



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service

m2331A  
Food and Drug Administration  
555 Winderley Place, Suite 200  
Maitland, Florida 32751

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

**WARNING LETTER**

FLA-99-27

January 14, 1999

**FACILITY ID# 173203**

Diane Hill  
Director of Imaging  
Memorial Imaging San Pablo  
14444 Beach Boulevard  
Jacksonville, Florida 32250

Dear Ms. Hill:

Your facility was visited on December 10, 1998 by a representative of the State of Florida, on 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:

**Level 1**

Failure to have documentation that the interpreting physician, [REDACTED], meets the requirement of being licensed by a State to practice medicine.

**Level 2**

Failure to have documentation that the interpreting physicians, [REDACTED], [REDACTED] and [REDACTED], meet the continuing experience requirements of having completed a minimum of 15 credits in mammography over 3-year period.

The specific deficiencies noted above appeared on the List of Observations which was issued to your facility on December 10, 1998. These deficiencies are symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of the deficiencies identified during the inspection and to promptly initiate permanent corrective action.

Ms. Diane Hill  
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If you fail to properly address the 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 comply with the Standards.
- 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.

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 State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply or any questions regarding this letter or how to ensure you are meeting the MQSA Standards should be directed to Carlos I. Medina, Compliance Officer, U.S. Food and Drug Administration, 6601 N.W. 25th Street (P.O. Box 592256), Miami, FL 33159-2256, telephone (305) 526-2800, extension 921.

Sincerely,

  
Douglas D. Tolen  
Director, Florida District

cc: State of Florida