DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

October 28, 2002

WARNING LETTER NYK 2003-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Azad K. Anand, M.D.
Radiation Safety Officer
Long Island Diagnostic Imaging
100 Lafayette Drive
Syosset, New York 11791

RE: Facility ID Number 141341

Dear Dr. Anand:

A representative of the Nassau County Department of Health, acting on behalf of the United States Food and Drug Administration (FDA), conducted an inspection of your facility on September 25, 2002. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, 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 finding at your facility:

- ***Processor QC records for the [redacted] processor were missing in the month of September 2002 for at least 30% of the operating days. Processor QC records were missing for 9/4, 10, 17, 18, and 24 (see 21 C.F.R. 900.12(e)(1)).***

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 requirement.

This condition represents a violation of the law, which may result in FDA taking regulatory action against 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.

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 that you receive this letter each step your facility is taking to correct this violation and to prevent the recurrence of similar violations.

In addition, your response should address the Level 2 observations listed on the inspection report. The Level 2 observations noted include the following:

- ***Processor QC records were missing on at least 2 consecutive days for the [redacted] processor (see 21 C.F.R. 900.12(e)(1)).***

- ***Failure to produce documents verifying that the interpreting physician [redacted] met the initial experience requirement of having interpreted 240 mammograms in a six month period (21 C.F.R. 900.12(a)(1)(i)(D)).***

- ***Failure to conduct a medical audit and outcome analysis for the facility as a whole (see 21 C.F.R. 900.12(f)(1)).***

- ***Failure to conduct a medical audit and outcome analysis separately for each individual interpreting physician at the facility (see 21 C.F.R. 900.12(f)(1)).***

- ***Failure to conduct a medical audit and outcome analysis annually (see 21 C.F.R 900.12(f)(2).***

Please submit your response to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, NY 14202, telephone (716) 551-4461 ext. 3117.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your 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.

Sincerely,

Andy Mroczkowski

for Jerome G. Woyshner
District Director