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
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May 30, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

02-SWR-WL-43/0

Kevin Trimble
Service Vice President
St. Luke's Northland Hospital
5830 N.W. Barry Road
Kansas City, MO 64154

Dear Mr. Trimble:

Re: Inspection ID - 1396830007

We are writing to you because on April 17, 2002, a representative of the State of Missouri, 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 a United States Federal law, the Mammography Quality Standards Act of 1992, 42 U.S.C. § 263b (MQSA), 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 level 1 findings at your facility:

Level 1: Failed to produce documents verifying that the interpreting physician [redacted], DO met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having 2 months of initial training in the interpretation of mammograms prior to 4/28/99. (see 21 CFR 900.12(a)(1))

Level 1: Failed to produce documents verifying that the radiologic technologist [redacted], RT met the initial requirement of holding either a valid state license or a valid certificate from an FDA-approved body. (see 21 CFR 900.12(a)(2))

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. A Level 1 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.

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 Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography (see, 42 U.S.C. § 263b (h) (j)).

In addition, the inspection report provided to you at the close of the inspection listed Level 2 violations that may compromise the quality of mammography services offered by the facility. The inspection revealed the following level 2 findings:

Level 2: Failed to produce documents verifying that the interpreting physicians [redacted], MD and James Fitzsimmons, MD met the initial experience requirement of having interpreted or multi-read 240 mammograms in 6 months. (see 21 CFR 900.12(a)(1))

Level 2: Failed to produce documents verifying that the interpreting physicians [redacted] MD; James Fitzsimmons, MD and Thomas Gleason, DO met the initial requirement of having 40 hours of medical education in mammography prior to 4/28/99. (see 21 CFR 900.12(a)(1))

Level 2: Failed to produce documents verifying that the interpreting physicians [redacted], MD and Pablo Delgado, MD (0 CME's in 36 months) met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months. (see 21 CFR 900.12(a)(1))

Level 2: Failed to produce documents verifying that the interpreting physician [redacted], MD met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months. (see 21 CFR 900.12(a)(1))

Level 2: Failed to produce documents verifying that the radiologic technologist [redacted], RT(R-M) (12 CEU's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months. (see 21 CFR 900.12(a)(2))

Level 2: Failed to produce documents verifying that the radiologic technologist [redacted], RT (R-M) (10.5 CEU's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months. (see 21 CFR 900.12(a)(2))

Level 2: Failed to produce documents verifying that the radiologic technologist [redacted], RT met the alternative initial requirement of having training specific to mammography under the interim regulations. (see 21 CFR 900.12(a)(2))

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 to **correct** all of the violations noted in this letter;

2. each step your facility is taking to **prevent the recurrence** of similar violations;

3. equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

4. 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

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.

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,

Gary L. Pierce
Regional Food and Drug Director