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 - 2005

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 by one-third.

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, 2005, there were 8,873 fully certified MQSA mammography facilities operating in the United States.

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 MQSA accreditation bodies (AB) for reports of revocation or suspension of accreditation and cease and desist orders.

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

- 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.

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

- All States and U.S. territories for actions they have taken against mammography facilities.

The following are adverse events and corrective actions taken in 2005:

MEDICARE/MEDICAID

The HHS Inspector General lists no conviction data under **Medicare** or **Medicaid** for cases related to mammography facilities in 2005. There were no prosecutions or convictions of mammography facilities under Federal or State laws relating to fraud, abuse, false billings, or kickbacks.

ACCREDITATION BODIES (AB)

Each year, FDA asks all of the accreditation bodies to report whether they suspended or revoked the accreditation of facilities accredited by them. 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 two revocations of accreditation and the State of Texas reported one revocation of accreditation, and the States of Arkansas and Iowa reported no revocations of accreditation in 2005.

The American College of Radiology (ACR)

Baltimore Imaging Center
724 Maiden Choice Lane, Suite 102
Baltimore, MD 21228

FDA Facility ID: 110957

Adverse Event: During an annual MQSA inspection, FDA found that the facility performed mammography when processor quality control testing was out of limits and with documentation for phantom image quality control testing missing. Based on this information and the history of other violations at the facility, FDA required an additional mammography review (AMR) to assess the quality of mammography. The AMR found a serious risk to human health at the facility.

Action Taken: Based on the results of the AMR, the ACR revoked the facility's accreditation on June 29, 2005. The facility ceased performing mammography at that time.

Corrective Action: The facility was required to complete a corrective action plan before the ACR would reinstate its accreditation. The facility successfully completed a corrective action plan, and its accreditation was reinstated on April 18, 2006.**

Status of Facility: Performing mammography

***For **FDA actions** see **FDA's** Office of Communication, Education, and Radiation Programs *section*

Geisinger Health Systems (Geisinger Clinic Lock Haven)
955 Bellefonte Avenue
Lock Haven, PA 17745

FDA Facility ID: 113712

Adverse Event: The facility contacted the State of Pennsylvania and self-reported that a radiologic technologist falsified phantom images between July and December of 2004. Based on this information, FDA required an AMR to assess the quality of mammography at the facility. The AMR found a serious risk to human health at the facility.

Action Taken: Based on the results of the AMR, the ACR revoked the facility's accreditation on June 6, 2005. The facility ceased performing mammography at that time.

Corrective Action: The facility was required to complete a corrective action plan before the ACR would reinstate its accreditation. The facility decided not to reinstate.**

Status of Facility: Not performing mammography

***For **FDA actions** see **FDA's** Office of Communication, Education, and Radiation Programs section*

State of Texas (STX)

Cyvon Imaging, Inc.
Dba Community Diagnostics Imaging, Inc.
1114 N. Bishop Street
Dallas, Texas 75208

FDA Facility ID: 223125

Adverse Event: The STX issued an Order of Revocation to the facility for failure to pay outstanding fees, but the facility continued to provide mammography services. STX performed an unannounced inspection. Based on this inspection, STX required an AMR. The facility failed the AMR with deficiencies but did not have a serious risk to human health.

Action taken: Based on the results of the AMR, the advice of STX legal counsel, and the bankruptcy court proceedings, STX revoked the facility's accreditation on November 29, 2005.

Corrective Action: The facility filed bankruptcy and ceased performing mammography at that time. The facility decided not to reinstate.

Status of Facility: Not performing mammography

STATES AS CERTIFIERS (SAC)

Each year, FDA asks all of the FDA-approved State certification agencies 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), and South Carolina (SSC).

SIL and SSC reported no actions against mammography facilities in 2005.

State of Iowa (SIA)

Knoxville Area Community Hospital Clinic
1202 West Howard
Knoxville, Iowa 50138

MQSA Facility ID: 230116

Adverse Event: During an annual inspection, SIA issued Level 1 observations when the facility's interpreting physician (IP) and the radiologic technologist (RT) failed to produce documentation that each met MQSA and State requirements for valid licenses.

