



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

m29947

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

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-99-96

September 28, 1999

FACILITY ID # 139220

Sandy Siebert
Director of Radiology
St. Joseph Hospital
3001 W. M.L. King Blvd.
Tampa, Florida 33607

Dear Ms. Siebert:

Your facility was inspected on September 17, 1999 by a representative of the State of Florida, on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standard for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Repeat Level 2

Failure to have documentation that the interpreting physician, [REDACTED], MD has met the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36 month period.

The specific deficiency noted above appeared on the Inspectional Observations which was issued to your facility on August 27, 1999. This deficiency may be symptomatic of serious underlying problem 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 these deficiencies identified during the inspection and to promptly initiate permanent corrective actions.

If you fail to properly address this deficiency, 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.

Ms. Sandy Siebert
Page 2
September 28, 1999

- 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. Therefore, when you plan your corrective action(s), 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 corrections will be completed.

Your reply should be directed to Carlos I. Medina, Compliance Officer, U.S. Food and Drug Administration, 6601 N.W. 25th Street (P.O. Box 59-2256), Miami, FL 33159-2256, telephone (305) 526-2800, extension 921.

Sincerely,



Douglas D. Tolen
Director, Florida District