DEPARTMENT OF HEALTH & HUMAN SERVICES 3407

New York District

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

June 26, 2002

WARNING LETTER NYK 2002-37

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Harvey Lefkowitz
Medical Director
Millennium Diagnostic Services
220 E. 161 Street
Bronx, New York 10451

RE: Facility ID Number 219030

Dear Mr. Lefkowitz:

Your facility was inspected on June 10, 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 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:

- ***Phantom quality control (QC) records were missing for at least four (4) weeks for unit [redacted] (see 21 C.F.R. 900.12(e)(2)).***

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 represents a failure to meet a significant MQSA requirement.

The following Level 2 observations, which were also noted on your MQSA Facility Inspection Report, were made during the inspection:

- ***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 (see 21 C.F.R. 900.12(a)(2)(iii)).***

- ***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 (see 21 C.F.R. 900.12(a)(2)(iii)).***

- ***Failure to produce documents verifying that the radiologic technologist, [redacted] met the continuing experience requirement of having performed 200 mammography examinations in 24 months (see 21 C.F.R. 900.12(a)(2)(iv)).***

- ***Failure to enter all positive mammograms into a tracking system (see 21 C.F.R. 900.12(f)(1)).***

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 that may result in FDA imposing regulatory action without informal 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, seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the MQSA standards, seeking suspension or revocation of your facility's FDA certificate, or seeking a court injunction against performing further mammography. (See 42 U.S.C. 263b(h)-(j)).

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 received this letter:

- the specific steps you have taken or will take to **correct** all of the violations noted in this letter, any reason that corrective action has not been taken, and the time within which any steps not yet taken will be complete;
- each step your facility is taking to **prevent the recurrence** of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- documentation showing that correction is complete including, if the findings relate to quality control or other records, sample records that demonstrate proper record keeping procedures **(Note: Patient names or identification should be deleted from any copies submitted)**.

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

cc: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Program
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