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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

February 17, 2000

WARNING LETTER NYK 2000-35

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Cheryl Byk, M.D.  
Gramercy Radiology Group, P.C.  
201 East 19th Street  
New York, New York 10003

RE: Facility ID Number 114421

Dear Dr. Byk:

Your facility was inspected on February 7, 2000 by a representative of the New York City Bureau of Radiological Health acting in behalf of the Food and Drug Administration. This inspection revealed a serious regulatory problem 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 finding at your facility:

- *The system to communicate results is not adequate because:*
  - *there is no system in place to provide timely medical reports,*
  - *there is no system in place to provide timely lay summaries,*
  - *there is no system in place to communicate serious or highly suggestive of cancer cases as soon as possible.*

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 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; obtaining a court injunction against further mammography.

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

- *The medical physicist's survey for the [REDACTED] x-ray unit is incomplete because an artifact evaluation for the Rh filter was not done (the Inspector also noted the HVL test was not done for the Rh filter).*
- *The radiologic technologist [REDACTED] did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36-month period.*
- *Five of five reports reviewed at random did not contain an assessment category.*
- *There were no examples of, nor attempts to obtain biopsy results.*

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 that you receive this letter:

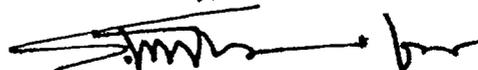
- The specific steps you have taken to correct all of the violations noted in this letter including supporting documentation;
- Each step your facility is taking to prevent the recurrence of similar violations.

Please submit your response to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Olympic Towers, Suite 100, Buffalo, New York 14202.

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>.

If you have any questions about mammography facility requirements, you may contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely,



Brenda J. Holman  
District Director

Gramercy Radiology Group, P.C.  
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cc: Pamela A. Wilcox-Buchalla, R.N., M.B.A.  
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cc: Dorothy Pender  
New York City Bureau of Radiological Health  
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cc: James Sheffield  
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