



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 4, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

01-SWR-WL-82/0

Sherry L. Mohr
 Vice President of Specialty and Ambulatory Services
 SSM DePaul Health Center
 12303 DePaul Drive
 Bridgeton, MO 63044-2588

Dear Ms. Mohr,

On July 11-13, 2001 and August 6-8, 2001, representatives of the Food and Drug Administration (FDA) conducted an investigation at your facility. This investigation 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 investigation revealed the following findings at your facility:

As required by 21 CFR 900.12 (e)(2), facilities shall perform an image quality evaluation test using an FDA approved phantom at least weekly. The investigation revealed that the phantom image quality control records were falsified during the time frame of March 1999 through May 2001. Therefore, the regulation was not met.

These findings are 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.

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

In addition, we have asked the American College of Radiology (ACR) to conduct an Additional Mammography Review of mammograms done by your facility during the time frame when phantom images were falsified (we have enclosed a copy of 21 CFR 900.12(j) as a reference). The ACR will contact you regarding the selection of films for this review. Also, [REDACTED] M.D., who is the [REDACTED] at the [REDACTED], has agreed to evaluate a sample of 30 mammograms from your facility as an additional review. We will contact you at a later date regarding how you should select these 30 mammograms.

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 this investigation and does not necessarily address other obligations you have under the law. Additionally, you should be aware that the State of Missouri may require you to take additional actions.

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, sweeping initial "G" and a long, horizontal flourish extending to the right.

Gary L. Pierce
Regional Food and Drug Director

Enclosure: 21 CFR 900.12(j)