DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-44

May 29, 2002

FACILITY ID # 123299

Dr. Joe B. Harbison,
Medical Director of Radiology
The Diagnostic Center at Gulf Coast Medical Center
2024 State Avenue
Panama City, Florida 32405

Dear Dr. Harbison:

We are writing to you because on April 25, 2002, a representative of the State of Florida, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed serious regulatory problems involving the mammography at your facility.

Under United States Federal law, the Mammography Quality Standards Act of 1992, 42 USC § 263b, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following violations at your facility:

1. Your facility failed to send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. When assessments are listed as "Suspicious" or "Highly" suggestive of malignancy, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible, as required by 21 CFR 900.12(c)(2). For example, your facility did not have an adequate system to communicate results in a timely fashion to patients. Documentation available at the time of the inspection revealed that a patient who had a mammogram done on November 20, 2001 did not receive a lay letter until February 15, 2002.

2. Your facility failed to establish and maintain a mammography medical outcomes audit program to follow-up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings, as required by 21 CFR 900.12(f)(1). For example, each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among patients imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy. Your facility was unable to provide the annual medical audit and outcome analysis for individual radiologist(s) and for the facility as a whole.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious 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 $10,000.00 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

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 you receive this letter:

- 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 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 Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4728.

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 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, Maryland 21045-6057, telephone no. (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please contact D. Janneth Caycedo, Boca Resident Post, Food and Drug Administration, Interstate Plaza, 1499 W. Palmetto Park Rd., Ste. 110, Boca Raton, Florida 33486, telephone no. (561) 338-5236, ext. 23.

Sincerely,

Emma R. Singleton
Director, Florida District