DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 1, 2000

Dear Mammography Quality Advocate:

Under the Mammography Quality Standards Act (MQSA) of 1992, the Food and Drug Administration is required to report adverse actions taken against mammography facilities, as part of an annual report which was mandated by Congress. The enclosed document is titled "**Mammography Facility Performance for Calendar Year 1999.**" The purpose of this report is to assist health professionals and consumers in evaluating the performance of mammography facilities. In the future, we will continue to send you annual reports as they are published. We encourage you to make this information available to your constituents, especially physicians and the general public.

The report includes the following:

- Background information
- A list of mammography facilities against which adverse actions were taken in 1999

You may also find this report, along with other MQSA related documents on the FDA mammography website, http://www.fda.gov/cdrh/mammography, Click on "Publications" and then select "Reports" from the list of choices below.

If you have any questions regarding this report, send them to Denise Robinson via e-mail at djr@cdrh.fda.gov.

Sincerely yours,

John L McCrohan

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MAMMORGRAPHY FACILITY PERFORMANCE FOR CALENDAR YEAR 1999

Congress enacted MQSA to ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages. In the fall of 1998, Congress reauthorized MQSA, extending the program to 2002.

Congress charged FDA with developing and implementing MQSA regulations. Interim regulations, issued in December 1993, became effective in February 1994. In 1995, FDA began enforcing MQSA when it initiated the inspection program. On October 28, 1997, FDA issued more comprehensive final regulations, which became effective on April 28, 1999.

On July 6, 1999, FDA implemented the new version of its MQSA inspection software, allowing the Agency to conduct MQSA inspections under the final regulations. Since implementation of the new software, the number of facilities with the most serious findings ("level 1") and those with moderate findings ("level 2") has increased. The number of facilities with only minor findings ("level 3") with "no findings" has decreased. Under the final regulations, several level 3 findings were raised to level 2 findings and some level 2 findings were elevated to level 1 findings. FDA expects citations to decrease as the mammography community becomes more familiar with the requirements under the final regulations.

As of September 20, 1999, there were 10,079 MQSA certified mammography facilities operating in the United States. Of these, 9,968 facilities are fully certified. The remaining facilities are provisionally certified and in the process of becoming accredited. Facilities that fail accreditation must cease providing mammography services. However, once the deficiencies resulting in failure are corrected, a facility may apply for reinstatement to resume the accreditation process. To track certification activities and other aspects of the MQSA program, FDA uses a state-of-the-art database that allows FDA to assess MQSA compliance.

Facilities against which Adverse Actions Were Taken in Calendar Year 1999

Medicare/Medicaid Actions

No medicare or medicaid actions against facilities were reported in 1999.

Accreditation Body Actions

The American College of Radiology and the Accreditation Bodies of the States of Arkansas, California, Iowa, and Texas reported no accreditation revocations for any facilities in 1999.

FDA Actions Against Facilities (2)

Shenandoah Valley Mobile X-Ray, Inc.
110 B East High Street
Woodstock, VA 22664
Facility ID: 189183

Adverse action: Warning Letter and Criminal Prosecution

Reason for action: Uncertified operation and other activities related to the uncertified operation.

Corrective action: On September 14, 1999, the facility owner was sentenced to 18 months in prison, 36 months of supervised release, and was ordered to pay a $3,000 fine for activities related to performing mammography services without a valid FDA certificate.

Patient notification requirement was satisfactorily met by the companies with whom Shenandoah contracted providing the notification.

Date of inspection/adverse action: 03/02/98

Status of facility: No longer performing mammography

Total Care Clinic
121 Virginia Avenue
Pineville, KY 40977
Facility ID: 162321

Adverse action: Patient/Physician Notification Process

Reason for action: Phantom image failure

Corrective action: Patient/physician notification was satisfactorily conducted

Date of inspection/adverse action: 10/20/98 with a follow-up inspection on 11/16/99

Status of facility: Performing mammography

Other FDA Actions (2)

Adverse action:	Criminal prosecution of an individual
Reason for action:	Falsification of processor quality control charts
Charge:	Providing false information to the government
Result:	On 08/26/99, a mammography technologist pleaded guilty to a misdemeanor, was fined and put on probation.

