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-02-52

July 8, 2002

FACILITY ID # 223462

Ronda Duncan, Director of Imaging
Holy Cross Medical Center
1309 South Federal Hwy
Fort Lauderdale, Florida 33316

Dear Ms. Duncan:

We are writing to you because on May 22, 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 REPEAT violations at your facility.

Your facility failed to 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 as required by 21 CFR 900.12(f)(1). 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 your facility that subsequently became known to your facility, shall prompt your facility to initiate follow up on surgical and/or pathology results and to review the mammograms taken prior to the diagnosis of a malignancy. For example, your facility failed to conduct medical audit(s) and outcome analyses for all interpreting physicians both individually and collectively. This represents a repeat violation identified during the previous inspection of your facility dated May 17, 2001.

Your facility failed to conduct an audit analysis at least once every 12 months to permit completion of diagnostic procedures and data collection as required by 21 CFR 900.12 (f)(2). For example, no medical audit or outcome analysis has been performed in the last 12 months since the last inspection of your facility on May 17, 2001. This represents a repeat violation identified during the previous inspection of your facility dated May 17, 2001.

Your facility failed to designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months as required by 21 CFR 900.12(f)(3). For example, no interpreting physician has been designated to conduct medical audits and outcome analyses at your facility. This represents a repeat violation identified during the previous inspection of your facility dated May 17, 2001.

The problems noted above appeared in summary form on the MQSA Facility Inspection Report issued to your facility at the close of the inspection on May 22, 2002 and in more detail in the revised MQSA Facility Inspection Report faxed to your offices on July 2, 2002. 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 initiating regulatory action without further informal 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, seeking civil money penalties up to $10,000.00 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA, seeking suspension or revocation of your facility's FDA certificate, or seeking 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