



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158 - 15 Liberty Avenue
Jamaica, New York 11433-1034

g1152d

WARNING LETTER

April 18, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-2001-58

Jose R. Rodriguez
Office Manager
Professional Health Imaging, P. C.
3802 14th Avenue
Brooklyn, New York 11218

Facility ID: #188920

Dear Mr. Rodriguez:

Your facility was inspected on March 28th, 2001 by a representative of the New York City Department of Health, Bureau of Radiological Health, acting on behalf of the U. S. Food & Drug Administration (FDA). This inspection revealed serious regulatory problems involving the mammography operation at your facility. Under a *United States Federal Law, the Mammography Quality Standards Act of 1992*, your facility must meet specific requirements for mammography operations. These requirements help protect the health of women by assuring that a facility can perform quality mammography procedures. This inspection revealed the following Level 1 noncompliance findings at your facility:

- 1. Processor QC records in the month of 11/2000 were missing for at least 30% of operating days for the Kodak processor in the mammography room.*
- 2. Processor QC records were missing at least five (5) consecutive days for the Kodak processor, in the mammography room.*
- 3. Phantom QC records were missing for at least four (4) weeks for unit #1, General Electric, Co. in the Senographe DMR mammography room.*
- 4. Failure to produce documents verifying that the Interpreting Physicians, Alan Berlly and David Rosenthal, met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having two (2) months of initial training in the interpretation of mammograms prior to 04/28/99.*

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These 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 noncompliances, because they identify a failure to meet significant MQSA requirements and indicate failure by your facility to implement permanent correction of problems found.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography operations 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 were also Level 2 noncompliance findings that were listed on the inspection report provided at the close of the inspection. These Level 2 noncompliance findings were:

1. *The measured fog density is equal to 0.13 for the darkroom at the site.*
2. *Failure to produce documents verifying that the Interpreting Physicians, [REDACTED] and [REDACTED], met the initial requirement of having forty (40) hours of medical education in mammography prior to 04/28/99.*
3. *Failure to produce documents verifying that the Interpreting Physician, [REDACTED], met the initial experience requirement of having interpreted or multi-read 240 mammograms in six (6) months.*
4. *Failure to produce documents verifying that the Radiologic Technologist, [REDACTED], met the continuing education requirement of having taught or completed at least fifteen (15) continuing education units in mammography in 36 months (0 CEU's in 36 months).*
5. *Failure to produce documents verifying that the Radiologic Technologist, [REDACTED], met the alternative initial requirement of having training specific to mammography under the interim regulations.*

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6. *One (1) of ten (10) random reports reviewed did not contain an acceptable assessment category for the site.*
7. *There is no designated audit (reviewing) interpreting physician for the site.*

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 Arthur S. Williams, Jr., Compliance Officer, U. S. Food & Drug Administration (FDA), 158 - 15 Liberty Avenue, Jamaica, New York 11433-1034, Tel.: (718)/662-5568.

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, U. S. Food and Drug Administration (FDA), P.O. Box 6057, Columbia, Maryland 21045-6057, Tel.: 1(800)/838-7715, or through the Internet at <http://www.fda.gov>.

Sincerely yours,



Edward W. Thomas
Acting District Director
New York District