DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

October 18, 2002

VIA FEDERAL EXPRESS

FACILITY ID #116160

Jeff Fee, Chief Executive Officer
Hendersonville Gynecology & Obstetrics
353 New Shackle Island Road
Suite 211-B
Hendersonville, TN 37075

Warning Letter No. 03-NSV-02

Dear Mr. Fee:

Your facility was inspected on September 23, 2002 by a representative of the State of Tennessee acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious compromise in the quality of the mammography services offered by your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA) 42 U.S.C. § 236b, 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 recent inspection at your facility revealed the following Level 1 Repeat, Level 1 and Level 2 Repeat findings:

Level 1 (Repeat)

Processor QC records were missing at least 5 consecutive days for processor 1, model not listed, Room 1 at site Hendersonville Gynecology & Obstetrics - *21 CFR 900.12(e)(1)(i),(ii),(iii)*

Level 1

Mammograms were processed in processor 1, model not listed, Room 1, at site Hendersonville Gynecology & Obstetrics, when it was out of limits on at least 5 days - *21 CFR 900.12(e)(1),(ii),(iii)*

Phantom QC records were missing for at least 4 weeks for unit 2, [redacted], Room Mammo Rm - *21 CFR 900.12(e)(2),(ii),(iii),(iv)*

Failed to produce documents verifying that the radiologic technologist [redacted] met the initial requirement of holding either a valid state license or a valid certificate for an FDA-approved body - *21 CFR 900.12(a)(2)(i)(A) and (B)*

Note: Nashville Branch was able to determine that this individual had a valid certificate from the American Registry of Radiologic Technologists through August 2002.

Level 2 (Repeat)

Medical audit and outcome analysis was not performed annually at site Hendersonville Gynecology & Obstetrics – *21 CFR 900.12(f)(2)*

There is no designated audit (reviewing) interpreting physician for site Hendersonville Gynecology & Obstetrics – *21 CFR 900.12(f)(3)*

There were no examples of, nor attempts, to get biopsy results for site Hendersonville Gynecology & Obstetrics – *21 CFR 900.12(f)(1)*

These specific deficiencies as noted above appeared on your MQSA Post Inspection Report which was sent to your facility by the state inspector along with instructions on how to respond to these findings. Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, this represents violations 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 Direct 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 MQSA standards, seeking suspension or revocation of your facility's FDA certificate, or seeking a court injunction against further mammography. [See 42 U.S.C. §263b(h)-(j)]

In addition, you should also address the following deficiencies that were also listed on the inspection report as follows:

Level 2

Corrective actions for processor QC failures were not documented at least once for processor 1, model not listed, Room 1, at site Hendersonville Gynecology & Obstetrics – *21 CFR 900.12(b)*

Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 2, [redacted], Room Mammo Rm. – *21 CFR 900.12(b)*

The phantom QC is not adequate for unit 2, [redacted], Room Mammo Rm., because:

- The image was not taken at clinical setting – *21 CFR 900.12(e)(i)*
- The operating level for background density was < 1.20– *21 CFR 900.12(e)(2)(i)*

The medical physicist's survey for x-ray unit 2, [redacted], Room Mammo Rm., is incomplete because the following tests were inadequate or not done:

No artifact evaluation – *21 CFR 900.12(e)(5)(ix); - 21 CFR 900.12*(c)(1)(e)*(9)(i),(ii),(iii),(iv),(v)*

Level 2 (cont.)

Failed to produce documents verifying that the radiologic technologist [redacted] met the alternative initial requirement of having training specific to mammography under the interim regulations – *21 CFR 900.12(a)(2)(ii)(A)(B) and (C)*

2 of 10 random reports reviewed did not contain an acceptable assessment category for site Hendersonville Gynecology & Obstetrics – *21 CFR 900.12(c)(1)*

Medical audit and outcome analysis was not done for the facility as a whole at site Hendersonville Gynecology & Obstetrics – *21 CFR 900.12(f)(1)*

Medical audit and outcome analysis was not done separately for each individual at site Hendersonville Gynecology & Obstetrics – *21 CFR 900.12(f)(1)*

Not all positive mammograms were entered in the tracking system for site Hendersonville Gynecology & Obstetrics – *21 CFR 900.12(f)(1)*

Level 3 (Repeat)

The fixer retention QC is not adequate for processor 1, model not listed, at site Hendersonville Gynecology & Obstetrics because:

- The fixer retention QC tests were not done at the required frequency - *21 CFR 900.12(e)(3)(i),(ii)*

The required personnel qualification documents were not available during the inspection – *21 CFR 900.12(a)(4)*

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies as identified and to promptly initiate permanent corrective actions.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violations. Your response should include:

- The specific steps you have taken to correct the Level 1 Repeat, Level 1, Level 2 Repeat, Level 2, and Level 3 Repeat violations as outlined in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Sample records that demonstrate proper record-keeping procedures relating to quality control or any other records that are appropriate to the noncompliance finding (NOTE: Patient names or identification should be deleted from any copies submitted).

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

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Tennessee. Should you have questions regarding the technical aspects of this letter or concerning MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,

Carl E. Draper
Director, New Orleans District

CED:JEH:bds

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