



MSZ/gm

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

February 28, 2001

**VIA FEDERAL EXPRESS**

**FACILITY ID# 214684**

Ron Orso, M.D.  
Medical Director  
Birmingham OB/GYN  
806 St. Vincent Drive, Suite 415  
Birmingham, AL 35205

**Warning Letter No. 01-NSV-15**

Dear Dr. Orso:

Your facility was inspected on February 23, 2001 by a representative of the State of Alabama on contract to the Food and Drug Administration (FDA). Records were reviewed for the past inspectional year and equipment testing was performed. 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**

The system to communicate results is not adequate for site Birmingham OB/GYN because:

- There is no system in place to provide timely lay summaries
- There is no system in place to communicate serious or highly suggestive cases ASAP

**Level 2**

Mammograms were processed in processor [REDACTED] or [REDACTED] located in the Mammo darkroom, at site Birmingham OB/GYN, when it was out of limits on 4 days

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, or limit information provided to patients in a timely manner.

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 identified deficiencies and to promptly initiate permanent corrective actions.

**Birmingham OB/GYN**  
**Ron Orso, M.D., Medical Director**

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 any similar violations.

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 Richard Glass of the State of Alabama. Should you have questions regarding this letter or MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,



Carl E. Draper  
Director, New Orleans District

CED:KRS:man

cc: State of Alabama  
Dept. of Public Health  
Office of Radiation Control  
P.O. Box 303017  
Montgomery, AL 36130-3017  
ATTN: Richard Glass