



DEPARTMENT OF HEALTH & HUMAN SERVICES

M 23531
New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

January 28, 1999

REF: NYK-1999-24

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Earl Kabnick, M.D.
Director
Williamsbridge Imaging Associates
1957 Williamsbridge Road
Bronx, NY 10461

Facility ID: 199638

Dear Dr. Kabnick:

Your facility was inspected on December 21, 1998 by a representative of the New York City Bureau of Radiological Health, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem 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:

The number of fibrils scored in the phantom image was 2.5 and did not meet the required number. The minimum number required for fibrils is 4.

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 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.

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

1. The interpreting physician, [REDACTED], did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months. He failed to meet the continuing education requirement of having completed a minimum of 15 credits in mammography over a 3-year period (an average of 5 credits per year), and he did not meet the initial training requirement of having 40 hours of continuing medical education in mammography. In addition, Dr. [REDACTED] did not meet the requirement of having read and interpreted mammograms from the examination of at least 240 patients in six months.

2. The radiologic technologist, [REDACTED], did not have specific training in mammography.

The repeated Level 3 findings are:

1. The need for corrective action was indicated on the quality control (QC) records for the Screen Film Contact Test, but the execution of corrective actions was not documented on at least one occasion.

2. Corrective actions for phantom image failure were not documented on at least one occasion.

3. Documentation was missing from the quality assurance (QA) program. The missing QA items are: Personnel Responsibilities and the Technique Tables/Charts.

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 you received 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 technique factors), raw test data, and new phantom image, and

- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (**Note: Patient names or identification should be deleted from any copies submitted**).

Please submit your response to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232, Tel. (718) 340-7000, ext. 5142.

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>.

If you have questions about mammography facility requirements in general, please feel free to contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely yours,



Brenda J. Holman
District Director