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Food and Drug Administration
Rockville MD 20857

DEC 2 1999

Transmitted via Facsimile and
Certified Mail - Return Receipt Requested

WARNING LETTER

Mr. Julio Andino-Rodriguez
Hospital Administrator
Ponce University Hospital
Carretera #14 Bo. Machuelo
Ponce, Puerto Rico 00731

Re: MQSA Facility ID# 214270
CFN 2620029

Dear Mr. Andino-Rodriguez:

Investigator Jorge Martinez of the Food and Drug Administration (FDA), San Juan District, visited your facility on September 21, 1999. The purpose of his visit was to investigate a complaint referred to the FDA alleging that Ponce University Hospital (Ponce) was conducting mammography without performing the required quality control tests and quality assurance procedures. The Mammography Quality Standards Act of 1992 (MQSA) provides that no facility may conduct examinations or procedures involving mammography after October 1, 1994, unless the facility obtains an FDA certificate (42 USC 263b(b)(1)(A)) and meets and maintains quality standards for personnel qualifications, equipment quality assurance programs, and record keeping and reporting.

During the September 21, 1999 visit, Mr. Martinez met with Mr. Jorge Ortiz, X-Ray Department Administrator. Mr. Martinez asked to see and review the quality control records since the date of the last MQSA inspection, May, 4, 1999. Mr. Ortiz informed Mr. Martinez that all matters relating to MQSA quality control were the responsibility of [] a consultant.

Investigator Martinez returned to your facility on October 1, 1999 to conduct a limited-reinspection to review the quality control and quality assurance records. As you are aware, our investigation revealed that your facility failed to comply with the minimum quality standards for the legal operation of a mammography facility. There are also concerns about the integrity of some of the facility's records.

We are aware that on October 8, 1999, you and Mr. Ortiz met with San Juan District Office management. You stated that your facility had voluntarily ceased performing mammography and would not resume mammography services until such time as Ponce corrects all violations and can demonstrate to FDA that it can comply with all of the requirements of MQSA and the final implementing regulations (21 CFR Part 900).

The investigation and re-inspection revealed the following failures to comply with the minimum quality standards for mammography including, but are not limited to:

Personnel Requirements – Radiologic Technologist (21 CFR 900.12(a)(2))

There was no documentation available to substantiate that Radiologic Technologist

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□;

- had met the requirement of being licensed by a State (21 CFR 900.12(a)(2)(i)(A)) or board certified by any of the bodies approved by FDA to certify radiologic technologists (21 CFR 900.12(a)(2)(i)(B)); and
- had, prior to April 28, 1999, qualified as a radiologic technologist under paragraph (a)(2) of the interim regulations of December 21, 1993, or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor (21 CFR 900.12(a)(2)(ii)); and
- had met the continuing education requirements (21 CFR 900.12(a)(2)(iii)).

Quality Assurance – General (21 CFR 900.12(d))

The facility failed to establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility (21 CFR 900.12(d)).

The facility failed to ensure the assignment of responsibility for the quality assurance program and for each of its elements to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties (21 CFR 900.12(d)(1)).

The lead interpreting physician responsible for ensuring that the quality assurance program meets all of the requirements failed to determine that the radiologic technologist assigned to perform the quality assurance program did so adequately (21 CFR 900.12(d)(1)(i)).

The quality control technologist responsible for all the individual tasks within the quality assurance program failed to perform the tasks that were not assigned to the lead interpreting physician or medical physicist. The quality control technologist failed to perform the tasks necessary to meet the requirements of paragraph (e) of this section (21 CFR 900.12(d)(1)(iv)).

Quality Assurance – Equipment (21 CFR 900.12(e)(1))

The facility failed to perform the required daily quality control tests for the film processor during the days when mammography services were performed beginning on or after May 5, 1999:

July 21 – 30	(14 mammography examinations performed)
August 2 – 31	(39 mammography examinations performed)
September 1 – 15	(25 mammography examinations performed)

Quality Assurance – Phantom Images (21 CFR 900.12(e)(2))

The facility failed to perform the required weekly phantom QC tests during the weeks when mammography services were performed beginning on or after May 5, 1999:

July 21 – 30	(14 mammography examinations performed)
August 2 – 31	(39 mammography examinations performed)
September 1 – 15	(25 mammography examinations performed)

As a result of our investigational findings, FDA has serious concerns about the quality of mammography performed by Ponce. FDA normally would have required Ponce undergo an Additional Mammography Review (AMR) conducted to assess the quality of all mammography performed during the affected time period pursuant to 21 CFR 900.12(j)(1). The review would have assessed whether there had been a compromise of quality sufficient to pose a serious risk to human health. If the results of the AMR indicated that the quality of mammography produced by your facility posed a serious risk to human health, FDA would have required your facility to submit a plan for a patient notification program under 42 USC 263b(h)(2) and 21 CFR 900.12(j)(2). However, we are aware that the mammography films are not retained by the facility making the above process impractical. In order to have the mammography films re-read by qualified interpreting physicians and/or repeat the examinations, as necessary, your facility will have to implement a patient and physician notification program. You should provide FDA with a list of qualified interpreting physicians that you propose to have re-read the films for our review and approval.

Your facility agreed to conduct a patient and physician notification program for the time periods when your facility failed to perform the required quality control and quality assurance procedures. FDA is requiring you to notify all of the patients, and their referring physicians, that had mammography examinations performed during:

July 21 – 30	(14 mammography examinations performed)
August 2 – 31	(39 mammography examinations performed)
September 1 – 15	(25 mammography examinations performed)

FDA may require your facility to notify additional patients and physicians based on the findings of our on-going investigation.

