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-02-43

May 28, 2002

FACILITY ID # 201517

Joe B. Harbison, Medical Director of Radiology
Calhoun Liberty Hospital
20370 N.E. Burns Avenue
Blountstown, Florida 32424

Dear Dr. Harbison:

We are writing to you because on April 18, 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 have an adequate system to send each patient a summary of the mammography report, written in lay terms, within 30 days of the examination as required by 21 CFR § 900.12(c)(2). For example, records show and statements made by the director of radiology reveal that no letters were sent to three (3) patients who had their mammograms done on March 11, 2002, or for nine (9) patients whose mammograms were done on March 25, 2002.

2. You facility failed to have processor QC records for March 1, 2002 as required by 21 CFR § 900.12(e). For example, review of the patient log on that day revealed mammography was performed on five (5) patients.

3. Your facility failed to conduct fixer retention QC at the required frequency as required by 21 CFR § 900.12(e)(3)(i). For example, fixer retention records revealed that no tests had been done since October 18, 2001. Mammograms were being processed from that date up to the date of the inspection on March 25, 2002.

4. Your facility failed to conduct compression QC at the required frequency as required by 21 CFR § 900.12(e)(4)(iii). For example, records revealed that the last compression test was performed on August 16, 2001. Mammograms were being processed from that date up to the date of the inspection on March 25, 2002.

5. Your facility failed to conduct repeat analysis at the required frequency as required by 21 CFR § 900.12(e)(3)(ii). For example, records reveal that the last repeat analysis was conducted on November 30, 2001. Mammograms were being processed from that date up to the date of the inspection on March 25, 2002.

6. Your facility failed to conduct screen-film contact testing at the required frequency as required by 21 CFR § 900.12(e)(4)(ii). For example, records reveal that the last screen-film contact test was conducted on April 3, 2001. Mammograms were being processed from that date up to the date of the inspection on March 25, 2002.

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 respond 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