



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

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Telephone (973) 526-6007

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

May 31, 2000

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Medhat El-Amir, MED  
President  
Union City Diagnostic Center  
120-152 48<sup>th</sup> Street  
Union City, New Jersey 07087

FILE NO.: 00-NWJ-40  
Inspection ID NO.: 1996790005

Dear Dr. El-Amir:

We are writing you because an inspection conducted by the State of New Jersey on behalf of the Food and Drug Administration (FDA) on May 16, 2000, revealed a serious regulatory problem involving mammography at your facility.

Under 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 One deficiency:

- The system used to communicate results is not adequate because it does not provide timely lay summaries.

This inspection also revealed the following Level 2 deficiencies:

- One of five random reports reviewed by the State inspector did not contain an assessment category.
- Phantom Quality Control (QC) records for Unit 2 [REDACTED] were missing for at least two weeks, but less than four weeks.
- The measured fog density was equal to [REDACTED] for the darkroom.

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- The time period between the previous and current surveys exceeded 14 months for Unit 2.
- Your facility does not have a designated reviewing, interpreting physician.
- Your facility does not have a written procedure for infection control.
- Your facility does not have a written procedure for handling consumer complaints.

The specific deficiencies noted above appeared on your MQSA Facility Inspection Report that was issued to your facility at the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law that 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, the Mammography Quality Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction prohibiting your facility from conducting mammography services.

You must act on this matter immediately. Please explain or provide to this office in writing within 15 working days from the date that you receive this letter:

- the specific steps you have taken to correct 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 calculated final results, where appropriate; 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\*).

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\*This note is not applicable for letters, which also address patient notification.

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 disclosed during the inspection of your facility 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, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have any specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Commander Heywood L. Rourk, Central Regional Radiological Health Representative, at (410) 962-4052.

Sincerely,



DOUGLAS I. ELLSWORTH  
District Director  
New Jersey District Office

cc: Bureau of Radiological Health  
Department of Environmental Protection  
P.O. Box 415  
Trenton, New Jersey 08625-0415

Priscilla F. Butler, M.S.  
Director, Breast Imaging Accrediation Programs  
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