

These specific deficiencies appear on the List of Observations which was faxed to your facility on October 3, 1997. These deficiencies are symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

We received your letter dated September 18, 1997 and found that it adequately addressed only the Level 3 repeats. This letter addressed the items listed on the List of Observations which was originally given to your facility. That List of Observations, dated 9/04/97, included item 1 on page one of this letter as a "Documents Pending". Since this information was not forwarded to the State of Alabama surveyor within five working days, this has now become a Level 1 finding.

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 that the inspection identifies and to promptly initiate permanent corrective actions.

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.
- 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.

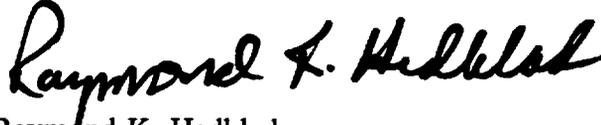
Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

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 correction will be completed.

Anniston Medical Clinic, P.C. - Page 3

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, C.S.O., at 615/781-5380, extension 144.

Sincerely,

A handwritten signature in black ink that reads "Raymond K. Hedblad". The signature is written in a cursive, flowing style.

Raymond K. Hedblad
Director, Nashville District

RKH/ks

cc: State of Alabama