

**VIA FEDERAL EXPRESS**Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751**WARNING LETTER****FLA-02-21**

January 8, 2002

FACILITY ID # 165704

Mr. Leigh Hershberger
Director Outpatient Center
Regional Diagnostic Imaging Center
14100 Yosemite Drive
Hudson, Florida 34667

Dear Mr. Hershberger:

We are writing to you because on November 21, 2001, a representative of the State of Florida, acting in behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, 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 level 2 finding at your facility:

Level 2 – REPEAT: Corrective action for a failing image score or a phantom background optical density, or density difference outside the allowable regulatory limits was not documented for unit 4, General Electric, Room 1 prior to conducting further exams.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents 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 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 received 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, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (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, MD 21045-6057 (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 feel free to contact D. Janneth Caycedo at 561-338-5236 ext 23.

Sincerely yours,



Emma R. Singleton
Director, Florida District

