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

g 40870

June 9, 2003

VIA FEDERAL EXPRESS

MQSA Inspection ID # 1089510010

Fred James
Radiology Manager
Davie County Hospital
223 Hospital Street
Mocksville, NC 27028

WARNING LETTER
(03-ATL-22)

Dear Mr. James:

On May 12, 2003, a representative of the North Carolina Department of Environment & Natural Resources (DENR), Division of Radiation Protection, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed serious problems involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA"),which is codified at 42 U.S.C. § 263b, 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 Level 1 and 2 violations are again identified below.

Level 1: The facility was performing mammography without a valid certificate for four days from 3/31/03 to 4/3/03. [21 CFR 900.11]

Level 2: The facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required. [21 CFR 900.12 (h)]

The facility failed to produce documents verifying that the interpreting physician, [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months. [21 CFR 900.12(d)(2); see 21 CFR 900.12(a)(1)(ii)]

The 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(d)(2); see 21 CFR 900.12(a)(2)(iv)]

These violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility. FDA may take additional actions, which may include, but are 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;
- Seeking to suspend or revoke your facility's FDA certificate; and
- Obtaining a court injunction enjoining further mammography.

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

It is necessary for you to act on this matter immediately. Please explain to this office in writing, within fifteen (15) working days after receiving this letter:

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. (Note: Patient names or identification should be deleted from any copies submitted.)

The other items identified as Level 3 Noncompliance on the facility inspection report from May 12, 2003, should also be corrected.

If your facility is unable to complete corrective action with 15 working days, you should state the reason for the delay and time within which corrections will be completed. 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:

North Carolina DENR, Division of Radiation Protection
3825 Barrett Drive
Raleigh, NC 27609-7221

&

Thomas Clarida, Investigator
U. S. Food & Drug Administration
5701 Executive Center Drive, Suite 104
Charlotte, NC 28212

Finally, you should understand that there are many requirements pertaining to mammography. This pertains only to violations related to the recent inspection of your facility and does not necessarily ad other obligations you have under the law. You may obtain general information about all of Fl requirements for mammography facilities by contacting the Mammography Quality Assurance Prog Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or thr the Internet at http://www.fda.gov/cdrh/mammography/index.html.

If you have additional or more specific questions about mammography facility requirements, or abou 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:

North Carolina DENR
Division of Radiation Protection
3825 Barrett Drive
Raleigh, NC 27609-7221

[redacted]