DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1350 Piccard Drive
Rockville MD 20850

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# MAMMOGRAPHY FACILITY ADVERSE EVENT AND ACTION REPORT - 2008

## BACKGROUND

Congress enacted the Mammography Quality Standards Act (MQSA) in 1992, marking the first time mammography facilities were required by the federal government to meet strict quality standards. The intent of MQSA is to assure the quality of mammography nationwide. Quality mammography can detect breast cancer in its earliest, most treatable stages. Studies show that widespread use of mammography can reduce deaths from breast cancer.

Congress charged the Food and Drug Administration (FDA) with implementing and enforcing MQSA. With the help of the National Mammography Quality Assurance Advisory Committee (NMQAAC), FDA developed interim regulations, initiated an inspection program, and issued comprehensive final regulations that became effective on April 28, 1999. The final regulations strengthen the 1994 interim standards for personnel, equipment, quality assurance and quality control activities, and reporting of exam results as well as requirements for the accreditation bodies. To help providers and patients understand how MQSA affects them, FDA developed the Mammography web site.

As of December 31, 2008, there were 8,817 facilities fully certified under the MQSA operating in the United States.

As part of MQSA, Congress mandated there be annual reporting of adverse actions taken against mammography facilities. Congress stipulated that the report be made available to physicians and the general public and that it should include information that is useful in evaluating the performance of mammography facilities nationwide. FDA provides this information in its annual Mammography Facility Adverse Event and Action Report.

To gather data for this report, FDA consulted with and received reports from the following federal, State, and territorial agencies, as well as the American College of Radiology (ACR):

- **The Inspector General, Health and Human Services (HHS), Center for Medicare and Medicaid Services (CMS) for data about fraud, abuse, kickbacks and false billing under Medicare and Medicaid.**

  The HHS Inspector General lists no conviction data under Medicare or Medicaid for cases related to mammography facilities in 2008. There were no prosecutions or convictions related to mammography facilities under Federal or State laws relating to fraud, abuse, false billings or kickbacks.

- **The MQSA Accreditation Bodies (ABs) for reports of revocation, suspension of accreditation, and cease and desist orders.**

  Each year, FDA asks all of the accreditation bodies approved under the MQSA to report whether they suspended or revoked the accreditation of facilities that they accredit. Revocation and suspension are means used by the accreditation body to withdraw a facility's accreditation prior to its expiration date for reasons other than voluntary withdrawal by the facility. Currently, the FDA-approved accreditation bodies are the ACR and the States of Arkansas (SAR), Iowa (SIA) and Texas (STX).

  The ACR reported one revocation of facility accreditation and the States of Arkansas, Texas, and Iowa reported no revocations of accreditation in 2008. The STX accreditation body reported an adverse event and required corrective action against one facility, as identified in this report.

- **The MQSA States as Certifiers (SAC) certification agencies for actions taken against mammography facilities in their respective States.**

  Each year, FDA asks all of the State certification agencies approved under the MQSA to report whether they took any actions against mammography facilities that they certify. Currently, the FDA-approved certification agencies are the States of Illinois (SIL), Iowa (SIA), South Carolina (SSC) and Texas (STX).

  The States of Illinois, Iowa, South Carolina and Texas reported no actions against mammography facilities in 2008.

- **FDA's Office of Communication, Education, and Radiation Programs (OCER), Division of Mammography Quality and Radiation Programs (DMQRP), Inspection and Compliance Branch (ICB) for actions taken against mammography facilities.**

The FDA reported three occasions when actions were taken against mammography facilities in 2008, as described in this report.

- **FDA's Office of Criminal Investigations (OCI) for criminal prosecution against individuals associated with mammography facilities.**

  The Office of Criminal Investigations reported no criminal prosecution or conviction cases related to mammography facilities in 2008.

- **All States and U.S. territories for actions they have taken under their own authority against mammography facilities.**

  MQSA does not preclude a State or U.S. territory from having stricter mammography requirements than those of MQSA. In States that have additional requirements, facilities are required to comply with both State and MQSA regulations to operate lawfully.

  States that reported adverse events and subsequent corrective actions are reported below. Only adverse events that compare to those actions under MQSA are included in this report. However, where a State has taken the same action that FDA would take, FDA does not duplicate the action. Four States reported adverse events and subsequent corrective actions for calendar year 2008.

**The following report provides information on facilities that have had adverse events and subsequent corrective actions taken by them for the calendar year 2008.** The format is in alphabetical order by State, local agency, and U.S. Territory. When a State is not listed, there were no adverse events reported by the State that were comparable to actions that would be taken under MQSA.