Adverse action:	Criminal prosecution of an individual
Reason for action:	Falsification of processor quality control charts
Charge:	Providing false information to the government
Result:	On 08/03/99, a mammography technologist was found not guilty.

State Actions

MQSA does not preclude a State or U.S. territory from having stricter mammography requirements. In States that have additional requirements, facilities are required to comply with both State and MQSA regulations to operate lawfully. The adverse actions reported in this report were taken by States under their own legislation. A total of five (5) States reported adverse actions taken against facilities in Calendar Year 1999.

The adverse actions reported by the States begin on page 4.

ARKANSAS

Harris Hospital
1205 McClain Street
Newport, AR 72212
Facility ID: 203323

Adverse action: Fines/penalties (civil or administrative): Ongoing investigation by the Food and Drug Administration

Reason for action: Personnel qualifications and quality control program

Patient notification conducted: Yes

Patient notification voluntary: Yes

Corrective action:
1) Recall of 11 patients
2) Additional training for the staff technologist
3) Oversight training for the Lead Interpreting Physician by the Chair of the State's Clinical Image Review Committee
4) Submission of weekly phantoms to the Arkansas Department of Health for review until 04/01/00
5) Clinical Image Review of all films taken between 03/01/99 and 10/31/99 by the State's Clinical Image Review Committee.

Date of inspection/adverse action: 10/13/99

Date of corrective action/reinstatement: 12/07/99 with follow-up on 02/12/00

Status of facility: Performing mammography

CALIFORNIA

Levin CGR Mobile Mammogram
231 West Vernon, Avenue #111
Los Angeles, CA 90037
Facility ID: 196386

Adverse action: Cease and Desist Order

Reason for action: As a result of the June 24, 1999, State inspection revealed poor clinical image quality.

Corrective action: On September 14, 1999, the facility was required to perform an "Additional Mammography Review" of 100 examinations. On November 17, 1999, the State of California issued a Cease and Desist Order to the facility to cease performing mammography and to notify all patients who had received mammograms after November 1, 1997, and advise them to have a repeat examination. Los Angeles County was provided patient information and conducted the patient/physician notification process.

Date of inspection/adverse action: June 24, 1999, inspection and adverse action
November 16, 1999, Cease and Desist Order

Date of corrective action/reinstatement: The facility is still under Cease and Desist Order, patient/physician notification and follow-up is ongoing at this time.

Status of facility: The facility is currently under Cease and Desist Order pending accreditation revocation action. Certification status is currently effective until November 4, 2001. Cease and Desist Order prohibits mammography with violation provisions of criminal punishment and penalties.

MICHIGAN

Kelsey Memorial Hospital
418 Washington Avenue
Lakeview, MI 48850
Facility ID #166173

Adverse action:	Temporary License Suspension
Reason for action:	State advised mammography facility to temporarily stop performing mammography. (1) very poor image quality that failed to meet state imaging rules and (2) other serious problems that violated state mammography quality rules. In addition, four (4) Level 2 violations of FDA requirements were found during the inspection, including failure to adequately image masses and fibers in a mammography phantom.
Corrective action:	Image quality was improved after their operators, who had been short of continuing education credits, obtained the necessary credits.

Date of inspection/adverse action: 03/18/99

Date of corrective action/reinstatement: 05/21/99 with follow-up on 06/30/99

Status of facility: Performing mammography.

