DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

94991d

WARNING LETTER

September 28, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Re: MQSA Inspection I.D.: #225629
FEI: #3003469556

Leon Nitkin, M. D.
Owner
Metrotech Medical, Inc.
1120 Brighton Beach Avenue / Suite #1
Brooklyn, New York 11235

Re: NYK-2004-28

Dear Dr. Nitkin:

On January 5, 2004, a representative of the City State of New York, acting on behalf of the Food & Drug Administration (FDA) inspected your facility. No response to that inspection was received by this agency. On March 29, 2004, a follow-up letter was addressed and mailed to you at the facility address and once again, no response was received. An FDA follow-up inspection was conducted on June 21, 2004, by FDA Investigator James Wormuth. This follow-up inspection revealed serious problems involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA"), which is codified in Section 263b of Title 42 of the United States Code ("U.S.C."), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography procedures.

These inspections revealed several violations of MQSA at your facility. These violations were noted on both of the MQSA Facility Inspection Reports and the document *"Important Information about Your MQSA Inspection"* that NYC Inspector, Abraham Thomas, and FDA Investigator, James Wormuth mailed to your facility on January 5, 2004 and June 28, 2004.

The violations noted during the first inspection of January 5, 2004, are identified below:

Level 2:

a) A corrective action was not documented before further exams were taken after Unit #2 [redacted] room mammography had a failing image score, a phantom background optical density, or a density difference outside the allowable regulatory limits 21 CFR 900.12 (e)(8)(ii).

b) The medical physicist's survey for x-ray Unit #2, [redacted] room mammography is incomplete because the following tests were inadequate or not performed 21 CFR 900.12 (e)(9):

1) No AEC performance – Reproducibility
   - (Numerical results were not given)

2) No AEC performance capability –
   - (Test not done for 2, 4, and 6 cm phantom thicknesses at typical kVp(s).

On June 21, 2004, a representative of the FDA performed an MQSA follow-up inspection of your facility. This MQSA follow-up inspection revealed that your facility failed to correct the violations identified below:

Level 1:

a) Processor QC records in the month of 06/2004 were missing for at least 30% of operating days, for processor unit #1, [redacted] Dark room at site Metrotech Medical, Inc. 21 CFR 900.12 (d)(2).

b) Phantom QC records were missing for at least four weeks for Unit #2, [redacted], room mammography at site Metrotech Medical, Inc. 21 CFR 900.12 (e)(2).

Level 2 (***Repeat***):

a) The medical physicist's survey for x-ray Unit #2, [redacted] room mammography is incomplete because the following tests were inadequate or not performed ***(Repeat)*** 21 CFR 900.12 (e)(9):

1) No AEC performance – Reproducibility
   - (Numerical results were not given)

2) No AEC performance capability –
   - (Test not done for 2, 4, and 6 cm phantom thickness at typical kVp(s).
   - (Numerical results were not given)

Level 2:

a) Processor QC records were missing for at least two weeks, for processor Unit #1, [redacted] Dark room at site Metrotech Medical, Inc. 21 CFR 900.12 (e)(2).

Level 3:

a) The screen – film contact QC is not adequate for the site Metrotech Medical, Inc. because 21 CFR 900.12 (e)(4)(ii):

- The QC test was not done at the required frequency.

Because the continued failure to resolve these violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review;
- placing your facility under a Directed Plan of Correction;
- charging your facility for the cost of on-site monitoring;
- seeking civil money penalties up to $10,000 for each failure to substantially comply with the MQSA standards;
- seeking to suspend or revoke your facility's FDA certificate.

See 42 U.S.C. 263b (h)-(j) and 21 CFR 900.12 (j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

You should respond in writing to FDA within 15 working days from the date you received this letter. Your response should address the findings listed above and include:

1. the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps; and

3. the sample records that demonstrate proper record keeping procedures.

NOTE: Patient names and/or any other information that would likely reveal the patient's identity should be deleted from any copies of records you submit to the agency.

Finally, you should understand that there are many requirements pertaining to mammography operations. This letter pertains only to violations related to the recent inspections of your facility 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 & Drug Administration, P. O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at: http://www.fda.gov/cdrh/mammography/index.html.

If you have additional or more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Arthur S. Williams, Jr., Compliance Officer, New York District, 158–15 Liberty Avenue, Jamaica, New York 11433–1034 at (718) 662-5568.

Sincerely,

Jerome G. Woyshner
District Director
New York District

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