facility:

- (1) Processor QC records were missing 100% of the time for the [REDACTED] processor [REDACTED] or [REDACTED] located in the darkroom during the month of July, 2000. There were no QC records for this processor for 21 out of 21 days of operation during this month.*
- (2) Processor QC records were missing on 62 consecutive days for the [REDACTED] processor, [REDACTED] or [REDACTED] located in the darkroom during the months immediately preceding August of 2000.*
- (3) Phantom QC records were missing for 32 weeks for the [REDACTED] unit #2 located in the Mammo Room during the months immediately preceding August of 2000.*

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 because they identify failures to meet significant MQSA requirements.

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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.

There was also a repeat Level 3 finding that was listed on the inspection report provided at the close of the inspection. This repeat finding was:

- *The darkroom fog QC is not adequate in that QC was not conducted during the year 2000 until August.*

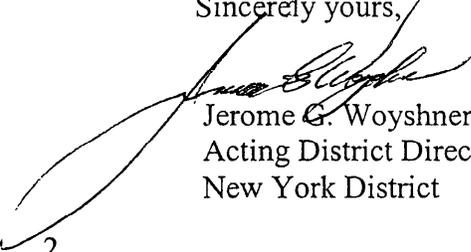
It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the violation noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; and
- sample records that demonstrate proper record keeping procedures.

Please submit your response to the above issues to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433.

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, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

Sincerely yours,



Jerome G. Woyshner
Acting District Director
New York District