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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
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February 12, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

01-SWR-WL-25/0

Marty Boyers, Mammography Manager
University of Kansas
Mobile Mammography Program
3901 Rainbow Boulevard
Kansas City, KS 66160

RE: Inspection ID - 2105750005

Dear Marty Boyers,

On January 25, 2001, a representative of the State of Kansas, 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 10 out of 10 days of operation in month 03/2000. Processor QC records missing 100%, for processor 1, Kodak, X-OMAT, room-mobile darkroom.

Level 1: Phantom QC records were missing for 4 weeks for unit 1, Fisher Imaging Corporation.

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:

- Placing your facility under a Directed Plan of Correction.
- Charging your facility for the cost of on-site monitoring.

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- 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, the inspection revealed the following level 2 finding:

Level 2: Processor QC records were missing 4 consecutive days for processor 1, Kodak, X-OMAT, room mobile darkroom.

We have received your documentation submitted in response to the noncompliances found during the inspection. Based on a review of the documentation, your facility has addressed the Agency's immediate concerns regarding the missing processor and phantom QC records.

Please be aware that it is your responsibility to ensure adherence to the requirement of the Mammography Quality Standards Act of 1992 and FDA's regulations. It is your responsibility to investigate and determine the causes of any problems within your program and promptly initiate permanent corrective actions.

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

- Each step your facility is taking to prevent the recurrence of similar violations.

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>.

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,



Gary L. Pierce
Regional Food and Drug Director