To assist you in the notification program, we have enclosed samples of patient and physician notification letters for you to use. We strongly encourage you to closely follow the enclosed samples when you prepare your notification program. FDA will oversee the notification process, including the review and approval of the patient and physician notification letters before you mail them. Therefore, we ask that you share your draft letters with us within 15 working days after receiving this letter, as directed below.

Upon receipt of your proposed letters, we will review them and provide you with our comments by mail or facsimile. Under no circumstances should you send letters to the physicians or to the patients until FDA has reviewed and sent you written approval of the finalized documents. Additionally, FDA will monitor and audit your notification process.

Physician Notification

The following recommendations should be taken into consideration in the preparation and implementation of the physician notification program:

- Each patient's referring physician should receive notification letters written in English and Spanish.
- The notification letters should be issued on your facility's stationary.
- The notification letters should be sent by certified mail and return receipt.
- The notification letters should include an explanation of the problems with your facility's mammography services and the steps that your facility has taken to correct the problems. If your facility intends to re-read the films for free or pay for a repeat examination at another FDA-certified facility, this information should be communicated to the physician.
- You should mail the physician notification letters no later than five (5) business days after the FDA has approved the finalized letter.
- You should collect and retain all of the physician notification certified mail return receipts. FDA will review the return receipts as part of our monitoring and auditing activities.

Patient Notification

The following recommendations should be taken into consideration in the preparation and implementation of the patient notification program:

- Each patient should receive a notification letter written in English and Spanish.
- You should begin mailing the patient notification letters five (5) business days after the last physician notification is mailed.

- If a patient's letter is returned because the patient no longer lives at the address and you are unable to obtain a new address, you should take reasonable steps to locate the patient through her referring physician.
- If a patient has already had a mammogram since the [INSERT DATE of the patient's examination] taken by Ponce, there is no need for her to take any action other than to continue to get routine mammograms.
- If a patient has not had a mammogram since the [INSERT DATE of the patient's examination] taken by Ponce, we suggest that she contact her doctor or health care professional to discuss this situation and her need for any medical follow-up. Because your facility has ceased performing mammography, Ponce cannot perform any repeat mammograms. If the patient does not have her films re-read or the patient elects to have a repeat examination performed at another facility, we are enclosing a list of FDA-certified facilities in your area to assist your patient in locating the closest alternative certified mammography facility.
- If a patient needs to schedule a repeat mammogram but her health insurance will not pay for it, she may wish to contact the National Cancer Institute's (NCI) information number at 1-800-422-6237. Experts at this number can determine whether there is a facility in or near her area that provides free or low cost mammograms. These experts can also answer questions about breast health and mammograms.
- If your facility intends to re-read the films for free or pay for a repeat examination, this information should be communicated to the patient. For example, "If you choose to have your films re-read at our facility, it will be free." If the patient has lost her films or chooses to have a repeat mammogram: "If you chose to have a repeat examination, we will pay for it."
- You should prepare and retain a log for each of the patients to record the activities/steps that you have taken in your efforts to notify the patient. FDA will review the logs as part of our monitoring and auditing activities.

Within 15 working days after receiving this letter, you should send FDA a written response to this Warning Letter including:

- a copy of you patient logs for May, June, July, August and September of 1999;
- a list of the names and addresses of the patients and physicians that will be notified;
- copies of your proposed patient and physician notification letters;
- a list of qualified interpreting physicians that you intend to have re-read the films for our review and approval;
- the specific steps you have taken to correct all of the violations noted in this letter
- each step that our facility is taking to prevent the recurrence of similar violations; and
- your future plans for conducting mammography.

Please send your written response to:

Ellyce F. Ratskoff, R.Ph., J.D.
Food and Drug Administration
Center for Devices and Radiological Health
Division of Mammography Quality and Radiation Programs
1350 Piccard Drive (HFZ-240)
Room 220H
Rockville, Maryland 20850

Additionally, FDA regulations do not preclude States and local jurisdictions from independently enforcing their own laws and regulations. In some cases, those requirements may be more stringent than FDA's. Therefore, when you plan your corrective actions, you should consider the more stringent State or local jurisdictional requirements, if any.

FDA may, without further notice, initiate further regulatory action(s) such as:

- Assessing civil money penalties in an amount not to exceed \$10,000 against an owner, operator, or any employee of a facility required to have a certificate, for:
 - each failure to substantially comply with the quality standards (21 USC 263b(b)(h)(3)(B)),
 - each failure to notify a patient of risk (42 USC 263b(h)(3)(C)), and
 - each violation, or for aiding or abetting in a violation of any provision of the MQSA or FDA's implementing mammography regulations, 21 CFR Part 900 (42 USC 263b(h)(3)(D)).
- Seeking an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health. (43 USC 263b(j)).

If you have any questions regarding the content of this letter, specifically the procedures for conducting the patient and physician notification program, or your response, please contact Ms. Ratskoff at (301) 827-2980.

Sincerely yours,



John L. McCrohan, M.S.

Director

Division of Mammography Quality
and Radiation Programs (HFZ-240)
Office of Health and Industry Programs
Center for Devices and Radiological Health

Enclosures:

1. Sample Physician Notification Letter
2. Sample Patient Notification Letter
3. List of FDA-certified facilities

cc: Ramiro Milan, M.D.

David Saldana, Director
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