NEVADA

William B Ririe Hospital
1500 Ave H.
Ely, NV 89301
Facility ID #172270

Adverse action:	Fines/penalties (civil or administrative)
Reason for action:	Fine imposed for failure to complete proper processor quality control for 28 days during October and November 1999. During that period 112 mammography examinations were conducted with a total of 438 films. The State reviewed strips run, but not plotted, and concluded that the processor was in control. Additionally, after performing a random review of films taken during October/November, the State concluded that the film processing was acceptable.
Corrective action:	The facility is required to submit monthly reports to the State to demonstrate an increased level of personnel oversight of the facility's quality control program. A fine was imposed as follows: (1) $5,000.00 of suspended fine imposed for repeated violation. (2) $2,500.00 imposed for findings of State inspection completed on November 16, 1999. Total fine imposed: $7,500.00. The facility paid $3,500.00 on February 24, 2000, with $4,000.00 suspended until January 1, 2002, pending no future violations of this type.

Date of inspection/adverse action: 11/16/99 and 11/19/99

Date of corrective action/reinstatement: 12/30/99

Status of facility: Performing mammography

TEXAS

Brownsville Medical Center
1040 West Jefferson
Brownsville, TX 78520
Facility ID # 181958

Adverse action:	Other State action: enforcement conference
Reason for action:	Noncompliances found during the annual MQSA inspection. Enforcement conference scheduled on January 27, 2000.
Corrective action:	The facility provided a satisfactory response to all items noted on the Notice of Violation. They agreed to an increased inspection frequency and unannounced inspections to prove they are capable of operating in full compliance, all with the understanding that any repeat or similar violations are grounds to immediately assess administrative penalties.

Date of inspection/adverse action: 10/05/99

Date of corrective action/reinstatement: 01/27/00

Status of facility: Performing mammography

Colorado Fayette Medical Center
400 Youens Drive
Weimar, TX 78962
Facility ID #179556

Adverse action:	Other State action: enforcement conference
Reason for action:	Enforcement conference held on April 1, 1999. Investigation continuing - two (2) employees were interviewed at the facility on April 29, 1999. Notice of administrative penalty issued on June 3, 1999. Settlement conference was held on September 21, 1999.
Corrective action:	The facility agreed to pay a five hundred dollar penalty and perform 200 mammograms, at no cost to the public, over the next two years.

Date of inspection/adverse action: 02/28/99

Date of corrective action/reinstatement: 09/21/99

Status of facility: Performing mammography

Doris Kupferle Breast Centers – Harris Methodist
1300 W. Terrell Street
Fort Worth, TX 76104
Facility ID# 110437, 172601 and 210682

Adverse action:	Other State action: enforcement conference
Reason for action:	An enforcement conference was scheduled for January 17, 2000, to discuss a serious repeat violation cited during the October 20, 1999, inspection. The facility was also cited, in 1998, for an un-accredited machine problem.
Corrective action:	The facility provided a satisfactory response to all items noted on the Notice of Violation. They agreed to an increased inspection frequency and unannounced inspections to prove they are capable of operating in full compliance, all with the understanding that any repeat or similar violations, are grounds to immediately assess administrative penalties.

Date of inspection/adverse action: 10/20/99

Date of corrective action/reinstatement: 01/17/00

Status of facility: Performing mammography

Downtown Plaza Imaging Center
2101 Crawford Suite 111-A
Houston, TX 77002
Facility ID #205047

Adverse action:	Fines/penalties (civil or administrative) Facility license suspension (temporary)
Reason for action:	Based on the inspection findings, an enforcement conference was scheduled for February 16, 1999. The registrant declined to attend the conference and administrative penalty was assessed. A settlement hearing was conducted on June 20, 1999 resulting in a reduced penalty in exchange for a five-year suspension of mammography services at the facility.
Corrective action:	State received notice from facility that mammography services were terminated on April 20, 1999.

Date of inspection/adverse action: 01/18/99

Date of corrective action/reinstatement: 04/20/99

Status of facility: No longer performing mammography.

