



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *m24891*

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6007

June 8, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Morris Pilchik
President
Mammography Imaging Center, Inc.
40 Ferry Street
Newark, New Jersey 07105

FILE NO.: 98-NWJ-26
Inspection ID NO.: 199885004

Dear Mr. Pilchik:

A representative from the Food and Drug Administration (FDA) inspected your facility on March 18, 1999. On March 22, 1999, you notified this office that you were no longer providing mammography services. In a Facility Listing dated May 14, 1999, your facility was identified as being Provisionally Re-Instated to perform mammography services. The March 18, 1999 inspection revealed serious regulatory problems involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) 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. The interpreting physician, [REDACTED], did not meet the requirement of being certified by an FDA recognized board, or having the alternative of 2 months training in the interpretation of mammograms.
2. Processor Quality Control charts were missing 18 out of [REDACTED] days of operation in June 1998. Processor charts were missing [REDACTED] for the processor in the darkroom at Mammography Imaging Center.

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 significant MQSA requirements.

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 repeat Level 3 noncompliances that are listed on the inspection report (copy enclosed). These Level 2 and repeat Level 3 noncompliances are:

3. Processor QC charts were missing 21 consecutive days for processor 1, room darkroom at site Mammography Imaging Center, Inc.
4. The interpreting physician, [REDACTED] did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6 month period).
5. The interpreting physician, [REDACTED] did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36-month period.
6. The interpreting physician, [REDACTED], did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.
7. The interpreting physician, [REDACTED] did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.

8. The medical physicist, [REDACTED] did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36-month period.
9. Phantom QC records were missing for at least one month but less than 3 months for Unit 1, [REDACTED]

The following Level 3 items were also identified:

10. The chest wall side of the x-ray field extends beyond the chest wall edge of the image receptor by more than 2% of the SID for Unit 1, [REDACTED]
11. The fixer retention QC is not adequate for the processor at Mammography Imaging Center, Inc. The missing or incomplete item(s) are listed below:
 - The fixer retention QC records were incomplete.
12. The phantom QC is not adequate for Unit 1, [REDACTED] because:
 - The operating level for background density was < 1.00;
 - The image scores were not charted.
13. The screen-film contact QC is not adequate for Mammography Imaging Center, Inc. because the QC records were incomplete.
14. The darkroom fog QC is not adequate for the darkroom at Mammography Imaging Center, Inc. because:
 - The QC records were incomplete;
 - The background density was < 1.00.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within five (5) working days from the date 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 (include technique factors), raw test data, and calculated final results, where appropriate; and

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- 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 note that [REDACTED] must immediately cease the interpretation of mammography films until this office has received the following documentation:

1. Documentation of board certification by an FDA recognized board, or documentation of 2 months training in the interpretation of mammograms.
2. Documentation of initial experience in mammography of having read or interpreted 240 patient examinations in a 6-month period.
3. Documentation of the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.
4. Documentation of having a minimum of 40 CME credit hours of initial training in mammography.

Please submit your response to: Rosa L. Brown, Compliance Technician, Food and Drug Administration, New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054.

Finally, you should understand that 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 may 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, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

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If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Ms. Toniette Williams, Supervisory Investigator at (973) 526-6018.

Sincerely,

Douglas I. Ellsworth, Acting Dir.
DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

Enclosure as Stated

cc: Radiation Protection Programs
Department of Environmental Protection and Energy
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