



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

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

Telephone: 504-253-4500  
FAX: 504-253-4566

December 17, 1999

**WARNING LETTER NO. 2000-NOL-10**

**FEDERAL EXPRESS**  
**OVERNITE DELIVERY**

Elouise Strickland, Imaging Director  
The Baton Rouge Clinic, AMC  
7373 Perkins Road  
Baton Rouge, Louisiana 70808

Dear Ms. Strickland:

On November 29, 1999, your facility was inspected by a representative of the State of Louisiana, acting on behalf of the U. S. 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 finding at your facility:

**Phantom Quality Control (QC) records were missing for four (4) weeks for unit 1, Lorad Medical Systems Inc.**

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.

Because this condition 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 finding that was listed on the inspection report provided to you at the close of the inspection. This Level 2 finding is:

**The time period between the previous and current surveys for x-ray unit 1, Lorad Medical Systems Inc., exceeds fourteen (14) months.**

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

- 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; and,
- Sample records that demonstrate proper record keeping procedures, if the findings relate to quality control (Phantom QC).

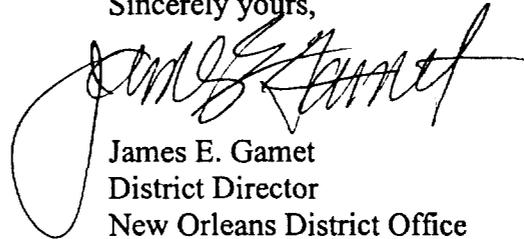
Please submit your response to:

Carolyn S. Olsen, Compliance Officer  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127  
Telephone: (504) 253-4516

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 Stacy G. Marshall at (504) 253-4554.

Sincerely yours,



James E. Gamet  
District Director  
New Orleans District Office