DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

93323d

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-47

June 3, 2002

FACILITY ID #166082

Kelly Haufman, Center Administrator
Imaging Center of Orlando
51 W. Kaley Street
Orlando, Florida 32806

Dear Ms. Haufman:

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.

Your facility failed to perform weekly quality control tests as required by 21 CFR 900.12(e)(2). Specifically, facilities with screen-film systems shall perform an image quality evaluation test, using a FDA-approved phantom at least weekly. Phantom QC records were missing for a minimum of four weeks for unit 2, Gendex-Del, MAMX, room MAMMO 02 (Phantom QC records for the Gendex-Del unit were not available from 1/1/2001 through 12/31/2001).

Your facility failed to perform quarterly QC tests at the required frequency as required by 21 CFR 900.12(e)(3)(i) and (ii), respectively. For example, QC tests were not performed to ensure the residual fixer is no more than 5 micrograms/square cm (Last fixer retention test occurred on 4/9/2001); to ensure that repeat analysis from the previously determined rate differed by no more than 2.0% of the total films included in the analysis (Last repeat analysis was performed on 6/4/2001). The dates of missing records were from January 1, 2001 to December 31, 2001.

Your facility failed to perform semiannual QC tests at the required frequency as required by 21 CFR 900.12(e)(4)(i), (ii) and (iii), respectively. For example, the optical density attributable to darkroom fog (last fog test was performed on 3/19/2001); the testing for screen-film contact (last screen-film contact test was performed on 2/20/2001); and the compression force of the device (Last compression test was performed on 3/19/2001 and the records fail to specify which unit was last tested).

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).

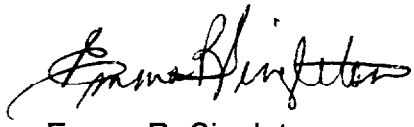
Please submit your response to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4728.

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, Consumer Safety Officer, 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