



U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT

850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

443

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

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Morteza Behbahani, M.D.
Director, Radiology
Lutheran Medical Center
150 55th Street
Brooklyn, NY 11220

November 3, 1997

Re: 4-NYK-98

Dear Dr. Behbahani:

Your facility was inspected on September 12, 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 (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 board certified by any of the approved boards, or having 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 at the close of the inspection. These Level 2 noncompliances are:

also, please submit records that demonstrate Drs. [REDACTED] and [REDACTED] qualifications, if such records exist. The records you sent concerning Dr. [REDACTED] interpretations add up to only 839 cases since October 1, 1995. Dr. [REDACTED]' review course for board certification in radiology would not suffice since it would not have included 40 hours devoted to mammography.

With respect to the items concerning Dr. [REDACTED] FDA understands that these records may not be obtainable, but because of their serious nature, FDA is still requesting the above documentation for these violations.

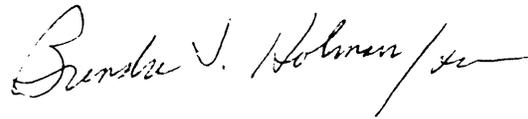
With respect to Dr. [REDACTED] if you cannot document his interpreting 960 cases since October 1, 1995, he will have to requalify by reading 240 examinations within six months under direct supervision of a qualified physician. He cannot read independently until he has completed this task. At the conclusion of this process, the supervising physician will have to prepare a letter acknowledging the successful completion of this task, and send a copy to this office. Any cases Dr. [REDACTED] may have read since September 12 to the present, as well as the cases that were read by Dr. [REDACTED] should be reviewed by a qualified physician. This would give some medical-legal protection to the facility and the physician by assuring that all the cases in question have been reviewed by a physician meeting all MQSA requirements. It would also correct the issue of having an "unqualified" physician signing the original reports.

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 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 Turnpike, Suite 109E, Syosset, NY 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 FDA and City 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,

A handwritten signature in black ink that reads "Brenda J. Holman" followed by a horizontal flourish.

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: Dorothy Pender
New York City Bureau of Radiological Health
2 Lafayette Street
New York, NY 10007