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

August 14, 2002

WARNING LETTER NO. 2002-NOL-41

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Randolph Deaton III, Administrator
Imaging Center-Baton Rouge Radiology Group
5422 Dijon Drive
Baton Rouge, Louisiana 70808

Dear Mr. Deaton:

We are writing to you because on May 29, 2002, 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 serious regulatory problems involving the mammography at your facility.

Under 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:

- **Your facility failed to produce documents verifying that the interpreting physician, [redacted] met the initial requirement of holding a valid state license to practice medicine [see 21 CFR 900.12(a)(1)(i)(A)].**

Also, the inspection revealed the following Level 2 finding at your facility:

- **Your facility failed to produce documents verifying that the interpreting physician, [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months [see 21 CFR 900.12(a)(1)(ii)(A)].**

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 Level 1 and 2, because they identify a failure to meet significant MQSA requirements.

Because these violations may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional action including, but not limited to, placing your facility under a Directed Plan of Correction, charging

your facility for the cost of on-site monitoring, seeking 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, seeking suspension or revocation of your facility's FDA certificate, or seeking 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 [see 21 CFR 900.12(a)(4)].**

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, or will take, to correct all of the violations noted in this letter; and,

- Each step your facility has taken, or will take, to prevent the recurrence of similar violations.

Please submit your response to:

Mark W. Rivero, Compliance Officer
U.S. Food and Drug Administration
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127
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, 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 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