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

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781)596-7896

WARNING LETTER

NWE-20-02W

VIA FEDERAL EXPRESS

June 24, 2002

Paul Martland
President
Hubbard Regional Hospital
340 Thompson Rd.
Webster, MA 01570

Dear Mr. Martland:

We are writing to you because on May 17, 2002, your mammography facility, located at Hubbard Regional 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), 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 violation, which was identified as Level 1 on the MQSA Facility Inspection Report that your facility received at the close of the inspection:

- Your records revealed that mammograms were processed in the [redacted] mammography processor, when it was out of limits on at least 5 days. [21 CFR 900.12(e)(1)(ii) & (iii)]

During the inspection, the inspector observed that the processor was used to process mammograms on seven (7) days in November 2001 when the control chart showed that the processor was operating outside the regulatory limits for density difference and/or medium (mid) density. The dates observed were:

November 7, 2001 density difference and mid density
November 8, 2001 mid density
November 9, 2001 density difference and mid density
November 12, 2001 mid density
November 13, 2001 density difference and mid density
November 14, 2001 mid density
November 21, 2001 mid density

This condition is Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law that may result in FDA initiating regulatory action without informal 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, 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 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. (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 Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Your records revealed that your facility failed to document corrective actions before further exams, for a failing background optical density or density difference outside the allowable regulatory limits, on the [redacted] Contour mammography system in the mammo room. [21 CFR 900.12(e)(8)]

  During the inspection, the inspector observed that the processor was used to process mammograms on twenty-three (23) days when the phantom background optical density or density difference were charted outside the regulatory limits. The dates observed were:

  June 4 and 11, 2001 density difference
  August 13, 2001 density difference
  September 4, 10, 17 and 24, 2001 background optical density
  October 1, 2001 background optical density
  October 16, 2001 density difference and background optical density
  November 12 and 26, 2001 density difference and background optical density
  December 3, 10, 17, 24 and 31, 2001 density difference and background optical density
  January 21, 2002 density difference and background optical density
  January 29, 2002 background optical density
  February 4, 2002 density difference and background optical density
  February 11, 2002 density difference
  March 18, 2002 density difference and background optical density
  April 8, 2002 density difference
  April 22, 2002 density difference (background optical density was not charted)

  Your records also revealed that your facility failed to document corrective actions on the [redacted] mammography processor, before processing mammography films. Your records showed that the medium (mid) density and/or density difference were charted outside the regulatory limits on the November 2001 dates noted on page 2 above and that corrective action was not documented. Service records were available for November 9 and 30, 2001; however, the failed tests were not repeated to show that the actions taken resulted in test results within the action limits. [21 CFR 900.12(e)(8)]

- Your records revealed that you failed to perform processor equipment evaluations (by a medical physicist) for the [redacted] mammography processor or the [redacted] general x-ray processor. [21 CFR 900.12(e)(10)]

For the [redacted] processor, the chemistry was changed, specific gravity was changed, replenishment rates were changed, a pump was replaced and the developer heater failed, but an equipment evaluation was not performed.

The [redacted] processor, which was used as a backup processor for mammography, was not evaluated prior to its being used as a backup mammography processor.

- Your records revealed that the phantom QC was not adequate on September 4 and 10, 2001 for the [redacted] Contour mammography system in the mammo room because the operating level for background optical density was less than 1.20. Your records showed that the background optical density was 1.12 on both of those days. [21 CFR 900.12(e)(2)(i)]

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:

Ricardo Rosales M.D.
Lead Interpreting Physician
Hubbard Regional Hospital
340 Thompson Rd.
Webster, MA 01570

Kevin McLaughlin
Radiology Manager
Hubbard Regional Hospital
340 Thompson Rd.
Webster, MA 01570