



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Southwest Region
7920 Elmbrook Drive
Suite 102
Dallas, TX 75247-4982

Telephone: 214-655-8100
FAX: 214-655-8130

December 20, 2001

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

02-SWR-WL-19/8

MSgt Russell S. Habersang II
NCOIC
49th Fighter Wing Hospital
280 First Street
Building 15
Holloman AFB, NM 88330

RE: Inspection ID – 1000320009

Dear MSgt. Habersang,

On 12/10/2001, a representative of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility.

The Mammography Quality Standards Act of 1992 requires your facility to meet specific standards. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 finding at your facility:

- Level 1: Processor QC records in the month of 05/2001 were missing for at least 30% of operating days, for processor 0000000001, Kodak, Other, room mammo at site 49th Fighter Wing Hospital

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

Level 1 findings may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility. They represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to:

- Placing your facility under a Directed Plan of Correction.
- Charging your facility for the cost of on-site monitoring.
- Assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.

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- Suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

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

- Level 2: Phantom QC records were missing for at least two weeks but less than four weeks for unit 2, Lorad Medical Systems Inc., MIV, room mammo
- Level 2: The mammography processor equipment evaluation (by a medical physicist) for processor 0000000001, Kodak, Other, room mammo, site 49th Fighter Wing Hospital was not done
- Level 2: Processor QC records were missing at least 2 but less than 5 consecutive days for processor 0000000001, Kodak, Other, room mammo at site 49th Fighter Wing Hospital
- Level 2: The facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required at site 49th Fighter Wing Hospital

It is necessary for you to act on this matter immediately. You are required to respond to this office in writing within fifteen (15) working days from receipt of this letter. Please address the following:

- The specific steps you have taken to correct all of the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.
- Equipment settings (including technique factors), raw test data, and calculated final results, where appropriate.
- Sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Angela T. Moak, Radiation Specialist
Food and Drug Administration
7920 Elmbrook Drive, Suite 102
Dallas, Texas 75247-4982

This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography/index.html>.

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If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Angela Moak at (214) 655-8100 ext. 135.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary L. Pierce". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Gary L. Pierce
for Regional Food and Drug Director