



776 11/17/98

U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

Telephone: [718] 340-7000 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

JAN 3 1998

Azad K. Anand, M.D.
Chief Executive Officer
Lake Success Imaging
444 Lakeville Road
Lake Success, NY 11042

Re: 15-NYK-98

Dear Dr. Anand:

Your facility was inspected on November 25, 1997 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:

The interpreting physician, Dr. [REDACTED] did not meet the requirement of being licensed by a State to practice medicine.

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.

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 deficiency that the inspection identified and promptly initiating corrective action.

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 the violation noted in this letter;

each step your facility is taking to prevent recurrences of similar violations.

If your facility is unable to provide the requested documentation within 15 working days, you should state the reason for the delay and the time within which the correction 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 U.S. Food and Drug Administration, 6800 Jericho Turnpike, Suite 109E, Syosset, 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.

Azad K. Anand, M.D.

Page 3

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,



Brenda J. Holman
District Director
U.S. Food and Drug Administration
New York District

BJH:mlk

cc: Jim Potter

Director, Government Relations
American College of Radiology
1891 Preston White Drive
Reston, VA 22091

cc: James Selock

Nassau County Dept. of Health
240 Old Country Road
Mineola, NY 11501

cc: Gerald O'Connor

New York State Dept. of Health
2 University Place
Albany, NY 12203