



FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

WARNING LETTER
SJN-97-02

January 28, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Edna Berrios, M.D.
Supervisor
Dept. de Radiologia Digital
Hospital Hermanos Melendez
Box 306
Bayamón, Puerto Rico 00621

Dear Dr. Berrios:

Your facility was inspected on November 15, 1996 by a representative of the Commonwealth of Puerto Rico, Department of Health, acting in behalf of the Food and Drug Administration (FDA). 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 is unqualified to interpret mammograms due to the lack of both board certification from any of the approved boards and two months full-time training in the interpretation of mammograms: [REDACTED], MD.

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies 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:

The interpreting physician's initial experience was inadequate (reading and interpreting mammograms from the examinations of at least 240 patients in 6 months): [REDACTED], MD.

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 causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct 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 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.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the noncompliances that were found relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

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

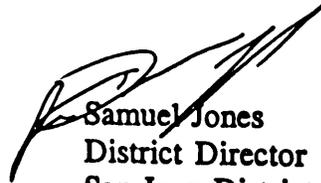
Please send the original copy of your response to John M. Mc Innis, Compliance Officer, Food and Drug Administration, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00901-3223. Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

Edna Berrios, MD
January 28, 1997

3

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call John M. Mc Innis, Compliance Officer at (787) 729-6894.

Sincerely yours,



Samuel Jones
District Director
San Juan District