



U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 Third Avenue, Brooklyn, New York 11232

717

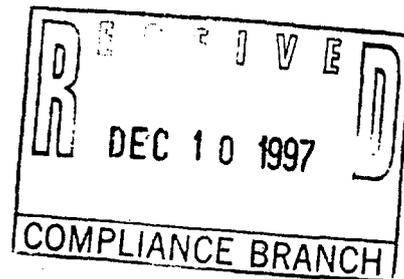
Telephone: [718] 340-7000 Ext. 5301

WARNING LETTER

DEC 09 1997

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Joseph Munley, Administrative Director
St. John's Queens Hospital
90-02 Queens Boulevard
Elmhurst, New York 11373



Re: 9-NYK-98

Dear Mr. Munley:

Your facility was inspected on November 5 and 13, 1997 by a representative of the New York City Bureau of Radiological 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 (MQSA) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

The interpreting physicians, Dr. [REDACTED] and Dr. [REDACTED] did not meet the requirement of being licensed by a State to practice medicine. This deficiency 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 at the close of the inspection. Under Level 2 Repeats, the following appeared:

Interpreting physicians, Drs. [REDACTED], [REDACTED], and [REDACTED] did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months.

Under new Level 2 noncompliances, the following appeared:

Interpreting physicians, Drs. [REDACTED], [REDACTED], and [REDACTED] did not meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a 3 year period (an average of 5 credits/year).

HF I-36
(redacted copy for public display)
12/11/97

In addition, your response should address the Level 3 Repeats that were listed on the inspection report. These are:

Corrective action for processor QC failures were not documented on at least one occasion, for the [REDACTED]. In addition, mammograms were processed at least once in the [REDACTED] with the medium density, or density difference, or base plus fog out of control.

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

If you fail to promptly correct these deficiencies, the FDA may without further notice initiate regulatory action. Under MQSA, the 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 the FDA regulations do not preclude the City from enforcing its own mammography laws and regulations. In some cases, these requirements may be more stringent than the FDA's. When you plan your corrective action, therefore, you should consider the more stringent City requirements, if any.

Within 15 working days after receiving this letter, you should notify the FDA in writing of the specific steps you have taken to correct the violations noted in this letter; each step your facility is taking to prevent a recurrence of similar violations; and, please submit records that demonstrate the interpreting physicians' qualifications, if such records exist. 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 corrections will be completed.

Please send your response to me at the above address, and a copy to Mr. Murray L. Kurzman, at US Food and Drug Administration, 6800 Jericho Turnpike, Suite 109E, Syosset, New York 11791. Also, send a copy to the City radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and City requirements in your response. If you have any questions regarding this letter or how to ensure you are meeting FDA standards, please call Mr. Kurzman at (516) 921-2035.

Sincerely yours,



Brenda J. Holman
District Director

BJH:mlk

- cc: Jim Potter
Director, Government Relations
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091
- cc: Dorothy Pender
New York City Bureau of Radiological Health
2 Lafayette Street
New York, New York 10007