



July 1, 1998

WARNING LETTER
SJN-98-11

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Teodoro Muñiz
Executive Director
Hato Rey Community Hospital
Ave. Ponce de Leon #435
Hato Rey, Puerto Rico 00917

MQSA ID #: [REDACTED]
CFN : [REDACTED]

Dear Mr. Muñiz:

The Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. 263b(g)(1)(A)) provides for the annual inspection of certified facilities to determine compliance with the Quality Standards established under subsection (f) of the MQSA. An Annual inspection of your facility was conducted on October 26, 1995. When a representative of the Commonwealth of Puerto Rico's Health Department contacted your facility to schedule an annual inspection in October of 1996 and March of 1997, he was informed that your facility ceased performing mammography examinations or procedures on or before October of 1996.

On April 28, 1998, MQSA Inspector Jorge Martinez of the Food and Drug Administration (FDA), San Juan District, conducted an annual inspection of your facility. Mr. Martinez' inspection revealed that your facility had been performing mammography examinations or procedures continuously between the time of the October 26, 1995 annual inspection and September 1997 without having undergone an annual inspection.

The inspection revealed that your facility failed to comply with the minimum Quality Standards for mammography, as specified in 42 U.S.C. 263b(f) and Title 21 of the Code of Federal Regulations (CFR), Section 900.12, including, but not limited to, the following:

Quality Assurance - Equipment (21 CFR 900.12(d)(1))

There was no documentation available to substantiate that:

- 1) processor Quality Control (QC) tests were performed between August 1996 and

Mr. Teodoro Muñiz
July 1 1998
page 2

June 1997 although mammograms were taken during that time period. In addition, when QC test results for Middle Density (MD) and Density Difference (DD) were out-of-limits 50% of the time in July, 1997 and 80% of the time, in August, 1997 mammograms continued to be processed.
(21 CFR 900.12(d)(1)(i))

- 2) QC tests were performed and charted or recorded for the following: darkroom fog, screen film contact, fixer retention analysis and compression.
(21 CFR 900.12(d)(1)(i))

Quality Assurance - [REDACTED] (21 CFR 900.12(d)(2))

There were only two [REDACTED] QC charts present for 1996 or 1997; one chart for July 1996 and one for August 1996, both charts were incomplete or showed problems performing the test. (21 CFR 900.12(d)(2))

Quality Assurance - Clinical Images (21 CFR 900.12(d)(3))

There was no documentation available to substantiate that repeat analysis was performed. (21 CFR 900.12(d)(3)(i))

Quality Assurance - Clinical Image Interpretation (21 CFR 900.12(d)(4))

There was no documentation available to substantiate that a system for collecting and reviewing medical outcome data and correlating pathology results, or for tracking of positive mammograms was in place. (21 CFR 900.12(d)(4))

Quality Assurance - Surveys (21 CFR 900.12(d)(5))

There was no documentation available to substantiate that corrective actions were taken when requested in the medical physicist's survey report. (21 CFR 900.12(d)(5))

The June 27, 1997 Mammography Equipment Evaluation Report failed to document the evaluation of the technologist's QC testing or of the Quality Assurance Program.
(21 CFR 900.12(d)(5))

Mr. Teodoro Muñiz
July 1, 1998
page 3

This letter is not intended to be an all-inclusive list of the deficiencies found at your facility. Within 15 working days after receiving this letter, you should notify FDA in writing of:

- * the specific steps you have taken to correct the deficiencies identified in this letter;
- * each step that your facility is taking to prevent the recurrence of similar deficiencies
- * sample records that demonstrate that proper recordkeeping procedures, if the deficiencies that were found relate to quality control, or other records (Note: Patient names or identification should be deleted from any copies submitted); and
- * your future plans for conducting mammography.

Please send your written response to:

Mary L. Mason, Compliance Officer
Food and Drug Administration
466 Fernandez Juncos Ave.
San Juan, Puerto Rico 00901-3223.

FDA's investigational findings demonstrate that your facility has engaged in serious violations of the MQSA. FDA may, without additional notice, initiate further regulatory action(s) such as:

- * imposing a directed plan of correction which affords a facility an opportunity to correct deficiencies in a timely manner
- * assessing civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day on which a facility fails to substantially comply with the Quality Standards.
- * suspending or revoking a facility's certificate for failure to comply with the Quality Standards
- * seeking an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health

Mr. Teodoro Muñiz
July 1, 1998
page 4

If you have any questions regarding this letter or your response, please call Ms. Mason at (787)-729-6894.

Sincerely,



Samuel Jones
District Director

cc: Tulio Ortiz, M.D.
Director of Radiology

[REDACTED]

Mr. David Saldaña
Director Radiological Health Division
Commonwealth of Puerto Rico
Department of Health
Office of the Secretary
Call Box 70814
San Juan, Puerto Rico 00936

Mr. Charles Showalter
Director Government Relations
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091