



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

MZ9781

Telephone (973) 526-6007

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

July 06, 2000

WARNING LETTER

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Romolo Maurizi, MD
Medical Director
Open MRI of Englewood Cliffs
532 Sylvan Avenue
Englewood Cliffs, New Jersey 07632

FILE NO.: 00-NWJ-45
Inspection ID NO.: 2214690002

Dear Dr. Maurizi:

We are writing you because on June 19, 2000, a representative of the Food and Drug Administration (FDA) conducted an inspection, which 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:

- Processor Quality Control (QC) records were missing 4 out of 4 days of operation in February 2000. Processor QC records missing 100% for the processor, [REDACTED], located in the Control Room at this site.

This inspection also revealed the following Level Two deficiencies:

- Mammograms were processed in the processor, [REDACTED], located in the Control Room at this site when the processor was out of limits on three days.
- Processor QC records were missing three consecutive days for the processor, [REDACTED], located in the Control Room at this site.

- The time period between the previous and current surveys exceeded 14 months for Unit 1 [REDACTED].
- 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.
- The interpreting physician, [REDACTED] did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.
- The interpreting physician, [REDACTED] did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.

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;

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- 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*).

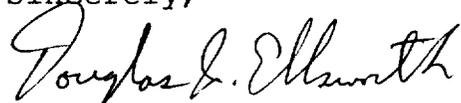
*This note is not applicable for letters, which also address patient notification.

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
Attn: Romona Chambus
P.O. Box 415
Trenton, New Jersey 08625-0415