DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

3472d

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WARNING LETTER
NWE-28-02W

VIA FEDERAL EXPRESS

August 19, 2002

Elaine Ullian
President and CEO
Boston Medical Center
720 Harrison Avenue
Boston, MA 02118

Dear Ms. Ullian:

We are writing to you because on June 14, 2002, your mammography facility, located at Boston Medical Center, Suite 703, was inspected by a representative of the Commonwealth of Massachusetts, acting on behalf of the Food and Drug Administration (FDA). 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 (MQSA), 42 U.S.C. 263b, 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 violation, which is included on the MQSA Facility Inspection Report that your facility received at the close of the inspection:

- Your records revealed that image quality evaluation tests, using an FDA-approved phantom (Phantom QC), were missing for at least 4 weeks for unit 3, [redacted] Room 3, in violation of 21 CFR 900.12(e)(2)(i)(ii)(iii)&(iv). During the inspection, the inspector observed that there were no weekly phantom quality control charts or films between June 1, 2001, and October 1, 2001. Your records, and your subsequent undated response letter, indicated that these records had been discarded with debris from the renovation of room 4. Your records also showed that mammography examinations were performed using that unit during that time period.

This violation may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, and represents a violation of the law that may result in FDA initiating regulatory action. Possible 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 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 U.S.C. 263b(h)-(j)).

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of this deficiency as identified and to promptly initiate permanent corrective actions.

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:

- the specific steps you have taken to correct the Level 1 violation noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- a copy of your written procedures for performing the weekly phantom QC test, including the criteria for a passing phantom image and procedures for taking and documenting corrective action when the phantom QC test fails for any of the required parameters
- a copy of records for the weekly phantom QC test that demonstrate proper record keeping procedures since June 14, 2002. (Note: Patient names or identification should be deleted from any copies submitted)

Please submit your response to Karen N. Archdeacon, Compliance Officer, New England District Office, at the address noted above.

You should also send a copy of your response to:

Mr. Robert Hallisey
Radiation Control Program
Department of Public Health
174 Portland Street, 5th Floor
Boston, MA 02114

In addition, your response should address the following finding that was listed on the inspection report provided to you at the close of the inspection:

- There was no documentation to show that the radiologic technologist, [redacted] met the minimum requirement of having taught or completed at least 15 continuing education units (CEU's) in mammography in 36 months. Your records showed that [redacted] had earned 9 mammography CEU's during the prior 36-month period. [21 CFR 900.12(a)(2)(iii)(A)]

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.

If you have specific questions about mammography facility requirements you may contact Michael Leal, MQSA Auditor at (508) 793-0422. If you have any other questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely yours,

Gail T. Costello
New England
District Director

cc:

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