



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

m2995n

Telephone (973) 526-6007

September 28, 1999

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

WARNING LETTER

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Daniel Gillen, Director of Operations
West Jersey Hospital - Marlton
Department of Radiology
Route 73 & Brick Road
Marlton, New Jersey 08053

FILE NO.: 99-NWJ-41

Inspection ID NO.: 1462740010

Dear Mr. Gillen:

We are writing to you because on September 13, 1999, a representative of the State of New Jersey, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This 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 and Level 2 findings at your facility:

LEVEL 1

- The phantom image score (using an FDA-approved mammography phantom) is less than two masses for Unit 1, [REDACTED]

LEVEL 2

- Five of five random reports reviewed did not contain an assessment category for the West Jersey Hospital-Marlton site.

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□ The x-ray system for Unit 1, [REDACTED] does not include the following:

- Image receptors for two sizes.
- Moving grids for two sizes.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was sent to your facility at the end of the inspection.

Because these conditions 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.

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 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
- 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*).

*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, Ten Waterview Blvd, Third Floor, Parsippany, New Jersey 07054.

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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>.

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

Sincerely,

Edward H. Ellsworth, Sr.

DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

/RLB

cc: Ms. Joyce Zeisler
Bureau of Radiological Health
Department of Environmental Protection
P.O. Box 415
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