



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

May 9, 2002

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

02-SWR-WL-41/7

Lisa Pierce
Administrator of Radiology
Eureka Springs Hospital
24 Norris Street
Eureka Springs, AR 72632

Dear Ms. Pierce:

Re: Inspection ID - 2019390007

We are writing to you because on April 8, 2002, a representative of the State of Arkansas, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA"), 42 U.S.C. § 263b, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following violation of Section 354(f) of the Act at your facility:

Level 1: Phantom QC records were missing for at least four weeks for unit 2, Lorad Medical Systems Inc., ELIT. (21 CFR 900.12(e)(2)).

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. A Level 1 or repeated Level 2 finding indicates that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility.

In addition, the inspection report provided to you at the close of the inspection listed Level 2 violations. A Level 2 finding indicates that the facility's performance is generally acceptable. However, the inspector did find one or more deviations from MQSA standards that may compromise the quality of mammography services offered by the facility. The inspection revealed the following level 2 findings:

Level 2: Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 2, Lorad Medical Systems Inc., ELIT. (see 21 CFR 900.12(e)(2)).

Level 2: Medical audit and outcome analysis was not performed annually at site. (21 CFR900.12(f)(2)).

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents 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 mammography quality standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography (see Sections 354(h) through (j) of the Act).

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

1. the specific steps you have taken or will take to **correct** all of the violations noted in this letter;
2. any reason that corrective action has not been taken and the time within which any step not yet taken will be complete;
3. each step your facility is taking to **prevent the recurrence** of similar violations;
4. equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
5. documentation showing that correction is complete, including, if the findings relate to quality control or other records, sample records that demonstrate proper record keeping procedures, **(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

Finally, you should understand that there are many FDA requirements pertaining to mammography. 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 Deborah M. McGee at (214) 655-8100 extension 138.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary L. Pierce". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Gary L. Pierce
Regional Food and Drug Director

Cc: David Cox
Administrator
Eureka Springs Hospital
24 Norris Street
Eureka Springs, AR 72632