



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service d1702 b

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-34

March 10, 1998

FACILITY ID# 168732

Alan Shankman
President
Plantation Medical Imaging
7050 NW 4 Street Suite 202
Plantation, FL 33317

Dear Mr. Shankman:

Your facility was inspected on January 23, 1998, by a representative of the State of Alabama, 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

1. Records reflect that there was no medical physicist survey done for the Bennett x-ray system.

Level 2

2. Records for repeat analysis were not present since March 1997.
3. Almost all (99 percent) of the data points for either medium density (MD), density difference (DD), or base plus fog (BF) were missing for the month of July, 1997 (Konica developer).

These specific deficiencies appear on the List of Observations, which was issued to your facility on January 23, 1998. These deficiencies are symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

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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 these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

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

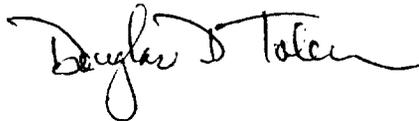
- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

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 should be directed to Carlos I. Medina, Compliance Officer, U.S. Food and Drug Administration, P.O. Box 592256, Miami, FL 33159-2256, telephone (305) 526-2800, extension 921. Any questions in regard to this letter or how to ensure you are meeting MQSA standards may be directed to Mr. Medina.

Sincerely,



Douglas D. Tolen
Director, Florida District

cc: State of Florida