



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

M2126N

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
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October 14, 1998

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

99-SWR-WL-02/8
CFN# 1723120
Facility ID# 197939

Anthony J. Plantier
Administrator
Artesia General Hospital
702 N. 13th
Artesia, NM 88210

Dear Mr. Plantier:

Your facility was inspected on August 19, 1998 by a representative 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(a)(1)(iv)(A): These 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]

21 CFR900.12(a)(1)(iv)(B): The interpreting physician did not meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a 3-year period (an average of 5 credits/year): [REDACTED]

21 CFR900.12(a)(1)(iii)(A)&(B): These 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]

October 14, 1998

The specific deficiencies noted above appeared under the level 2 repeats heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality mammography at your facility.

In addition, level 3 repeats noncompliances were listed on the inspection report provided to you at the close of the inspection. These level 3 repeats noncompliances are:

21 CFR900.12(d)(5): The kVp reproducibility test was not done at kVp commonly used clinically by the medical physicist: Lorad Medical Systems, Inc. M-II.

21 CFR900.12(d)(5): The Beam quality (HVL) measurement was not done at kVp commonly used clinically by the medical physicist: Lorad Medical Systems, Inc. M-II.

21 CFR900.12(d)(5): The Automatic exposure control reproducibility performance test was not done at kVp commonly used clinically by the medical physicist: Lorad Medical Systems, Inc. M-II.

21 CFR900.12(d)(5): The Average glandular dose determination was not done with exposure and HVL at the same clinical kVp by the medical physicist: Lorad Medical Systems, Inc. M-II.

21 CFR900.12(d)(5): The Phantom image test was not done at the typical clinical kVp by the medical physicist: Lorad Medical Systems, Inc. M-II.

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.

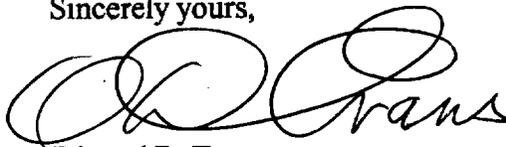
Within 15 working days after receiving this letter, you should notify FDA in writing of:

- ▶ 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.

Please send your response to Deborah M. McGee, Radiation Specialist, Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982. 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,



for Edward R. Esparza
Regional Food and Drug Director

cc: Director, Government Relations
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091