Action Taken: SIA required a limited AMR, which the facility failed, resulting in a full 30-AMR, which also had image quality problems but not at a serious risk to human health.

Corrective Action: Under a Corrective Action Plan (CAP), SIA required the facility to replace the viewbox at the facility, to notify three patients of the need to be re-imaged, and required remedial training for the IP and RT. The facility successfully completed its CAP. On July 6, 2005, a follow-up random Clinical Image Review resulted in a passing score.

Status of Facility: Performing mammography

Covenant Breast and Bone Density Center
3421 West Ninth Street, Suite G4600
Waterloo, Iowa 50702

FDA Facility ID: 108423

Adverse Event: During a May 2005 inspection of the facility, SIA found that the facility falsified phantom QC test records.

Action Taken: Due to the falsification of records, SIA required a limited AMR (two sets of images). The facility passed the limited AMR.

Corrective Action: Under a CAP required by SIA, the facility was required to terminate the technologist for falsifying records, perform a thorough review of all of its mammography records, bring in

an outside auditor to review all mammography QC, and report all findings from these actions during a meeting with SIA. The facility successfully completed its CAP.

Status of Facility: Performing mammography

FDA'S OFFICE OF COMMUNICATION, EDUCATION, AND RADIATION PROGRAMS (OCER)

Baltimore Imaging Center
724 Maiden Choice Lane, Suite 102
Baltimore, MD 21228

FDA Facility ID: 110957

Adverse Event: During an annual MQSA inspection, FDA found that the facility processed mammograms when the processor quality control testing was out of limits and failed to document phantom image quality control testing. Based on this information and the history of other violations at the facility, FDA required an AMR to assess the quality of mammography at the facility. Based on the results of the AMR, FDA determined that the quality of mammography at the facility posed a serious risk to human health.

Action Taken: On July 8, 2005, FDA required the facility to notify all patients and their referring physicians that the AMR found a serious risk to human health. On that date, the FDA also suspended the facility's certificate based on the history of the facility and the fact that the ACR revoked the facility's accreditation. The facility did not perform mammography from July 8, 2005 – April 18, 2006.

Corrective Action: The Patient and Physician notification is ongoing. The facility successfully completed a corrective action plan, and its accreditation was reinstated on April 18, 2006. FDA reactivated the facility's MQSA certificate on April 18, 2006.

Status of Facility: Performing mammography

Geisinger Health Systems (Geisinger Clinic Lock Haven)

955 Bellefonte Avenue
Lock Haven, PA 17745

FDA Facility ID: 113712

Adverse Event: The facility contacted the State of Pennsylvania and self-reported that a radiologic technologist falsified phantom images between July and December of 2004. On April 15, 2005, the State of Pennsylvania issued a Noncompliance letter to the facility. Based on this information, an AMR was performed to assess the quality of mammography at the facility. The facility failed the review, and mammography quality at the facility was determined to pose a serious risk to human health. Because of this, the ACR revoked the facility's accreditation on June 6, 2005.

Action Taken: On June 8, 2005, FDA declared the facility's certificate no longer valid based on the history of violations at the facility and the fact that ACR revoked the facility's accreditation. The State of Pennsylvania required the facility to notify patients and their referring physicians.

Corrective Action: The facility decided not to reinstate.

Status of Facility: Not performing mammography

Multiple Mammography medical facilities
States of Maryland, North Carolina, Pennsylvania,
Virginia, West Virginia, and the District of Columbia

Adverse Event: A medical physicist who provided services for multiple mammography facilities submitted false qualification documents to the facilities in order to conduct surveys of mammography units from a date unknown to FDA but beginning in or before 1990 and continuing until at least November 15, 2002.

Action Taken: FDA notified the affected States of Maryland, North Carolina, Pennsylvania, Virginia, West Virginia, and the District of Columbia, which in turn notified the affected facilities. FDA also reviewed the inspection of all affected facilities and determined the facilities were not at risk because of the safeguards built in the MQSA program.

Corrective Action: FDA notified the States that physicist surveys performed after November 15, 2002 by the medical physicist should not be accepted and all facilities utilizing the physicist must obtain a new medical physicist.

