



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

91023d

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

WARNING LETTER

March 21, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-2001-53

Myong Choi, M.D.
Radiologist/ Lead Interpreting Physician
Queens Open MRI
164 - 25 Northern Boulevard
Flushing, New York 11358

Facility ID: #214700

Dear Dr. Choi:

Your facility was inspected on March 7th, 2001 by a representative of the New York City Department of Health, Bureau of Radiological Health, acting on behalf of the U. S. Food & Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography operation 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 procedures. The inspection revealed the following Level 1 noncompliance finding at your facility:

- 1. Phantom QC records were missing for at least four (4) weeks for unit #1, General Electric, Co., (GE Medical Systems), in room #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 a Level 1 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 at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you.

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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.

There were also several Level 2 noncompliance findings that were listed on the inspection report provided at the close of the inspection. Those Level 2 noncompliance findings were:

1. *Processor QC records in the month of 12/2000 were missing for at least 10%, but less than 30% of operating days for processor, Konica (Sakura) in the darkroom.*
2. *Processor QC records were missing at least 2 but less than 5 consecutive days for processor Konica (Sakura) in the darkroom.*
3. *Your facility failed to produce documents verifying that the Interpreting Physicians, Alan Berlly and Elizabeth Lazzara, met the initial requirement of having 40 hours of medical education in mammography prior to 04/28/99.*
4. *Failure to produce documents verifying that the Interpreting Physicians, Elizabeth Lazzara & Allen Rothpearl, met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months.*
5. *Your facility failed to produce documents verifying that the Interpreting Physician, Allen Rothpearl met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.*
6. *Two (2) of ten (10) random reports reviewed did not contain an acceptable assessment category.*

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 you receive this letter:

- *The specific steps you have taken to correct the violation noted in this letter;*
- *Each step your facility is taking to prevent the recurrence of similar violations; and*

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- *Sample records that demonstrate proper record keeping procedures.*

Please submit your response to the above issues 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.

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, U. S. Food and 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>.

Sincerely yours,



Jerome G. Woysner
Acting District Director
New York District