



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
San Juan District
Compliance Branch
466 Fernandez Juncos Ave.
San Juan, PR 00901-3223

Telephone: 787-729-6894
FAX: 787-729-6658

August 25, 1999

WARNING LETTER
SJN-99-14

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Andre Galiber, M.D.
Radiologist
Island Medical Center
4500 Sion Farm
P. O. Box 1490
St. Croix, USVI 00821

MQSA ID #2016160005
CFN: 2620085

Dear Dr. Galiber:

We are writing to you because on August 2, 1999, your facility was inspected by Investigator Jorge Martinez of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirement for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 finding at your facility:

Quality Assurance – Equipment [21 CFR 900.12(d)(1)]

Processor¹ Quality Control (QC) tests during the periods of 4/17-30 and 5/1,3-10/99 showed that both the Density Difference (DD) and Mid Density (MD) were out of the established Optical Density ranges. (2.06 ± 15 and 1.29 ± 15 OD for the DD and MD respectively). No corrective action was taken and the processor was used to develop at least 69 mammography films during the period.

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The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 1, because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQAS standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 and 3 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 and 3 findings are:

- Level 2 - There was no documentation available to substantiate that corrective actions were taken to correct the processor's QC failures.
- Level 3 - The screen-film contact QC is not adequate in that,
Not all mammography cassettes in use are tested.
There was no documentation available to substantiate corrective action.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date that you received this letter:

- The specific steps you have taken to **correct** all of the violations noted in this letter;
- Each step you 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 findings relate to quality control or other records (**Note: Patient names or identification should be deleted from any copies submitted**).

Please submit your response to:

Daniel Gonzalez
Director, Compliance Branch
Food and Drug Administration
466 Fernandez Juncos Ave.
San Juan, Puerto Rico 00901-3223
Tel. (787) 729-6894
Fax (787) 729-6658

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations

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you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P. O. Box 6057, Columbia, MD 21045-6057 (1-800-7715) or through the Internet at <http://www.fda.gov>.

If you have more specific question about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Gonzalez at (787) 729-6894.

Sincerely,



Mildred R. Barber
District Director