

October 16, 2000

**WARNING LETTER NO. 2001-NOL-02****FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

William L. Kahlstorf, M.D., CEO  
Obstetrics and Gynecology Associates, P.A.  
Clinic for Women  
607 Brunson Drive  
Tupelo, Mississippi 38801

Dear Dr. Kahlstorf:

We are writing to you because on September 27, 2000, your facility was inspected by a representative of the State of Mississippi, acting on behalf of the United States Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal Law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

- **Phantom quality control records were missing for four weeks for unit 2, [REDACTED] Systems.**

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem has been identified as Level 1, because it identifies a failure to meet a significant MQSA requirement.

A Level 1 finding may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility. It represents a 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;
- 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, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- **Corrective actions for processor quality control failures were not documented at least once for the [REDACTED] processor.**
- **Processor quality control records were missing two out of 19 days of operation during the month of February 2000.**
- **Processor quality control records were missing three consecutive days for the [REDACTED] processor.**
- **The interpreting physician, [REDACTED], did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period.**
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- **The interpreting physician, [REDACTED], did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period.**

It is necessary for you to act on this matter immediately. You are required to respond to this office in writing within fifteen (15) working days from the date you receive this letter. Please address the following:

- 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 results, where appropriate; and,
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

Please submit your response to:

Nicole F. Hardin, Compliance Officer  
6600 Plaza Drive, Suite 400  
New Orleans, Louisiana 70127-2601

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, U. S. 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>.

If you have more specific questions about mammography facility requirements, or about the contents of this letter, please feel free to contact Ms. Stacy G. Marshall, MQSA Auditor, at (504) 253-4554.

Sincerely,



Richard D. Debo  
Acting District Director  
New Orleans District Office

cc: Priscilla F. Butler, M.S.  
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