



DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN:1125889
Facility ID:222795
Inspection ID #227950003

Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 773-5454

May 3, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Carol D. Merrill, Administrator
Marion Health Care Hospital.
401 Guffey Street
Fairmont, West Virginia 26554

Dear Ms. Merrill:

A representative from the State of West Virginia, under contract to the Food and Drug Administration (FDA), inspected your facility on February 20, 2002. 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, [42 U.S.C. 263b], 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 following finding was listed on the MQSA Facility Inspection Report provided to you at the close of the inspection.

- **Your facility failed to document that Phantom QC testing was performed for at least 4 weeks for the [REDACTED] mammography unit located in the mammography room.**

This problem identifies a failure to comply with a significant MQSA requirement outlined in 21 CFR 900.12(e)(2). This condition may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility. 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 violation 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 Steven B. Barber, Compliance Officer.

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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,

A handwritten signature in black ink, appearing to read "Lee Bowers", with a long horizontal flourish extending to the right.

Lee Bowers
Director, Baltimore District