

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

M 876N

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
FACSIMILE: 214-655-8130

May 1, 1997

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

CFN #1648005
Facility ID #198689
Facility ID #213116--Mobile
Mammography Service

Ms. Diane Ringeisen
Manager Breast Care Services
East Texas Medical Center
700 Olympic Plaza Suite 101
Tyler, TX 75701-1951

Dear Ms. Ringeisen:

Your facility was inspected on April 3, 1997 by a representative of the State of Texas, acting on behalf of the Food and Drug Administration. This inspection revealed that your facility failed to comply with certain parts of the Quality Standards for Mammography (Standards) as specified in Title 21, *Code of Federal Regulations (CFR)*, Part 900.12, as follows:

21 CFR 900.12(a)(1)(ii)(A)&(B): The interpreting physician did not meet the requirement of being board certified by any of the approved boards or having two months full-time training in the interpretation of mammograms: [REDACTED]

The specific deficiency noted above appeared under the level 1 heading on your MQSA Facility Inspection Reports, which were issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection reports provided to you at the close of the inspection. These Level 2 noncompliances are:

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21 CFR900.12(a)(1)(ii)(C): The interpreting physicians did not meet the initial training requirement of having 40 hours of continuing medical education in mammography:

[REDACTED], M.D.; [REDACTED] M.D.; [REDACTED] M.D.

21 CFR900.12(a)(1)(iii)(A)&(B): The interpreting physicians did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months:

[REDACTED] M.D.; [REDACTED] M.D.; [REDACTED] M.D.

21 CFR900.12(a)(1)(iv)(A): The interpreting physicians did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months:

[REDACTED] M.D.; [REDACTED] M.D.; [REDACTED] M.D.

21 CFR900.12(d)(1)(i): The measured darkroom fog exceeded 0.05 (the measured fog level was 1.04) for the darkroom servicing the Mobile Mammography Services unit.

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 causes of the deficiencies that the inspection identifies and promptly initiating 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.
- ▶ **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 actions, you should consider the more stringent State requirements.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- ▶ 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;

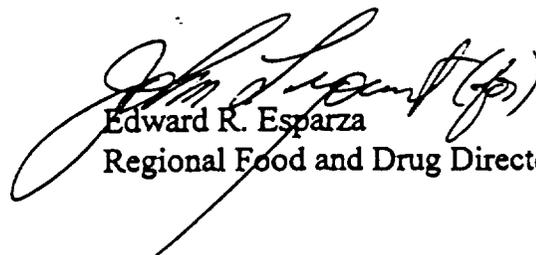
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If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to Deborah M. McGee, Radiation Specialist, Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982. Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Ms. McGee at 214-655-8100, extension 138.

Sincerely yours,


Edward R. Esparza
Regional Food and Drug Director

cc: Thomas C. Cardwell, Deputy Director
X-Ray & Non-Ionizing Enforcement
Division of Compliance and Inspection
Texas Department of Health
Bureau of Radiation Control
1100 W. 49th Street
Austin, Texas 78756