



# U.S. FOOD AND DRUG ADMINISTRATION

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

Telephone: [718] 340-7000 Ext. 5301

## **WARNING LETTER**

November 26, 1997

### **CERTIFIED MAIL** **RETURN RECEIPT REQUESTED**

Matthew Taylor, Assistant Administrator  
Metropolitan Hospital Center  
1901 First Avenue  
New York, New York 10029

Re: 8-NYK-98

Dear Mr. Taylor:

Your facility was inspected on November 17, 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 medical physicist, [REDACTED] did not meet the requirement of being licensed or approved by a State, or being certified by any of the approved boards. The specific deficiency as noted appeared under the Level one 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 the 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 this deficiency, 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.

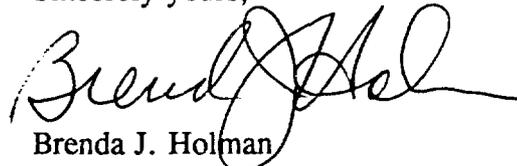
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Please note that the FDA regulations do not preclude the City from enforcing its own mammography laws and regulations. In some cases, these requirements may be more stringent than the FDA's. When you plan your corrective action, therefore, you should 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 violation noted in this letter; each step your facility is taking to prevent a recurrence of a similar violation; or, please submit records that demonstrate Mr. Sajid's 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

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Orig.: Addressee

cc: HFA-224

cc: HFC-210

cc: HFC-240

cc: HFI-35(redacted copy for public display)

cc: HFZ-300

cc: HFZ-240

cc: HFZ-322

cc: HFR-NE1

cc: HFR-NE19

cc: HFR-NE100

cc: HFR-NE140

cc: HFR-NE150

cc: HFR-NE1500

cc: EF (Metropolitan Hospital Center)

cc: circ/chron