Houston Medical Imaging
7000 Fannin M-40
Houston, TX 77030
Facility ID #221735

Adverse action:	Other State action: enforcement conference
Reason for action:	Due to the facility's reluctance to respond to inquiries from the Registration Branch of this agency, an unannounced inspection was conducted. The inspection revealed significant quality assurance issues. Enforcement conference was conducted on November 4, 1999.
Corrective action:	The facility agreed to address outstanding violations and registration issues by close of business, November 12, 1999. The facility claimed to be committed to abide by all State rules. To prove their commitment they agreed to submit to more frequent, unannounced inspections, with the understanding that any repeat or similar violations found, would be grounds to immediately assess administrative penalties.

Date of inspection/adverse action: 07/8/99

Date of corrective action/reinstatement: 11/04/99

Status of facility: Performing mammography

Little York Medical Center
2708 Little York
Houston, TX 77093
Facility ID #193680

Adverse action:	Other State action: enforcement conference
Reason for action:	Due to the facility's reluctance to respond to inquiries from the Registration Branch of this agency, an unannounced inspection was conducted. The inspection revealed major quality control problems. Enforcement conference was conducted on November 30, 1999.
Corrective action:	The facility provided a satisfactory response to all items noted on the Notice of Violation. The Little York Medical Center is no longer operational. The owner agreed to an increased inspection frequency and unannounced inspections at the new Tidwell site, when and if owner begins mammography at that site. In addition, the owner has to prove that the facility is capable of operating in full compliance, all with the understanding that any repeat or similar violations, are grounds to immediately assess administrative penalties.

Date of inspection/adverse action: 07/09/99

Date of corrective action/reinstatement: 11/30/99

Status of facility: No longer performing mammography at the Little York Medical Center site.

Millennium Diagnostic Imaging
122 West Colorado
Dallas, TX 75208
Facility ID #130880

Adverse action:	Other State action: enforcement conference
Reason for action:	Referred to Escalated Enforcement Branch due to failure to respond to a Notice of Violation. The Escalated Enforcement program requested a follow-inspection.
Corrective action:	Attempted inspection revealed facility is closed (with records in storage). Patient notification has been initiated. The enforcement action is now closed.

Date of inspection/adverse action: 06/25/98

Date of corrective action/reinstatement: 11/18/99

Status of facility: Facilty is closed. Organization is bankrupt.

Ross Breast Center
910 E. Houston, Suite 650
Tyler, TX 75702
Facility ID #147694 and 182246

Adverse action:	Other State action: enforcement conference
Reason for action:	An enforcement conference has been scheduled to discuss several serious health related violations cited during the November 8, 1999, inspection report.
Corrective action:	The facility provided a satisfactory response to all items noted on the Notice of Violation. They agreed to an increased inspection frequency and unannounced inspections to prove they are capable of operating in full compliance, all with the understanding that any repeat or similar violations, are grounds to immediately assess administrative penalties.

Date of inspection/adverse action: 11/08/1999

Date of corrective action/reinstatement: 02/01/00

Status of facility: Performing mammography

How to Find an FDA-Certified Facility

Cancer Information Service. To operate legally, a mammography facility must have and prominently display a Food and Drug Administration (FDA) certificate. This certificate shows that the mammography facility is certified by FDA as meeting baseline quality standards for equipment, personnel and practices under the Mammography Quality Standards Act of 1992 (MQSA). Consumers and health professionals can locate FDA certified facilities in their geographical area by calling the Cancer Information Service at 1-800-4-CANCER (1-800-422-6237). Information specialists at this number have been trained to answer questions about mammography and breast cancer. Written documentation on mammography is also available on request.

Internet. The FDA Mammography Website, http://www.fda.gov/cdrh/mammography, provides a listing of all FDA certified facilities by selected State (or U.S. territory) and ZIP code.

National Technical Information Service: The list is available on a computer diskette and is sold as either a single issue (the most recent diskette) or a subscription (the diskette is updated quarterly).

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

To order a single disk, call 1-800-363-2068. The NTIS order number is SUB-5386/Code D01.