



DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN:1124339
Facility ID:159947
Inspection ID #1599470008

Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 100
Baltimore, MD 21215-3215
Telephone: (410) 773-5454

02-BLT-02

November 7, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Herman East, Diagnostic Radiology Manager
Fair Oaks Hospital Medical Plaza
3700 Joseph Siewick Drive
Suite 408
Fairfax, Virginia 22033

Dear Mr. East:

A representative of the Food and Drug Administration (FDA) inspected your facility on October 23, 2001. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding:

- **Your facility failed to document that phantom image testing was performed for the weeks of September 2, 2001, September 9, 2001, September 16, 2001, September 23, 2001, September 30, 2001, and October 7, 2001 on your [REDACTED] mammography machine.**

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as a Level 1 finding because it identifies a failure to comply with a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, it represents a violation of the law that 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 MQSA

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standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, the following Level 2 findings were listed on the inspection report provided to you at the close of the inspection:

- **Your facility failed to document that processor quality control tests were performed on October 10, 2001, October 11, 2001, October 12, 2001, and October 15, 2001;**
- **Your facility failed to document at least once that corrective action was performed when your processor exceeded preset operating limits; and**
- **Your facility failed to perform an annual medical audit and outcome analysis.**

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 receive this letter:

- The specific steps you have taken to correct the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to: Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Ms. Anita Richardson, Director, Compliance Branch.

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 may 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 technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 779-5441.

Sincerely,



Lee Bowers
Director, Baltimore District