**MAMMOGRAPHY FACILITIES AGAINST WHICH THERE WERE ADVERSE ACTIONS**

## The State of Arizona

**Phoenix Diagnostic Imaging (dba Dobson Imaging)**
**1133 South Dobson Road Suite 101**
**Mesa, AZ 85202**

**FDA Facility ID: 101311**

**Adverse Event:** On April 18, 2008, an annual MQSA inspection found multiple quality control (QC) program failures, including phantom image testing, medical audit facility reporting, infection control and compression QC testing. The State also later learned that the facility failed to disclose, at the time of the inspection, several locum tenens interpreting physicians working at the facility.

**Action Taken:** **State of Arizona authority –** The State conducted a follow-up inspection on July 17, 2008 to evaluate the credentials of the several locum tenens interpreting physicians.

The State imposed civil money penalties on the facility, totaling $3,500.

**Corrective Action**: The State of Arizona found the facility's response addressing the findings from the annual MQSA inspection satisfactory and closed the inspection on September 23, 2008.

**Status of Facility:** Performing mammography

## The State of California

**Clinica Medica General Los Angeles East Whittier**
**6125 East Whittier Boulevard**
**Los Angeles, CA 90022**

**FDA Facility ID:** **196147**

**Adverse Event:** On March 6, 2008, an annual MQSA inspection found multiple serious quality control (QC) program failures, including processor QC and phantom image testing not performed for a period of over 5 months, and personnel qualification findings for interpreting physicians and a radiologic technologist.

**Action Taken:** **Mammography Quality Standards Act (MQSA) authority -** FDA required the facility to undergo an additional mammography review (AMR) for the time

period July 14, 2006 through July 14, 2008 to assess the quality of mammography. The facility passed the AMR.

**State of California authority –**

- The State issued the facility a "Notice of Violation and Radiation User's Declaration," a voluntary cease and desist order and on April 29, 2008, the facility ceased performing mammography. Upon hiring a new interpreting physician, the facility was allowed to resume performing mammography on May 6, 2008.

- On April 29, 2008, the State of California served the facility's lead interpreting physician with a notice of suspension of her California X-ray Supervisor and Operator's Certificate. This is a State-issued Certificate that authorizes a physician to supervise radiology personnel and operate radiographic equipment. The physician has filed an appeal with the State and a hearing date is currently scheduled for May 2009.

**Corrective Action**: The State of California found the facility's response addressing the findings from the annual MQSA inspection satisfactory and on October 21, 2008 the inspection was closed.

**Status of Facility:** Performing mammography

## The State of Florida

**Strax Institute, Inc.**
**4300 North University Drive, Suite E200**
**Lauderhill, FL 33351**

**Facility ID:** **113902**

**Adverse Event:** The facility's accreditation body received multiple complaints from patients who had been unsuccessful in getting their past mammogram films from Strax

Institute. The accreditation body's attempts to get a response from the facility were also unsuccessful. In August 2008, the accreditation body reported the matter to FDA.

**Action Taken:** **Mammography Quality Standards Act (MQSA) authority –** Working with the State of Florida, FDA was able to secure and establish custodianship for the mammography records abandoned by Strax Institute.

These records are currently housed at Westside Regional Medical Center, 8201 West Boward Blvd., Plantation, FL 33326. Persons interested in obtaining their records may call (954) 916-5483.

On November 16, 2008, the facility's certification expired.

**The American College of Radiology (ACR) authority –** On November 16, 2008, the ACR revoked the Strax Institute's accreditation due to the facility's non-responsiveness to the accreditation body. The facility has not taken any actions to begin reinstatement of its accreditation.

