



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

HFI-35

M42787

One Montvale Avenue  
Stoneham, Massachusetts 02180  
(781) 279-1675  
FAX: (781) 279-1742

October 4, 2000

**WARNING LETTER**  
**NWE - 01 -01W**

**VIA FEDERAL EXPRESS**

Mark Lerner, M.D.  
Brigham Radiology Group @ Newton Corner  
272 Centre Street  
Newton, MA 02158

Re: Inspection ID: 2228910001

Dear Dr. Lerner,

We are writing to you because on September 8, 2000, your facility was inspected by a representative of the Commonwealth of Massachusetts, acting in 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, 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 findings at your facility:

- **Level 1:** Mammograms were processed in processor 1, [REDACTED] RP X-OMAT M6B,6AN,6AW, room MAIN at site Brigham Radiology Group @ Newton Corner, when it was out of limits on 5 days.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 1, because it identifies a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious 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, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

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 findings are:

- **Level 2:** Corrective actions for processor QC failures were not documented at least once for processor 1, [REDACTED], RP X-OMAT M6B,6AN,6AW, room MAIN at site Brigham Radiology Group @ Newton Corner.
- **Level 2:** Corrective action for a failing image score (before further exams) was not documented for unit 1, [REDACTED] OTH, room MAMMO.

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:

Michael J. Leal  
MQSA Auditor  
U.S. Food & Drug Administration  
120 Front St., Suite 680  
Worcester, MA 01608  
Phone: (508) 793-0422  
FAX: (508) 793-0456

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 more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Leal at the above phone number.

Sincerely yours,



Gail T. Costello  
District Director  
New England District Office

cc:

Robert Hallisey  
Director, Radiation Control Program  
Department of Public Health  
174 Portland St, 5<sup>th</sup> Floor  
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cc:

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