



DEPARTMENT OF HEALTH & HUMAN SERVICES

6182

New York District

Food & Drug Administration
158 - 15 Liberty Avenue
Jamaica, New York 11433-1034

WARNING LETTER

February 14, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-2001-45

Howard Gelber, M.D.
Director, Radiation Safety Officer (RSO)
Long Island Radiology Associates, P. C.
227 Franklin Avenue
Hewlett, New York 11557

Facility ID: #120956

Dear Dr. Gelber:

Your facility was inspected on February 2nd, 2001, by a representative of the Nassau County Department of Health, Office of Radiological Health, acting on behalf of the U. S. Food & Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography operations at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography operations. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following repeat Level 2 noncompliance finding at your facility:

1. *One (1) of five (5) random reports reviewed did not contain an assessment category for the site.*

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 was identified as a repeat Level 2 noncompliance because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography operations and service at your facilities, it represents a violation of the law which may result in *FDA* taking regulatory action without further notice to you.

Long Island Radiology Associates, P. C. – February 14, 2001

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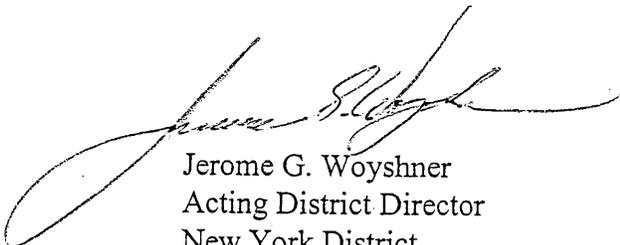
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These actions include, but are not limited to placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply 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.

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

Please submit your response to the above issues to this office in writing within fifteen (15) working days from the day you received this letter. Your response should be sent to the attention of Arthur S. Williams, Jr., Compliance Officer, U. S. Food & Drug Administration (FDA), 158 - 15 Liberty Avenue, Jamaica, New York 11433-1034, Tel.: (718)/662-5568.

Sincerely yours,



Jerome G. Woysner
Acting District Director
New York District