FDA'S OFFICE OF CRIMINAL INVESTIGATIONS (OCI)

Cushing Regional Hospital
1027 East Cherry Street
Cushing, OK 74023

FDA Facility ID: 179044

Adverse Event: In 2001, a radiologic technologist submitted false documents to a government official for daily processor quality control and weekly phantom quality control that were not done. A review of the records indicated that a set of falsified processor and phantom film was made to fill in the missed dates.

Action Taken: Criminal prosecution of Angela S. Miles, a former employee of Cushing Regional Hospital, resulted in an October 6, 2004 Pre-Trial Diversion Agreement.

Corrective Action: Ms. Miles was sentenced to probation pursuant to the Pre-Trial Diversion agreement.

Status of Facility: Performing mammography

Multiple Mammography medical facilities
States of Maryland, North Carolina, Pennsylvania,
Virginia, West Virginia, and the District of Columbia

Adverse Event: A medical physicist providing services for multiple facilities submitted false qualification documents to a government official to conduct surveys of mammography units from a date unknown to FDA but beginning in or before 1990 and continuing until at least November 15, 2002.

Action Taken: Criminal prosecution of Mr. Perry M. Beale under Title 18 USC, Section 1341 Mail Fraud.

Corrective Action: Mr. Beale was arraigned on July 22, 2004 before the U.S. District court where he pled guilty to 38 counts in violation of Title 18 USC, Section 1341, Mail Fraud. On May 12, 2005, Mr. Beale was sentenced to 54 months incarceration and ordered to pay $375,831.20 in restitution.

Graham Regional Medical Center
1301 Montgomery Road
Graham, TX 76450

FDA Facility ID: 179929

Adverse Event: In 2001, a radiologic technologist submitted false documents to a government official for daily processor quality control and weekly phantom quality control that were not done. A review of the records indicated that falsified processor and phantom films were made to fill in the missed dates.

Action Taken: Criminal prosecution of Jennifer M. Coley, a former employee of Graham Regional Medical Center, that resulted in a May 6, 2005 Pre-Trial Diversion agreement.

Corrective Action: Ms. Coley was ordered to pay restitution pursuant to a Pre-Trial Diversion Agreement.

Status of Facility: Performing Mammography

STATES AND U.S. TERRITORIES

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 took adverse events and subsequent actions reported below. Only adverse events that compare to those actions under MQSA are reported. However, where states take the same action that FDA would take, FDA does not duplicate the action. A total of two (2) States reported adverse events and subsequent actions for calendar year 2005.

Pennsylvania

Geisinger Health Systems (Geisinger Clinic Lock Haven)
955 Bellefonte Avenue
Lock Haven, PA 17745

FDA Facility ID: 113712

Adverse Event: The State of Pennsylvania was contacted by the facility that the radiologic technologist had falsified phantom images between July and December of 2004. Based on this information, an AMR was performed to assess the quality of mammography at the facility. The facility failed the AMR. The quality of mammography at the facility was determined to pose a serious risk to human health.

Action Taken: Based on the results of the AMR, the ACR revoked the facility's accreditation on June 6, 2005. The facility ceased performing mammography at that time.

Corrective Action: As part of an agreement with the State of Pennsylvania, the facility sent letters to all patients who had mammograms performed between May 18, 2003, and the time it stopped performing mammography on Feb. 10, 2005, offering to pay for new mammograms at a facility of the patient's choice.

Status of Facility: Not performing mammography

Hawaii

Kapiolani Womens Center at Pali Momi
98-1079 Moanalua Road 2nd Floor
Aiea, HI 96701

FDA Facility ID: 119123

Adverse Event: During the annual MQSA inspection, problems were found with the processor and phantom QC program at the facility.

Action Taken: On March 14, 2005, the State mailed a Notice of Violation to the facility. The State also assessed the facility a penalty of $25,000.

Corrective Action: In June 2005, the State agreed to suspend $20,000 of the penalty if the facility agreed to comply with the state and federal regulations, to submit a written report every quarter no later than the 15th of the month for the next 3 years, and to pay a $5000 penalty.

Status of Facility: Performing mammography

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

There were no States that missed reporting for 3 or more months for actions they may have taken against mammography facilities under State laws for the time period of January 1 – December 31, 2005.

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.