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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161
FAX: 404-253-1202

March 28, 2003

VIA FEDERAL EXPRESS

MQSA Inspection ID # 1687400008

Merrill Berman, M.D.
Chief Radiologist
Southside Medical Center
1039 Ridge Avenue
Atlanta, GA 30315

WARNING LETTER
(03-ATL-16)

Dear Dr. Berman:

On February 21, 2003, a representative of the State of Georgia, Department of Human Resources, Division of Radiation Protection, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA") which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA at your facility. These violations were noted on the MQSA Facility Inspection Report that the inspector left with your facility at the close of the inspection. The violations are again identified below.

Level 1: Processor Quality Control records were missing for at least five consecutive days for processor #1, [redacted], located in mammography room #1. [21 CFR 900.12(e)(1) and 900.12(d)(2)].

Level 1: Phantom Quality Control records were missing for at least four weeks for unit #3, [redacted] located in the mammography room. [21 CFR 900.12(e)(2) and 900.12(d)(2)].

Level 2: A medical physicist's survey has not been conducted for x-ray unit #3 within the last 14 months. [21 CFR 900.12(e)(9)(i)].

Level 2: Your facility failed to produce documents verifying that the interpreting physician, Merrill Berman, met the continuing education requirment of having taught or completed at least 15 category I continuing medical education units in mammography in 36 months (0 CMEs in 36 months). [21 CFR 900.12(a)(1)(ii)(B) and 900.12(a)(4)].

Level 2: Your facility failed to produce documents verifying that the radiologic technologist, [redacted] met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months (0 CEUs in 36 months). [21 CFR 900.12(a)(2)(iii)(A) and 900.12(a)(4)].

Level 2: Your facility failed to produce documents verifying that the radiologic technologist, [redacted] met the continuing experience requirement of having performed 200 mammography examinations in 24 months. [21 CFR 900.12(a)(2)(iv)(A) and 900.12(a)(4)]

Because the failure to resolve these violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- Requiring your facility to undergo an Additional Mammography Review;
- 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 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards; and
- Seeking to suspend or revoke your facility's FDA certificate.

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

If you choose to respond to the above violations, your response should include:

1. The specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. The specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps; and

3. Sample records that demonstrate proper record keeping procedures.

Please submit your response to this letter to:

Serene A. Kimel, Compliance Officer
Food and Drug Administration
60 8th Street, NE
Atlanta, GA 30309

Please send a copy of your response to:

State of Georgia
Department of Human Resources
Division of Radiation Protection
2 Peachtree Street
Atlanta, GA 30303

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection of your facility 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/cdrh/mammography/index.html.

If you have additional or more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Serene A. Kimel, Compliance Officer at 404-253-1296.

Sincerely yours,

Mary Woleske

Mary H. Woleske, Director
Atlanta District

cc:

State of Georgia
Department of Human Resources
Division of Radiation Protection
2 Peachtree Street
Atlanta, GA 30303

[redacted]