Food and Drug Administration
Atlanta District Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

June 3, 2002

VIA FEDERAL EXPRESS

James Richard Amerson Jr., M.D.
Obstetrics and Gynecology of Atlanta, P.C.
975 Johnson Ferry Road NE
Suite 400
Atlanta, GA 30342

Inspection ID: 1287690008

WARNING LETTER
(02-ATL-26)

Dear Dr. Amerson:

Your facility was inspected on 5/2/02 by a representative of the Georgia Department of Human Resources, 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 requirements for mammography under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, and specified in FDA's regulations at Title 21, Code of Federal Regulations, (C.F.R), Section 900.12. These requirements help protect the health of women by assuring that a facility can perform mammography.

The inspection revealed the following Level 1 finding at your facility:

- Phantom QC records were missing for at least 4 weeks for unit #2, [redacted] located in the mammography room.

The specific deficiency noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 1, because it identifies a failure to meet a significant MQSA requirement. This Level 1 finding is a violation of 21 C.F.R § 900.12 (e) (2).

Because this deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation 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 Directed Plan of Correction (DPC), charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, there were Level 2 findings listed on the inspection report provided to you at the close of the inspection. The Level 2 findings are as follows:

- Medical audit and outcome analysis was not done for the facility as a whole.
- Medical audit and outcome analysis was not done separately for each individual.
- Medical audit and outcome analysis was not performed annually.

The above Level 2 findings are a violation of 21 C.F.R § 900.12(f).

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within 15 working days after receiving this letter 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. A copy of your response should also be sent to the Georgia Department of Human Resources, Division of Radiation Protection, 2 Peachtree St., Suite 33-285, Atlanta, GA 30303 and Thomas Clarida, U.S. Food and Drug Administration, 5701 Executive Center Drive, Suite 104, Charlotte, NC 28212.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please feel free to call Thomas Clarida at 704-344-6116.

Sincerely yours,

Ballard H. Graham, Director
Atlanta District