

**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED

May 30, 2000

WARNING LETTER
SJN-00-14**FACILITY ID # 1000526690**

German Chavez, MD
Interpreting Phycician
Caribbean Imaging & Radiation Treatment Center
2225 Ponce By Past, Parra Building Suite 103-105
Ponce, Puerto Rico 00731-7779

Dear Dr. Chavez:

Your facility was inspected on April 14, 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

Phantom QC records were missing for 12 weeks, for unit 1, phillips Medical Systems Inc., OTH, mammography room.

Noncompliance Level 2

The processing speed (using the S.T.E.P. procedure) is greater than or equal to 65, but less than 80 for standard processing: processor 0000000001, Kodak, RP X=OMAT m6B, 6An, 6AW, room mammo at site Caribbean Imaging & Radiation Treatment Center, Inc.

There is no written procedure for handling consumer complaints site Caribbean Imaging & Radiation Treatment Center, Inc.

There is no written procedure for infection control at site Caribbean Imaging & Radiation Treatment Center, Inc.

The specific deficiencies noted above appeared on the List of Observations, which was issued to your facility on April 14, 2000. These deficiencies are symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

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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.

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,



Mildred R. Barber
District Director

cc: Puerto Rico Department of Health, Radiological Health Division