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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

CIN–03-18154

June 25, 2003

Sent via Federal Express

Mr. William Lawrence
Chief Executive Officer
UHHS-Richmond Heights Hospital
27100 Chardon Rd.
Richmond Heights, OH 44143

Facility I.D.#: 133751

Dear Mr. Lawrence:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on May 22, 2003. This inspection revealed a serious problem involving mammography at your facility.

Under the Mammography Quality Standards Act (MQSA) of 1992, 42 U.S.C. § 263b, and the regulations set forth in Title 21, Code of Federal Regulations (C.F.R.), Part 900, 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 finding at your facility (identified on your MQSA Facility Inspection Report):

Quality Assurance – *Equipment – Weekly Quality Control Tests* -21 CFR § 900.12(e)(2)

Your facility's phantom quality control records for the mammography unit were missing for five (5) weeks. The MQSA regulation requires that the mammography unit be evaluated by performing the image quality evaluation test on at least a weekly basis. The inspection found that your facility failed to perform this quality control test during the weeks of September 23-27, September 30-October 4, November 4-8, 11-15 and 18-22, 2002.

The inspection also revealed the following issues (identified in the Inspector Remarks portion on your inspection report):

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

Your facility's mammography processor records in the month of January 2003 were missing for at least 10%, but less than 30%, of the operating days in the month. Also the processor records were missing for at least two consecutive days.

The inspector evaluated your facility records and found that mammograms were performed 13 days in January, 2003 and there is no record that daily processing quality control operation was performed on January 27, 29 and 30, 2003.

The inspector also observed the medical physicist's recommendations in his annual survey report dated November 18, 2002 that 1) mammography not be performed until a Quality Control Mammography Technologist is assigned to oversee the Quality Assurance/Quality control program; 2) quality control records are to be reviewed by a designated person of your facility on a monthly basis; 3) sensitometry and phantom control charts should be sent to the medical physicist for review on a quarterly basis. Your facility continued to perform mammography without a designated Quality Control Mammography Technologist from September 25, 2002 to February 4, 2003; all of the quality control tests were either not performed or documented inadequately; and no records were sent to the medical physicist for his review. The inspector further observed that the quality control deficiencies and the medical physicist's recommendations were brought to the attention of your facility's lead interpreting radiologist, [redacted]. Your facility did not follow the medical physicist's recommendations. The inspector observed that your facility hired a Quality Control Mammography Technologist five months after the resignation of the previous Quality Control Mammography Technologist. The inspector observed that phantom control films were taken between September 25, 2002 to February 4, 2003 and these were not evaluated or charted until after the hiring of the new Quality Control Mammography Technologist in February 2003.

The other items listed in your May 22, 2003 inspection report (identified as Level 3) should also be corrected. We will verify correction of these items during our next inspection. You are not required to address the Level 3 items in your written response.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent serious violations of the law that may result in FDA initiating regulatory action. 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; seeking civil money penalties of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the MQSA Standards; seeking suspension or revocation of your facility's FDA certificate; or seeking a court injunction against performing further mammography (see 42 USC §§ 263b(h)-(j) and 21 CFR § 900.12(j)). Before initiating any enforcement action against you, FDA may need to perform a follow-up inspection of your facility to determine whether these problems have been corrected. FDA assesses fees for MQSA inspections, including follow-up inspections 42 USC 263b(r).

It is necessary to act on these matters 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 the violations noted in this letter; and

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

Please also provide the following in answering this letter (note: If applicable, patient names or patient social security numbers should be deleted from any copies submitted):

1. A copy of your phantom control chart for the time period of January 1 through August 2003 and records that indicate dates that mammography was performed from May 22, 2003 to August 29, 2003.

2. A copy of your processor quality control charts for the time period of May 1, 2003 to August 29, 2003.

On June 9, 2003, this office received from your staff a letter, dated June 4, 2003 in response to the post inspection report. We have reviewed your staff letter and your facility is required to further answer this Warning Letter as instructed above.

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:

Ms. Terri Eckert
Ohio Department of Health
Radiological Technology Section
161 South High St., Suite 400
Akron, OH 44308-1616

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to certain 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 R. Terry Bolen at 513-679-2700, extension 138.

Sincerely yours,

Carol A. Heppe
District Director
Cincinnati District Office