



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

m319m

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

November 16, 1999

REF: NYK-2000-10

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mayer J. Saad, M.D.
372 Post Avenue
Westbury, New York 11590

Facility ID: 218065

Dear Dr. Saad:

Your facility was inspected on October 18, 1999 by a representative of the Nassau County Dept. of Health, 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.

1. *Processor QC records were missing on all 3 days of operation in September 1999, or 100% of the time, for the [REDACTED] processor.*
2. *Processor QC records were missing on 9 consecutive days for the [REDACTED] processor.*
3. *Phantom QC records were missing for 12 weeks for the [REDACTED] mammographic x-ray unit.*

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 Level 1 because they identify failures to meet significant MQSA requirements.

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Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography 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.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided at the close of the inspection. The Level 2 finding is:

The radiologic technologist, [REDACTED], did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36 month period.

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 received 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.

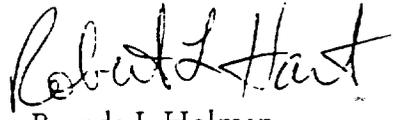
Please submit your response to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232, Tel. (718) 340-7000, ext. 5142.

Finally, you should understand there are many FDA requirements pertaining to mammography. 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 and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

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If you have any questions about mammography facility requirements in general, please feel free to contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely yours,



Brenda J. Holman
District Director

