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

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 29, 1997

**WARNING LETTER**

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

CFN# 1647870  
Facility ID# 180893

Dr. Salah Rafati  
Radiologist  
Radiology Clinic of Laredo  
5401 Springfield Avenue  
Laredo, TX 78041

Dear Dr. Rafati:

Your facility was inspected on March 25, 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 CFR900.12(d)(1): All processor QC records contained incorrect daily entries which prevented QC personnel from accurately assessing the optimum operating status of equipment used during film processing.

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

In addition, a Level 2 Repeat noncompliance was listed on the inspection report provided to you. This Level 2 Repeat noncompliance is stated below:

21 CFR900.12(d)(2): Phantom image data was invalid due to incorrect interpretations of the monthly phantom image films by the QC technologist. The performance of the mammographic system is evaluated using radiographic images obtained with a phantom.

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We have received your documentation submitted in response to the noncompliances found during the inspection. A review of your response fails to demonstrate specific corrective actions you will implement in order to train those employees involved in the performance of all quality assurance and quality control activities at your facility.

During the inspection, it was determined that personnel involved in the current noncompliances were not properly trained to perform these quality control program functions. While your facility provided replotted quality control charts for submission as a corrective action, the emphasis is on the fact that the correct information was not available to utilize during the time the patient mammograms were performed.

**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. When you plan your corrective actions, 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:

- ▶ **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;**

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.

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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  
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Division of Compliance and Inspection  
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