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Telephone: [718] 965-5300 [Ext 5301]

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

JAN 21 1997

Chandra Ganeshkumar, M.D.
Radiation Safety Officer
University Plaza Radiological Services
877 Stewart Avenue
Suite 2A
Garden City, New York 11530

Re: 28-NYK-97

Dear Dr. Ganeshkumar:

Your facility was inspected on November 25, 1996 by a representative of the Nassau County Department of Health, acting in behalf of the Food and Drug Administration. This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

You are unqualified to interpret mammograms due to the failure to present evidence that you are either certified by any of the approved boards or you have had two months full time training in the interpretation of mammograms.

The specific deficiency noted above appeared under the Level 1 heading of your MQSA Facility Inspection Report, which was issued after the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you after the close of the inspection. These Level 2 noncompliances are:

You presented no evidence that you completed 40 CME hours in mammography as part of your initial training requirements.

You presented no evidence as part of your initial experience requirement that you have read and interpreted mammograms from the examinations of at least 240 patients in a six month period.

You presented no evidence that you are meeting the continuing experience requirement of interpreting an average of 40 patient examinations per month over 24 months.

The measured darkroom fog exceeded 0.05. The measured fog level was 0.13.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.

suspend or revoke a facility's FDA certificate for failure to comply with the Standards.

seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude the County from enforcing its own mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, therefore, you should consider the more stringent County requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

the specific steps you have taken to correct all of the violations noted in this letter;

each step your facility is taking to prevent the recurrence of similar violations; sample records that demonstrate proper recordkeeping procedures, if the noncompliances that were found relate to quality control or other records.

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to me at the above address, and a copy to Mr. Murray L. Kurzman of my staff, at US Food and Drug Administration, 6800 Jericho Tpke., Suite 109E, Syosse., NY 11791. Also, send a copy to the County radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and County requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Mr. Kurzman at (516) 921-2035.

Sincerely yours,

DGF

David G. Field
Acting District Director
U . S. Food and Drug Administration
New York District

DGF:bb