**Corrective Action**: The facility is out of business and patients have access to their mammograms.

**Status of Facility:** Not performing mammography

## The State of Georgia

**Tift Regional Medical Center – West Campus**
**2225 U.S. Hwy 41 North**
**Tifton, GA 31793**

**Affinity Health Group, LLC**
**2225 U.S. Hwy 41 North**
**Tifton, GA 31793**

**Facility ID**: **199109**

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| **Adverse Event:** | On June 1, 2007, Tift Regional Medical Center (TRMC) purchased the mammography facility Affinity Health Group, LLC.<br><br>On September 7, 2007, TRMC self-reported that processor and phantom image testing quality control (QC) records were being falsified by the QC technologist. An FDA inspection performed in response to the report was conducted on September 19, 2007. The inspection found multiple QC program failures, including processor QC and phantom image testing failures. FDA required the facility to undergo additional mammography review (AMR) for the time period December 15, 2005 through September 14, 2007, to assess the quality of mammography. Based on the results of the AMR, FDA found that the quality of mammography represented a serious risk to human health. |
| **Action Taken:** | **Mammography Quality Standards Act (MQSA) authority -** On March 21, 2008, FDA required the facility to notify all patients and their referring physicians of the risk to health (patient and physician notification, "PPN") for those patients who had mammograms performed during the time period December 15, 2005 through September 14, 2007.<br><br>Additionally, TRMC terminated the lead QC technologist and radiology department supervisor on September 13, 2007. |
| **Corrective Action**: | The PPN was completed on July 28, 2008. The facility voluntarily closed on September 14, 2007. |
| **Status of Facility:** | Not performing mammography |

## The State of New Jersey

**American Mobile Med Surgical Group, Inc. - MOBILE**
**39 Tantum Court**
**Bordentown, NJ 08505**

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| **Facility ID:** | **236698** |
| **Adverse Event:** | Inmates at the Edna Mahan Correctional Facility for Women, in Clinton, New Jersey, had mammograms performed by American Mobile Med Surgical Group. FDA found that American Mobile performed mammography without a certificate and operated out of compliance with quality standards, including failure to comply with quality control testing requirements.<br><br>American Mobile failed to obtain accreditation and was not available to undergo inspection. On June 4, 2007, FDA informed American Mobile that it would not be issued a certificate. The facility agreed to undergo inspection. An inspection was performed on June 11, 2007, and serious problems were found. FDA required American Mobile to undergo additional mammography review (AMR) for mammograms performed during the time period January 1, 2006 through June 15, 2007 to assess clinical image quality. Based on the results of the AMR, FDA found that the quality of mammography represented a serious risk to human health. |
| **Action Taken:** | **Mammography Quality Standards Act (MQSA) authority -** On January 30, 2008, FDA required the facility to notify all patients and their referring physicians of the risk to health (patient and physician notification, "PPN") for those patients who had mammograms performed during the time period January 1, 2006 through June 15, 2007. American Mobile failed to respond to FDA's letter requiring PPN. FDA and the State of New Jersey Department of Corrections collaborated to perform the PPN at Edna Mahan Correctional Facility. |
| **Corrective Action:** | The PPN was completed on June 2, 2008. FDA denied the facility certification and it is currently out of business. |
| **Status of Facility:** | Not performing mammography |

## The State of Nevada

**Desert Springs Hospital**
**2075 East Flamingo Road**
**Las Vegas, NV 89119**

**FDA Facility ID:** **221912**

**Adverse Event:** On February 20**,** 2008, an annual MQSA inspection found that the facility performed mammography when it had failed to perform phantom image testing for 21 consecutive weeks, and processor quality control (QC) testing was either not performed or was determined to be out-of-limits with no documentation of corrective actions taken prior to performing mammography. Additional serious problems with the facility's quality assurance (QA) program were found.

**Action Taken:** **Mammography Quality Standards Act (MQSA) authority** - FDA required the facility to undergo an additional mammography review (AMR) for mammograms performed during the time period May 2007 through September 2007 to assess the quality of mammography. Based on the results of the AMR, FDA found that although there were deficiencies, the quality of mammography did not represent a serious risk to human health.

**State of Nevada authority -** The radiologic technologist and department manager were terminated. The radiologic technologist was denied renewal of her State mammography certification. Another radiologic technologist has assumed the mammography and QC testing duties, and the facility has a new department manager.

The State of Nevada pursued regulatory actions against the facility and the radiologic technologist under State authority, as follows:

- Desert Springs Hospital - (1) The hospital paid a fine of $228,000, and (2) agreed to provide

community service for a period of one year. The facility agreed to be monitored by the State of Nevada on a quarterly basis during this year.

- Radiologic technologist – Action against the radiologic technologist resulted in a fine of $2,500 and the requirement that she must successfully complete additional training in mammography before reapplying for her State mammography certification.

**Corrective Action**: Based on the AMR deficiency results, ACR required the facility to undergo a corrective action plan that was successfully completed on November 12, 2008.

**Status of Facility:** Performing mammography

## The State of New York

**Taylor Brown Health Center**
**369 East Main Street**
**Waterloo, NY 13165**

**Facility ID:** **141507**

**Adverse Event:** On June 26, 2008, an annual MQSA inspection found that the facility did not perform any quality control (QC) testing from May 1, 2007 through June 13, 2008.

