



September 25, 2000

**CERTIFIED MAIL - RETURN RECEIPT REQUESTED**

**WARNING LETTER-00-NSV-29**

*Quayle*  
*10/17/00*  
*JEA*

**FACILITY ID# 171801**

Susan Breeden, Administrator  
Baptist Memorial Hospital - Huntingdon  
631 R.B. Wilson Drive  
Huntingdon, TN 38344

Dear Ms. Breeden:

Your facility was inspected on September 21, 2000 by a representative of the State of Tennessee on contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

**Level 1**

Phantom QC records were missing for 4 weeks for unit 1; [REDACTED]  
Room: Mammography

**Level 2**

Not all positive mammograms were entered in the tracking system for site Baptist Memorial Hospital - Huntingdon

These specific deficiencies appeared on the Post Inspection Report, which was sent to your facility by the State inspector, along with instructions on how to respond to these findings. These deficiencies may be symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography. Also, the inspector made numerous recommendations based on inspectional observations which should be implemented to better ensure quality 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 cause of these deficiencies as identified and to promptly initiate permanent corrective action.

If you fail to properly address 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 comply with the Standards.

**Baptist Memorial Hospital - Huntingdon**  
**Susan Breeden, Administrator**

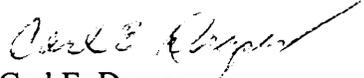
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

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 similar violations.

If your facility is unable to complete the 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, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,

  
Carl E. Draper  
Director  
New Orleans District Office

CED/krs

cc: State of Tennessee  
Dept. Of Environment and Conservation  
2700 Middlebrook Pike, Suite 220  
Knoxville, TN 37921  
ATTN:Darlene Nalepa-Whitmill

State of Tennessee  
Dept. of Environment and Conservation  
645 Perimeter Park, Suite E  
2510 Mr. Moriah Road  
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ATTN: Jessica Soileau

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