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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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WARNING LETTER

Cin WL – 13095-0
April 18, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Helen Henderson
Chief Clinical Officer
Memorial Hospital, Inc.
401 Memorial Dr.
Manchester, KY 40962

Facility I.D.#: 193912

Dear Ms. Henderson:

Mr. R. Terry Bolen, of our office and Mr. Jimmy Barnes, a representative from the Commonwealth of Kentucky acting on behalf of the Food and Drug Administration (FDA) inspected your facility on February 21, March 4-6, 2002. The inspection revealed serious regulatory problems involving the mammography 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 health of women by assuring that a facility can perform quality mammography. The inspection revealed the following violations of Section 354(f) of the Act, 42 U.S.C. § 263b(f), at your facility (identified on your inspection report):

Quality Assurance Records – (21 CFR 900.12(d)(2))

The inspection of your facility revealed evidence that [redacted], lead quality control mammography technologist had forged the following mammography quality control records:

1. Fixer retention films for the quarterly tests supposedly performed on January 17, April 17, July 18, October 17, 2001 and January 16, 2002 were actually films from tests performed in the previous year or previous years. The dates and markings were altered to appear that the tests were performed in 2001 and 2002.

2. The film screen contact test films for the semi-annual tests supposedly performed on August 15, 2001 and February 19, 2002 were actually films from tests performed in previous year or previous years. The dates and markings were altered to appear that the tests were performed in 2001 and 2002.

21 CFR 900.12(d)(2) states: "The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the correction actions), safety, protection, and employee qualifications to meet assigned quality assurance tasks are **properly maintained and updated**. These quality control records shall be kept for each test specified in paragraph (e) and (f) of this section until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency whichever is longer."

Quality Assurance – *Equipment* – (21 CFR 900.12(e)(1)(i)-(iii))

Your records showed that your facility processed mammograms when the processor quality control records were missing 10 consecutive days of operation in late September 2001 and early October 2001.

The inspection revealed that during the days of September 20, 21, 24-27 and October 1-4, 2002 your facility did not perform the required daily quality control tests on the processor used to process mammograms.

In addition, we found other areas where your facility failed to comply that were listed as Level 2 findings on your inspection report:

Quality Assurance – *Equipment* – (21 CFR 900.12(e)(6)(A)) *as required in 21 CFR 900.12(e)(2)(iv)*

Your 2001 phantom quality control record revealed that your facility failed to document on November 11, 2001 corrective action before further mammography exams for density difference data that was charted outside the allowable regulatory limit.

Personnel Requirements- *Radiologic Technologist* (21 CFR 900.12(a)(2))

[redacted] a radiologic technologist who performed mammography at your facility, did not meet the continuing education requirement of having taught or completed at least 15 continuing education units mammography in 36 months. Your facility revealed to the inspectors that [redacted] had 7.5 mammography continuing hours in the past 36 months. [redacted] was also your facility's quality control mammography technologist.

Quality Assurance – *Mammography Medical Outcomes Audit* (21 CFR 900.12(f)(1) -(3))

1. Your facility failed to maintain a program to follow-up all positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This includes your facility failed to obtain or attempt to obtain biopsy results for all positive mammographic assessments.

2. Your facility failed to show that an annual medical audit and outcomes analysis was performed for the calendar year 2000. Your facility also failed to show that the analyses of these outcome data were made individually and collectively for all interpreting physicians at your facility only.

Quality Assurance – *Equipment* – 21 CFR 900.12(e)(3)(i)

The quarterly fixer retention quality control tests were not performed in 2001 and in the beginning of 2002. As indicated in this letter under the heading: "Quality Assurance Records – (21 CFR 900.12(d)(2))", [redacted] misrepresented these tests by altering previous year or years fixer retention films.

Quality Assurance – *Equipment* – 21 CFR 900.12(e)(4)(ii)

The semi-annual screen film contact quality control tests were not performed in 2001 and in the beginning of 2002. As indicated in this letter under the heading: "Quality Assurance Records – (21 CFR 900.12(d)(2))", [redacted] misrepresented these tests by altering previous year or years screen film contact test films.

Quality Assurance – *Equipment* – 21 CFR 900.12(e)(4)(i)

The semi-annual darkroom fog quality control test was not performed in the beginning of 2002. Your facility failed to demonstrate that the darkroom fog quality control test was performed on the scheduled date, January 16, 2002. Your facility was unable to show the darkroom fog film or any documented result that the darkroom fog test was performed in early 2002.

On March 5 & 6, 2002, these specific problems were discussed with you and your staff. Also these specific problems appeared in your MQSA Facility Inspection Report that was issued to your facility. We recognized that your management personnel discovered the altered quality control records, that you took appropriate disciplinary action to remove the employee, immediately notified the appropriate regulatory authorities, voluntarily suspended mammography and cooperated fully throughout the investigation. The FDA considers conducting mammography with falsified mammography quality control records a very serious violation of the law. A facility conducting mammography with false quality control records is also not providing the minimal "Acceptable Standard of Care" for patients.

Because these conditions may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, these represent violations 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, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography. (See 42 USC 263b, Section 354(h) through (j) of the Mammography Quality Standards Act of 1992).

You must act on these matters immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violations noted in this letter; and

- Each step your facility is taking **to prevent the recurrence of similar violations.**

Please submit 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:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

Also, please **send a copy** to the State radiation control office:

Mr. Jimmy Barnes
Commonwealth of Kentucky
Radiation Control
275 East Main St.
Frankfort, KY 40621

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.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,

Henry L. Fielden
District Director
Cincinnati District Office

c.
KY/JBarnes

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