DEPARTMENT OF HEALTH & HUMAN SERVICES 93321d

New York District

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

May 24, 2002

WARNING LETTER NYK 2002-32

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Richard H. Hamilton, M.D.
Executive Health Medical Group
of New York, P.C.
10 Rockefeller Center
4th Floor
New York, New York 10020

RE: Facility ID Number 186551

Dear Dr. Hamilton:

Your facility was inspected on April 8, 2002 by a representative of the New York City Department of Health, acting on 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, 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 findings at your facility:

- ***Processor quality control (QC) records were missing for at least 30% of the operating days in the month of August 2001 (e.g. no processor QC records exist for 8/1, 2, 3, 9, 10, 21, 23, 24, 27-31/01) (see 21 C.F.R. 900.12(e)(1)).***

- ***Processor QC records were missing for at least five (5) consecutive days in the month of August 2001 (e.g. no processor QC records exist for 8/27-31/01) (see 21 C.F.R. 900.12(e)(1)).***

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 represent a failure to meet significant MQSA requirements.

These conditions 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.

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 these violations and to prevent the recurrence of similar violations. Your response should include documents that demonstrate proper record keeping.

In addition, your response should address the Level 2 and repeat Level 3 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 and repeat Level 3 findings are:

- *Failure to establish and/or follow adequate procedures for infection control (Repeat Level 2) (see 21 C.F.R. 900.12(e)(13))*
- *Failure to establish and/or follow adequate written procedures for collecting and resolving consumer complaints (Repeat Level 2) (see 21 C.F.R. 900.12(h)).*
- *Failure to document corrective action for a failing phantom image score, a phantom background optical density outside of acceptable limits, or a phantom density difference outside of acceptable limits before performing further mammography examinations (see 21 C.F.R. 900.12(e)(8)(ii)).*
- *Failure to produce documents verifying the radiologic technologist, [redacted] met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months (see 21 C.F.R. 900.12(a)(2)(iii)).*
- *Failure to produce documents verifying that the radiologic technologist, [redacted], met the continuing experience requirement of having performed 200 mammography examinations in 24 months (see 21 C.F.R. 900.12(a)(2)(iv)).*
- *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 at the facility (see 21 C.F.R. 900.12(f)(1)).*
- *Failure to conduct a medical audit and outcome analysis annually at the facility (see 21 C.F.R. 900.12(f)(2)).*
- *Failure to obtain, or attempt to obtain, biopsy results (see 21 C.F.R. 900.12(f)(1)).*
- *Failure to have an adequate quality assurance (QA) program in that the QA program fails to list personnel responsibilities (see 21 C.F.R. 900.12(d)(1)).*
- *Failure to have personnel qualification documents available during the inspection (see 21 C.F.R. 900.12(a)(4)).*

Please submit your response to the above issues 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,

Jerome G. Woyshner
District Director