



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *g/220d*

Telephone (973) 526-6007

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

April 9, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Fred Wishner
Corporate Director Medical Imaging
Kennedy Memorial Hospitals - VMC
18 East Laurel Road
Stratford, New Jersey 08084

FILE NO.: 01-NWJ-22
Inspection ID NO.: 1522490007

Dear Mr. Wishner:

A representative from the State of New Jersey under contract to the Food and Drug Administration (FDA) inspected your facility on March 16, 2001. This inspection revealed a serious regulatory problem involving mammography performed 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 public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding

- Phantom quality control records were missing for at least four weeks for your Instrumentarium Imaging mammography unit.

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 a Level 1 finding because it identifies a failure to comply with significant MQSA requirements.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, it represents a violation of the law that may result in FDA taking regulatory action without further notice to you.

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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, the following Level 2 repeat finding was listed on the inspection report provided to you at the close of the inspection:

- Six mammography reports were reviewed and it was found that of the 6 random reports did not contain an acceptable assessment category.

Also, the following Level 2 finding was listed on the inspection report:

- Your facility failed to produce documentation verifying that [REDACTED] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in the 24 months preceding the date of the inspection.

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.

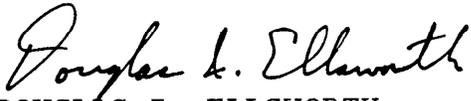
Please submit your response to Rosa L. Brown, Compliance Technician, Food and Drug Administration, New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054.

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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 technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591 x159.

Sincerely,



DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

cc: Mark Sciranka, NWJ MQSA
NJ Department of Environmental Protection
Bureau of Radiological Health
P.O. Box 415
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