

HFI - 35 (redacted copy for public display) 2/25/98



U.S. FOOD AND DRUG ADMINISTRATION

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

T1399M

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

WARNING LETTER

January 26, 1998

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Fouad Lajam, M.D.
Medical Director
Astoria Medical Group
25-35 31st Avenue
Long Island City, NY 11106

Re: 16-NYK-98

Dear Dr. Lajam:

Your facility was inspected on January 12, 1998 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 radiologic technologist, [REDACTED], did not meet the requirement of being licensed by a State or board certified by any of the approved boards. 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.

Under the Level 2 heading, it was observed that [REDACTED] did not have specific training in mammography.

Under the Level 3 Repeat noncompliances heading, the following appeared:

- ◆ No evaluation system for repeat analysis was present;

response adequately addresses all of them, and no further response is required. However, because of the serious nature of the noncompliances, we must issue this warning letter. Please assure that a copy of the response was sent to the City radiation control office that conducted the inspection.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Brenda J. Holman". The signature is fluid and cursive, with the first name "Brenda" being the most prominent part.

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