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

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WARNING LETTER

NWE-17-02W

June 5, 2002

VIA FEDERAL EXPRESS

John G. O'Brien
Chief Executive Officer
The Cambridge Public Health Alliance-Somerville Hospital
230 Highland Ave.
Somerville, MA 02143

Dear Mr. O'Brien:

We are writing to you because on April 25, 2002, your mammography facility, located at Somerville Hospital 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), 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:

Quality Assurance – Equipment – 21 CFR 900.12(e)(2)

Level 1: Your records revealed that Phantom QC records were missing for at least 4 weeks in a 12 week period for unit [redacted] in the mammo room.

During the inspection, the inspector observed that weekly phantom quality control records were missing for the weeks of August 20, 2001, October 8, 2001, October 22, 2001, and November 5, 2001. Your records also showed that mammography examinations were performed during those weeks.

Quality Assurance – Equipment – 21 CFR 900.12(e)(1)(i), (ii) & (iii)

Level 1: Your records revealed that mammograms were processed in the [redacted] model [redacted] processor, number 1, in the darkroom, when it was out of limits on at least 5 days. For example, during the inspection, the inspector observed that processor was operating outside the regulatory limits for medium (mid) density on the following days:

January 28 and 29, 2002,
February 5, 6, 7, 20 and 21 2002,
March 4, 5, 6, 7, 18, 25 and 27, 2002 and
April 2, 4, 10 and 22, 2002

This processor was used to process mammograms on seventeen (17) of these days. Your records also revealed that the processor was outside the regulatory limits for density difference on one day, April 2, 2002.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which your facility received at the close of the inspection. These problems are Level 1 because they identify one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation 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 the MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography (see Sections 354(h) through (j) of the Act, 42 U.S.C. 263b(h)-(j)).

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 all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors) raw test data, and calculated final results where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records.

For example, please include a copy of the most recent processor QC test record (Processing Control Chart) and the most recent phantom QC test record (Phantom Control Chart) with the comment pages. Please also include 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; and a copy of your written procedures for performing the daily processor QC test, including the acceptable limits and procedures for taking and documenting corrective action when the processor exceeds the limits; (Note: Patient names or identification should be deleted from an 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 Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. In the absence of a Level 1 finding, a Level 2 finding indicates that the facility's performance is generally acceptable. However, the inspector found one or more deviations from MQSA standards that may compromise the quality of mammography services offered by the facility. These Level 2 findings are:

Quality Assurance – Equipment – 21 CFR 900.12(e)(8)(ii): Your records revealed that your facility failed to document corrective actions on the [redacted] model [redacted] mammography system in the mammo room, before further exams. For example, your records showed that the phantom background optical density or density difference were charted outside the regulatory limits on February 19, 2002 and March 4, 11, and 18, 2002.

Quality Assurance – Equipment – 21 CFR 900.12(e)(8)(ii): Your records revealed that your facility failed to document corrective actions on the [redacted] model [redacted] 301, processor in the darkroom, before processing mammography films. For example, your records showed that the medium (mid) density and/or density difference were charted outside the regulatory limits on the dates noted above and that corrective action was not documented for these dates.

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
District Director
New England District Office

cc:

[redacted]