**Action Taken:** **Mammography Quality Standards Act (MQSA) authority** - FDA required the facility to undergo an additional mammography review (AMR) for mammograms performed during the time period August 18, 2006 through June 13, 2008, to assess the quality of mammography. Based on the results of the AMR, FDA found that the quality of mammography represented a serious risk to human health.

On October 10, 2008, FDA required the facility to notify all patients and their referring physicians of the risk to health (patient and physician notification, "PPN") for those patients who had mammograms

performed during the time period August 18, 2006 through June 13, 2008.

**Corrective Action**: The PPN was completed on January 15, 2009. The facility voluntarily discontinued performing mammography.

**Status of Facility:** Not performing mammography

## The State of Pennsylvania

**Hahnemann University Hospital**
**Outpatient Imaging Center**
**216 N. Broad St - Third Floor**
**Philadelphia, PA 19102**
**Facility ID: 115246**

**Hahnemann University Hospital**
**Broad and Vine Streets**
**Mail Stop #206**
**Philadelphia, PA 19102**
**Facility ID: 193110**

**Adverse Events:** On September 20, 2007 and October 4, 2007 (respectively), annual MQSA inspections of these two related mammography facilities found multiple serious quality control (QC) program failures, including processor QC and phantom image testing QC.

**Action Taken:** **Mammography Quality Standards Act (MQSA) authority** - On April 21, 2008, FDA conducted follow-up inspections at each facility.

**State of Pennsylvania authority -** The State of Pennsylvania imposed civil penalties totaling $31,250.

**Corrective Action**: The follow-up inspections and subsequent facility records confirmed that corrective actions had been successfully implemented at both facilities.

**Status of Facilities:** Both facilities performing mammography

## The State of Texas

**GMG Health Systems, Ltd.**
**dba Gonzaba Medical Group - Northwest**
**7616 Culebra Road**
**San Antonio, Texas 78251**

**FDA Facility ID:** **114157**

**Adverse Event:** An October 2007 targeted onsite visit performed by the State of Texas accreditation body (STX AB) because the facility was having difficulty with its clinical images during the reaccreditation process revealed possible problems with the interpretations of mammograms, as well as with the medical audit program. The STX AB required a limited image review that was performed by the AB in October 2007. The facility failed the review and a full additional mammography review (AMR) was required.

**Action Taken:** **State of Texas Accreditation Body (STX AB) authority –**

- A full AMR was performed for mammograms performed during the time period May 1, 2006 through May 12, 2008 to assess the quality of mammography, as well as the interpretive reports. Based on the results of the AMR, FDA found that the quality of mammography represented a serious risk to human health.

- The interpreting physician who read the mammogram films during the time period May 1, 2006 through May 12, 2008 is no longer working at the facility.

**Corrective Action**: The STX AB, with FDA concurrence, required the facility to undergo a corrective action plan that required all mammograms performed and interpreted at the facility during the time period May 1, 2006 through May 12, 2008 be reviewed (interpreted a

second time), for which the facility hired a new interpreting physician.

The facility was required to perform a modified patient and physician notification (PPN) by notifying only those patients and their physicians of the risk to health for those patients where the new interpretation revealed that the original interpretation had been incorrect. The PPN was completed on January 12, 2009.

**Status of Facility:** Performing mammography

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## STATES THAT DID NOT SUBMIT OR SUBMITTED INCOMPLETE ADVERSE EVENT AND ACTION INFORMATION

There were no States that missed any monthly reporting for actions they took against mammography facilities under State laws for the time period of January 1, 2008 through December 31, 2008.

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## HOW TO FIND AN FDA-CERTIFIED FACILITY

### Cancer Information Service

To operate legally, a mammography facility must have and prominently display an FDA MQSA certificate or a similar certificate from a State certifying body. This certificate shows that the mammography facility is certified as meeting baseline quality standards for equipment, personnel, and practices under the Mammography Quality Standards Act (MQSA). Consumers and health professionals can locate MQSA-certified facilities in their geographic area by calling the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237). Information specialists at this number are trained to answer questions about mammography and breast cancer. Written documentation on mammography and breast cancer is also available on request.

### Internet

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

**National Technical Information Service**

A list of all MQSA-certified mammography facilities is available on a computer diskette and sold as either a single issue (the most recent diskette) or a subscription (the diskette is updated quarterly) from:

> National Technical Information Service (NTIS)
> 5285 Port Royal Road
> Springfield, VA 22161
> http://www.ntis.gov/

To order a single disk, call 1-800-553-6847. The NTIS order number is SUB-5386/Code D01.

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