DEPARTMENT OF HEALTH AND HUMAN SERVICE

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

Telephone: 504-253-4519
FAX: 504-253-4520

May 22, 2002

WARNING LETTER NO. 2002-NOL-31

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Robert Burris, M.D.
Facility Accreditation Contact
LSU Earl K. Long Medical Center
5825 Airline Highway
Baton Rouge, Louisiana 70805

Dear Dr. Burris:

A representative of the State of Louisiana, acting on behalf of the U.S. Food and Drug Administration (FDA), inspected your facility on April 24, 2002. This inspection revealed serious regulatory problems involving the mammography at your facility.

Under a United States Federal Law, the Mammography Quality Standards Act of 1992 (MQSA), 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:

- **Documents fail to verify the interpreting physician, [redacted], met the initial requirement of having a valid state license to practice medicine.**

The following Level 2 was found at your facility:

- **Documents fail to verify the interpreting physician, [redacted], (0 CME's in 36 months) met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months.**

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. The problems have been identified as Levels 1 and 2, because they identify a failure to meet significant MQSA requirements.

Because these conditions 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, the inspection revealed a Level 3 finding that was listed on the inspection report provided to your facility at the close of the inspection. The finding is:

- **The required personnel qualification documents were not available during the inspection.**

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 received this letter:

- the specific steps you have taken to **correct** the violation noted in this letter;
- each step your facility is taking to **prevent the recurrence** of similar violations; and,
- include sample records that demonstrate proper record keeping procedures (Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Rebecca A. Asente, Compliance Officer
6600 Plaza Drive, Suite 400
New Orleans, LA 70127-2601
Telephone: (504) 253-4519

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.

If you have specific questions about mammography facility requirements, or about the technical contents of this letter, please feel free to contact Ms. Karen R. Smallwood, MQSA Auditor, at (615) 781-5380 ext. 144.

Sincerely,

Carl E. Draper
District Director
New Orleans District Office