DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOOD & DRUG ADMINISTRAT
466 FERNANDEZ JUNCOS AV
SAN JUAN, P.R. 00901-3223

May 15, 2003

WARNING LETTER
SJN-03-10

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Francisco C. Vargas
Lead Interpreting Physician
Hospital Episcopal Cristo Redentor
Guayama, PR 00785

FACILITY ID #2215890003
FEI: 3000209516

Dear Dr. Vargas:

On 2/28/03, a representative of the Commonwealth of Puerto Rico, acting on behalf of the Food and Drug Administration (FDA), inspected your mammography facility, Hospital Episcopal Cristo Redentor, located in Guayama, P.R. This inspection revealed a significant regulatory problem involving the mammography at your facility. Under United States federal law, the Mammography Quality Standards Act (MQSA) of 1992 [42 U.S.C. 263b], your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA at your facility. These violations were noted on the MQSA Facility Inspection Report and the document "Important Information about Your MQSA Inspection" that the inspector left with your facility management at the close of the inspection. The violations are again identified below.

Level 1: Your film processor, brand [redacted] model [redacted] Room Processor failed the daily quality control test (aka: performance test) for either the high-low density difference or mid-density established operating levels [21CFR900.12(e)] during dates June18, 2003, August 13, 2003, August 22, 2003, August 23, 2003August 27, 2003, August 29, 2003, and August 30, 2003. You failed to use these results appropriately [21CFR 900.12(e)(8)].

During the inspection, the inspector observed that the high-low density difference (HLDD) and mid-density (MD) established operating levels were [redacted] and [redacted] respectively. These values give an upper HLDD operating level of [redacted] and an MD of [redacted]. The inspector documented that during the above dates your HLDD operating level was above [redacted] and a MD above [redacted]. You failed to identify the source of the problem and take appropriate corrective action. This rendered this processor to be out of specification for both the HLDD and MD requirements. You further performed examinations to women patients using this unqualified processor. Your actions were in violation of **21CFR 900.12(e)(8)(ii)(A).**

Level 2: You failed to perform the annual quality assurance-mammography medical outcomes audit to ensure that the mammography assessment of all physicians working in your firm correlate with the interpreting physician's assessment [21CFR900.12(f)].

The inspector found that your facility has been operating for over twelve months after becoming certified, but you failed to perform the quality assurance-mammography medical outcomes audit, either as a whole facility or separately, for each physician working at your facility. This failure constitutes a violation of **21CFR 900.12(f)(1)**.

You have failed to respond to the MQSA Facility Inspection Report as requested in the document "Important Information about your MQSA Inspection."

Because the continued failure to resolve ~~this~~ (these) violation(s) may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review
- placing your facility under a Directed Plan of Correction
- charging your facility for the cost of on-site monitoring
- seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards
- seeking to suspend or revoke your facility's FDA certificate
- seeking a court injunction against your facility.

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

If you choose to respond to the above violations, your response should include:

1. the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps;

3. equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and sample records that demonstrate proper record keeping procedures.

Please submit your response to Food and Drug Administration, Attention: Mr. Andres Toro, Acting Director of Compliance Branch, at 466 Fernandez Juncos Avenue, San Juan, P.R. 00901-3223.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings disclosed during the inspection of your facility and does not necessarily address other obligations 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- 838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

If you have technical questions about mammography facility requirements contact Mr. Jorge Martinez, MQSA Specialist, or about the content of this letter, please feel free to contact Mr. Jose F. Pedró, Acting Compliance Officer at 787-474-9550.

Sincerely,

5/21/03

Donald J. Voeller
District Director

Enclosure: MQSA Facility Inspection Report

CC:

Mayra Toro
Director, Radiological Health Division
Puerto Rico Department of Health
P.O. Box 70184
San Juan, PR 00936-8184

Priscilla F. Butler, M.S., FAAPM
Director, Breast Imaging Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091