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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
**RELEASE** Atlantic Region

Telephone (201) 331-2907  
May 19, 1997

REVIEWED BY RLA Food and Drug Administration  
C.O. Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mercerville Radiology Associates, P.A.  
ATTN: Dr. Theodore R. Swartz  
2303 Whitehorse-Mercerville Road, Suite 4  
Mercerville, New Jersey 08619

FILE NO.: 97-NWJ-34  
Inspection ID NO.: 193938

Dear Dr. Swartz:

Your facility was inspected on April 11, 1997 by a representative from the State of New Jersey Radiation Control Program under contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

- The medical physicist [REDACTED] had neither a state license nor a state approval, nor board certification, and did not meet the alternative requirement to conduct MQSA mammography surveys. Please furnish us with documentation that demonstrates that Ms. Duffy is a qualified Medical Physicist or describe the actions you will take in order to obtain physicist report by a qualified Medical Physicist. Acceptable documentation that demonstrates Medical Physicist qualifications consist of:

- (1) a copy of a State License, or;
- (2) a copy of a State Approval Letter, or;
- (3) (a) copy of Masters or higher degree diploma,
- (b) letter from Medical physicist or copies of continuing education certificates or transcripts that document 1 year of training in medical physics,

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- (c) letters from facilities or copies of inspection reports that document 2 years of experience in conducting performance evaluation of mammography equipment; and
- (4) documentation of an average of 5 CEUs in mammography over 3 years.

If you decide to obtain another Medical Physicist and Medical Physicist Report, please furnish us a copy of the Medical Physicist Report and documentation that the Medical Physicist meets the requirements.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued on April 11, 1997. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility. It is your responsibility to verify the eligibility of all employees performing mammogram at your facility and to have copies of their credentials available.

There were also 3 Level 3 items identified in your MQSA Facility Inspection Report. The corrective action on these 3 items will be verified at your next MQSA inspection.

The above identifications of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.

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- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

You should notify this office in writing within 15 working days of receipt of this letter of:

- 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 (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper recordkeeping procedures, if the noncompliances that were found relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please direct your reply to Rosa L. Brown, Compliance Technician, Food and Drug Administration, New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054. Also, send a copy to the State Radiation Control Office listed below.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent requirements. You may choose to address both FDA and State requirements in your response.

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If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Ms. Alyssa Paolillo, Consumer Safety Officer at (908) 940-8946.

Very truly yours,



CHARLES B. THORNE  
Acting District Director  
New Jersey District Office

cc: Radiation Protection Programs  
Department of Environmental Protection and Energy  
ATTN: Joyce Zeisler  
CN 415  
Trenton, New Jersey 08625-0415

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