



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration  
158 - 15 Liberty Avenue  
Jamaica, New York 11433

WARNING LETTER

November 16, 2000

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

REF: NYK-2001-18

Mayer J. Saad, M. D.  
Chief Executive Officer (CEO)  
372 Post Avenue  
Westbury, New York 11590

Facility ID: #218065

Dear Dr. Saad:

Your facility was inspected on November 6<sup>th</sup>, 2000 by a representative of the Nassau County Dept. of Health, acting on behalf of the Food & Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography operation at your facility. Under a United States Federal Law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for conducting a mammography operation. These requirements help protect the health of women by assuring that a facility can perform quality mammography procedures. The inspection revealed the following repeat Level 2 findings at your facility:

1. *Processor QC records were missing one (1) out of four (4) days of operation in the month of 01/2000 {25%}, for the Kodak, RP X-OMAT M6B, 6AN, 6AW Processor.*
2. *Phantom QC records were missing for at least two weeks but less than four weeks for unit 1, Bennett X-Ray Corp., in the Mammography Room.*

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. These problems are identified as repeat Level 2, because they identify failures to meet significant MQSA requirements and indicate failure by your facility to implement permanent correction for problems found during your pervious inspection.

Handwritten note: 10/20/00

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Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography operations at your facility, they represent violations 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 operations.

In addition, your response should address the repeat Level 3 finding that was listed on the inspection report provided at the close of the inspection. The repeat Level 3 finding was:

- 1. The repeat analysis QC is not adequate for your facility because the QC was not done at the required frequency.*

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violations noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations; and
- Sample records that demonstrate proper record keeping procedures.

Please submit your response to the attention of Arthur S. Williams, Jr., Compliance Officer, U. S. Food & Drug Administration, 158 – 15 Liberty Avenue, Jamaica, New York 11433, Tel. (718)/340-7000, Ext. 5568.

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Finally, you should understand that there are many FDA requirements pertaining to a mammography operation. This letter pertains only to findings of our 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 & Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057, 1(800)/838-7715, or through the Internet address at <http://www.fda.gov>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'E. Thomas', with a long horizontal flourish extending to the right.

Edward W. Thomas,  
Acting District Director  
New York District