



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

October 27, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

01-SWR-WL-02/7

Kathie Aiello
 Director of Breast Center
 St. Paul Breast Center
 5909 Harry Hines Blvd.
 Dallas, TX 75235

RE: Inspection ID - 1758770007

Dear Kathie Aiello,

On October 10, 2000, a representative of the State of Texas acting in behalf 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 findings at your facility:

Level 1: Processor QC records were missing 11 out of 21 days of operation in month 02/2000. Processor QC records missing 52%, for processor 1, Kodak, RP X-OMAT, room Mammo #1.

Level 1: Processor QC records were missing 8 consecutive days for processor 1, Kodak, RP X-OMAT, room Mammo #1.

The specific problems 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:

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- 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.
- 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. The inspection revealed the following Level 2 findings:

Level 2: Corrective actions for processor QC failures were not documented at least once for processor 1, Kodak, RP X-OMAT, room Mammo #1.

Level 2: The medical physicist's surveys for x-ray unit 1, Lorad Medical Systems Inc., M III, room 4; unit 4, Lorad Medical Systems Inc., M IV, room 1; and unit 5, Lorad Medical Systems Inc., M III, room 5 are incomplete because the following test was not done:

-No artifact evaluation.

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:
Deborah M. McGee, Radiation Specialist
Food and Drug Administration
7920 Elmbrook Drive, Suite 102
Dallas, TX 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>.

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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 Deborah M. McGee at (214) 655-8100 ext. 138.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary L. Pierce". The signature is stylized with a large, looped initial "G" and a long, sweeping underline.

Gary L. Pierce
Regional Food and Drug Director