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

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

FEB 1 9 1997

Ronald F. Goldstein, M.D.  
265 Middle Country Road  
Smithtown, New York 11787

Re: 34-NYK-97

Dear Dr. Goldstein:

Your facility was inspected on January 22, 1997 by a representative of the Suffolk County Department of Health Services, 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:

**[REDACTED]** is unqualified to interpret mammograms due to the failure to present evidence that he had a currently effective state license to practice medicine. While we have a copy of a January 30, 1997 letter by Jack S. Deitch, M.D. stating that **[REDACTED]** holds a New York State license to practice medicine, we are required to see the license or a photocopy of it to confirm the expiration date. Dr. Deitch's letter makes no mention of this date.

Records indicate that there was no medical physicist survey done for the Lorad x-ray system in over a year.

The specific deficiencies 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 did not meet the continuing experience requirement of interpreting an average of 40 patient examinations per month over 24 months. We have your letter of January 26, 1997 in which you state that you no longer interpret x-ray examinations at this office. Inasmuch as the inspector observed evidence of your name only on mammography reports during 1996, we would like to know when you ceased reading mammograms and when Dr. McGuire or anyone else began. Your January 26 letter is, otherwise, a satisfactory response to this noncompliance.

Dr. McGuire presented no evidence as part of his initial experience requirement that he read and interpreted mammograms from the examinations of at least 240 patients in a six month period prior to reading independently for you. He cannot attest to this, unless it occurred prior to October 1, 1994. You must present documentation of actual numbers read, when and where, or a letter from a facility specifically acknowledging the above.

Dr. McGuire did not present evidence of having the initial training of 40 hours of continuing medical education in mammography. We have a copy of a letter from ACR, dated January 29, 1997 that shows he completed their Breast Diseases II Syllabus that month. However, these credits were earned after he began reading independently for you, whereas this requirement must be met prior. For this reason, the letter from University of Florida showing completion of a review course held April 26-28, 1996 may also not be satisfactory. You may wish to obtain a letter from his residency program wherein they state that this requirement was met during the course of his residency, and the inclusive dates.

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 the letter;

each step your facility is taking to prevent the recurrence of similar violations;

sample records that demonstrate proper record-keeping 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 U. S. Food and Drug Administration, 6800 Jericho Tpke., 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.

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

Sincerely yours,



Charles W. Sedgwick  
Acting District Director  
U. S. Food and Drug Administration  
New York District

CWS:bb

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