

HF1-35



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

*m 4/10/00
Purged RTW*

60 Eighth Street, N.E.
Atlanta, Georgia 30309

August 3, 2000

VIA FEDERAL EXPRESS

Ken Hightower
Radiology Manager
Transylvania Community Hospital
Hospital Drive
Brevard, NC 28712

Inspection ID: 1435940006

WARNING LETTER
(00-ATL-54)

Dear Mr. Hightower:

Your facility was inspected on 7/25/00 by 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). This inspection revealed that your facility failed to comply with certain Quality Standards for Mammography as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

- There is no system in place to provide timely lay summaries for site Transylvania Community Hospital.
- There is no system in place to provide timely lay summaries for site WNC Health Network Mammography.

The deficiencies noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliance items that were listed on the inspection report. The Level 2 noncompliance items are:

- There is no written procedure for handling consumer complaints at site Transylvania Community Hospital.
- There is no written procedure for infection control at site Transylvania Community Hospital.

- 3 of 5 random reports reviewed did not contain an assessment category for site Transylvania Community Hospital.
- 3 of 5 random reports reviewed did not contain an assessment category for site WNC Health Network Mammography.

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 causes of the deficiencies that the inspection identifies and promptly initiating permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- 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 recordkeeping procedures, if the noncompliances that were found relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

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

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

With a copy to:

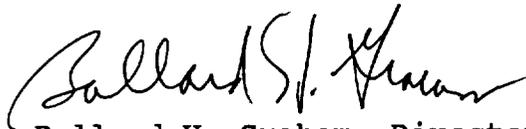
North Carolina DENR
Division of Radiation Protection
3825 Barrett Drive
Raleigh, NC 27609-7221

and

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

You may choose to address both FDA and state requirements in your response. If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Thomas Clarida at 704-344-6116.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District

Cc: Radiology Manager
Margaret Pardee Hospital
715 Fleming Street
Hendersonville, NC 28791

Mr. John Graeter, Executive Director
WNC Health Network Mammography
P.O. Box 2295
Asheville, NC 28802

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