



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

466 Fernandez Juncos
San Juan, Puerto Rico 00901
787-729-6894

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CERTIFIED MAIL # Z 351 116 169
RETURN RECEIPT REQUESTED

WARNING LETTER
SNJ- 00- 08

April 25, 2000

FACILITY ID # 2160360002

Nancy Mendez, MD
Radiologist
Barranquitas Ultrasound & Mammography Center
Hermandad # 3, P. O Box 989
Barranquitas, Puerto Rico 00794

Dear Dr. Mendez:

Your facility was inspected on April 6, 2000 by a representative of the Puerto Rico Department of Health, Radiological Health Division, on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standard for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Noncompliance Level 1

Mammograms were processed in processor # 1, Kodak, RP X-OMAT M7, M7A' M7B, Darkroom Processor at this site when it was out of limits, on 13 days.

Phantom Q.C records were missing for 12 weeks, for unit 1, Fisher Imaging Corporation, Room Mammography.

Noncompliance Level 2

The X- ray system for unit 1, Fisher Imaging Corp., ATH, Room mammography does not include, image receptor and moving grids for two sizes.

There is no written procedure for handling consumer complaints at this Barranquitas clinic.

There is no written procedure for infection control at this Barranquitas clinic.

Corrective actions for processor QC failures were not documented at least once for processor 1, Kodak, RP X-Omat M7, M7A, M7B, room Darkroom at site Barranquitas Mammography Center.

A Medical Physicist's Survey has not been conducted for x-ray unit 1, Fisher Imaging Corp., ATH, Room Mammography within the last 14 months.

Failure to have documentation that the technologist, [REDACTED] meets the continuing education requirement of having completed a minimum of 15 credits in mammography in a 36-month period. (0 CEU's in 36 months).

The specific deficiencies noted above appeared on the List of Observations, which was issued to your facility on April 6, 2000. These deficiencies are 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 FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

If you fail to properly address 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 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 a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Barranquitas Ultrasound & Mammography Center

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Your reply should be directed to Carlos I. Medina, Compliance Officer, U.S. Food and Drug Administration, 466 Fernandez Juncos Avenue, San Juan, Puerto Rico 00901, telephone (787) 729-6894, extension 2110.

Sincerely,

A handwritten signature in cursive script that reads "Mildred R. Barber".

Mildred R. Barber
District Director

cc: Puerto Rico Department of Health, Radiological Health Division