



**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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September 28, 2001

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

01-SWR-WL-79/0

Toni D. Weatherford  
Administrator  
Thousand Oaks Imaging Center  
1905 W. 32<sup>nd</sup> Street, suite 106  
Joplin, MO 64804

RE: Inspection ID - 2260360001

Dear Toni D. Weatherford,

On July 26, 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 findings at your facility:

Level 1: The facility was performing mammography without a valid certificate.

Level 1: Failed to produce documents verifying that the interpreting physician [REDACTED] met the alternative initial requirement of having prior to April 28, 1999, a bachelors degree or higher in a physical science with at least 10 semester hours of physics.

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.
- 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: The mammography equipment evaluation (by a medical physicist) for unit 1, Siemens Medical Systems, NOVA, was not done.

Level 2: The mammography processor equipment evaluation (by a medical physicist) for processor, Kodak, X-OMAT, was not done.

Level 2: The facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required.

Level 2: Failed to produce documents verifying that the medical physicist [REDACTED] met the alternative initial requirement of having, prior to April 28, 1999 and after fulfilling the degree requirement, 40 contact hours of documented specialized training in conducting surveys of mammography facilities.

Level 2: 5 of 6 random reports reviewed did not contain an assessment category.

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

We have requested that the American College of Radiology (ACR) conduct an Additional Mammography Review of mammograms produced by your facility while you were performing mammography without a certificate (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. If this review shows that the quality of mammography may represent a serious risk to human health, we may require that additional mammograms be evaluated or that you notify patients and physicians of the potential health risk.

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,

A handwritten signature in black ink, appearing to read "Gary L. Pierce", written in a cursive style.

Gary L. Pierce  
Regional Food and Drug Director

Enclosure: 21 CFR 900.12(j)