DEPARTMENT OF HEALTH & HUMAN SERVICES 937384

New York District

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

December 11, 2002

WARNING LETTER NYK 2003-08

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Harry Stulbach, M.D.
Metropolitan Hospital Center
1901 First Avenue
Room 202
Department of Radiology
New York, New York 10029

RE: Facility ID Number 125146

Dear Dr. Stulbach:

A representative of the New York City Department of Health, acting on behalf of the United States Food and Drug Administration (FDA), conducted an inspection of your facility on November 14, 2002. This inspection revealed a serious compromise in the quality of the mammography services offered by 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:

- ***Phantom quality control records (as required by 21 C.F.R. 900.12(e)(2)) for the [redacted] mammography units in Rooms 1 and 2 were missing for at least four weeks in the month of October 2002. No phantoms were performed during the month of October 2002.***

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 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, seeking civil money penalties, suspension or revocation of your facility's FDA certificate, or seeking 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.

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 concerns only the findings of your recent 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

cc: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Program
American College of Radiology
1891 Preston White Drive
Reston, VA 22091

cc: Dorothy Pender
New York City Department of Health
Office of Radiological Health
2 Lafayette Street, 11th Floor
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cc: Ceferina Ramos
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