



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

October 20, 1999

REF: NYK-2000-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James DeLuca, M.D.
530 Old Country Road
Westbury, New York 11590

Facility ID: 151142

Dear Dr. DeLuca:

Your facility was inspected on September 21, 1999 by a representative of the Nassau County Department of Health, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed serious regulatory problems 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. Phantom Q.C. records were missing for 6 weeks for unit #1 manufactured by [REDACTED]

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 requirements.

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 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.

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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. The level 2 findings are:

1. *A medical physicist's survey has not been conducted for x-ray unit #1, manufactured by [REDACTED], located in the Mammo Room within the last 14 months.*
2. *The medical physicist, [REDACTED], did not meet the requirement of conducting surveys for at least one facility and 10 units.*
3. *The medical physicist also failed to meet the requirement of having a minimum of 20 contact hours of training in conducting surveys.*

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 receive 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; 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,


for Brenda J. Holman
District Director