



VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-95

September 5, 2000

FACILITY ID # 124941

Arnie Friedman, M.D., Chairman of Radiology
Shands Jacksonville Medical Center
655 West Eight Street
Jacksonville, Florida 32209

Dear Dr. Friedman :

We are writing to you because on August 9, 2000, your facility was inspected by a representative of the State of FL, acting in behalf of the Food and Drug Administration (FDA). 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 1, level 2 and repeat level 3 findings at your facility:

Level 1: Mammograms were processed in the Agfa-Gevaert processor #2 (Methodist Medical Center) when it was out of limits on 10 days;

Phantom QC records were missing for the following units:

- Unit 2, Bennett X-Ray Corp missing for 12 weeks
- Unit 3, Lorad Medical Systems missing for 5 weeks
- Unit 4, Bennett X-Ray Corp missing for 5 weeks
- Unit 5, Bennett X-Ray Corp missing for 5 weeks
- Unit 6, Bennett X-Ray Corp missing for 5 weeks

Level 2: Corrective actions for processor quality control failures were not always documented (Methodist Medical Center);

[REDACTED] interpreting physician, did not meet the initial qualification of having documents showing 60 CME credit hours of initial training in mammography;

[REDACTED] interpreting physician, did not provide documents showing initial experience in mammography (240 exams/6 months).

Level 3: The measured fog density is 0.07 for darkroom Mammo (Methodist Medical Center).

The fixer retention QC records were not done at required frequency. Corrective action was not always documented. Darkroom fog QC records were not done at the required frequency. The background density was less than 1.2.

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 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:

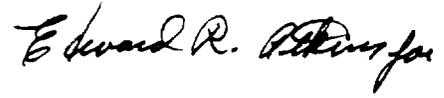
- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample 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,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with the first name being the most prominent.

Emma R. Singleton
Director, Florida District