



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *m4118n*

Telephone (973) 526-6007

August 30, 2000

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Robert Traslet
Owner
Magnetic Resonance of New Jersey
550 Kinder Kamack Road
Oradell, New Jersey 07649

FILE NO.: 00-NWJ-49
Inspection ID NO.: 2202930002

Dear Dr. Traslet:

We are writing to you because on August 15, 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 16 consecutive days for the processor 1 (██████████) located in the darkroom at this site.
- Processor QC records were missing 16 out of 25 days of operation in March 2000. Processor QC records missing 64% for the processor 1 (██████████) located in the darkroom at this site.

This inspection also revealed the following Level Two deficiencies:

- The time period between the previous and current surveys exceeded 14 months for Unit 1 (██████████).

- The radiologic technician, [REDACTED], did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36-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;
- 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.

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

Sincerely,

Edward H. Ellsworth, Sr.
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

Priscilla F. Butler, M.S.
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