



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

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

WARNING LETTER

July 17, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-2001-96

Dr. Masood Nejatheim
Radiological Safety Officer (RSO) / Lead Interpreting Physician
Dr. Socrates Demeterio & Dr. Masood Nejatheim
265 East Merrick Road / Suite #102
Valley Stream, New York 11580

Facility ID: #153577

Dear Dr. Nejatheim:

Your facility was inspected on July 11th, 2001, by a representative of the Nassau County Department of Health, Office of Radiological Health, acting on behalf of the U. S. Food & Drug Administration (FDA). This inspection revealed serious regulatory problems involving the mammography operations 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 *repeat* Level 2 noncompliance finding at your facility:

- *The measured fog density is equal to 0.24 for Darkroom #A at this site.*

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 repeat Level 2 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 operations and service 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, or obtaining a court injunction against further mammography operations.

Dr. Socrates Demeterio & Dr. Masood Nejatheim - July 17, 2001

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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 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
- Sample of 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 operations and procedures. This letter pertains only to the 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 & 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,



Edward W. Thomas
Acting District Director
New York District