



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

October 23, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF : NYK-2001-10

Marvin Weingarten, MD
Medical Director of Diagnostic Imaging
Yorktown Diagnostic Imaging
225 Veterans Road
Yorktown Heights, New York 10598

Facility ID : 194431

Dear Dr. Weingarten:

Your facility was inspected on September 18th, 2000 by a representative of the New York State Department of Health, acting on behalf of the Food & Drug Administration. This inspection has revealed serious regulatory problems 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. *Interpreting Physician (██████████) did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6 month period).*
2. *Interpreting Physician (██████████) did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.*
3. *Interpreting Physician (██████████) did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.*

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 of problems found during your previous inspection.

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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.

There were also non-repeat Level 2 findings that were listed on the inspection report provided to you at the close inspection. These Level 2 findings were:

1. *Interpreting Physician (██████████) did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.*
2. *Four (4) of six (6) randomly reviewed reports did not contain an assessment category for the Yorktown Diagnostic Imaging site.*

In addition, there was also one (1) 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 required personal qualification documents were unavailable during the inspection.*

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 of records that demonstrate proper record keeping procedures.

Please submit your response to the above issues 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)/662-5568.

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Finally, you should understand that there are many FDA requirements pertaining to a mammography. This letter pertains only to the 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 of <http://www.fda.gov>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert L. Hart". The signature is written in a cursive style with a large, prominent initial "R".

Robert L. Hart
Acting District Director
New York District