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 - 2006

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, 2006, there were **8,833** 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, 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 may have taken against mammography facilities.

The following are adverse events and corrective actions taken in 2006

MEDICARE/MEDICAID

The HHS Inspector General lists one conviction under **Medicare** or **Medicaid** for cases related to mammography facilities in 2006. There was one prosecution under Federal law relating to false billings.

Geisinger Clinic Lock Haven
955 Bellefonte Avenue
Lock Haven, PA 17745

FDA Facility ID: 113712

Adverse Action: During an annual MQSA inspection, it was found that a technologist failed to perform MQSA-required quality control tests on mammogram machines for a period of 24 weeks, leading to false Medicare/Medicaid billings. To cover this failure, the technologist created false log records and caused another employee to backdate phantom image tests.

Action Taken: Following a plea of guilty to 1 count of False Statements Relating to Health Care Matters (18 USC 1035), the radiologic technologist was sentenced on December 5, 2006 to 3 years probation, and ordered to perform 577 hours of community service and pay $21,873 in restitution, primarily to the facility for its losses in providing free retesting of patients. In 2005, FDA suspended the facility's certificate and the State required patient and physician notification (this action was reported in the 2005 edition of this report).

Corrective Action: The technologist surrendered her National Radiography and Mammography licenses and the facility completed the patient and physician notification.

Status of Facility: Not performing mammography

MQSA 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 States of Arkansas, Texas, and Iowa reported no revocations of accreditation in 2006.

The American College of Radiology (ACR)

Englewood Imaging Center
177 North Dean Street
Englewood, NJ 07631

FDA Facility ID: 111880

Adverse Event: During an ACR Scheduled On-Site Survey (SOSS), an ACR senior reviewer determined that the facility should undergo an additional mammography review (AMR) due to serious concerns about the clinical images. A SOSS is available to facilities when it requires extensive corrective action in order to pass accreditation. FDA reviewed the findings of the SOSS and based on this information agreed that ACR should conduct the 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 September 19, 2006. 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 5, 2007. **

Status of Facility: Performing mammography

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

Women's Breast Care Clinic
2124 14th Street
Meridian, MS 39301

FDA Facility ID: 147447

Adverse Event: During an MQSA inspection, FDA found that the facility performed mammography when phantom quality control testing was out of limits and documentation for phantom image quality control testing was missing. Quality control records appeared to be falsified. 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 October 9, 2006. 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 5, 2007. **

Status of Facility: Performing mammography

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

MQSA 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).

The States of Illinois, Iowa, and South Carolina reported no actions against mammography facilities in 2006.

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

The FDA reported five occasions when actions were taken against mammography facilities in 2006.

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 complete. 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

Baltimore Imaging Center
10151 York Road
Cockeysville, MD 21030

FDA Facility ID: 229858

Adverse Event: FDA requested this facility to submit clinical images for an AMR based on the results of AMRs at facilities that are under the same ownership and management, as well as employ the same technologists who worked at this facility and their sister facilities. Based on this information and the history of other violations at this and the sister facilities, 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 April 25, 2006, FDA required the facility to notify all patients and their referring physicians that the AMR found a serious risk to human health. The facility's certificate expired on March 13, 2006, and the facility has not applied for reaccreditation.

Corrective Action: The patient and physician notification is complete. The facility has not applied for reaccreditation.

Status of Facility: Not performing mammography

Ecumed Health Group
687 E. 9 Street
Hialeah, FL 33010

FDA facility ID: 224455

Adverse event: During an FDA MQSA inspection of the facility, it was found that the facility performed mammography without a valid MQSA certificate from December 2001 – April 23, 2003.

Action taken: On July 19, 2004, FDA issued an administrative order for civil money penalties against the facility for performing mammography without a valid MQSA certificate. In 2004, FDA issued a public notice to patients and their referring physicians about a serious risk to human health that had been found during additional mammography review (this action was reported in the 2004 edition of this report).

Corrective action: As of April 28, 2006, all involved parties agreed to pay a sum total penalty of $495,400.

Status of facility: Not performing mammography

Englewood Imaging Center
177 North Dean Street
Englewood, NJ 07631

FDA Facility ID: 111880

Adverse Event: During an ACR Scheduled On-Site Survey (SOSS), an ACR senior reviewer determined that the facility should undergo an additional mammography review (AMR) due to serious concerns about the clinical images. FDA reviewed the findings and based on this information agreed that ACR should conduct the AMR to assess the quality of mammography. The AMR found a serious risk to human health 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 October 5, 2006, 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, FDA also suspended the facility's certificate based on the fact that the ACR revoked the facility's accreditation. The facility did not perform mammography from September 19, 2006 – April 5, 2007.

Corrective Action: The patient and physician notification is complete. The facility successfully completed a corrective action plan, and its accreditation was reinstated on April 5, 2007. FDA reactivated the facility's MQSA certificate on that same date.

Status of Facility: Performing mammography

Women's Breast Care Clinic
2124 14th Street
Meridian, MS 39301

FDA Facility ID: 147447

Adverse Event: During an MQSA inspection, FDA found that the facility performed mammography when phantom quality control testing was out of limits and 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: On October 2, 2006, the facility agreed to voluntarily notify all patients and their referring physicians that the AMR found a serious risk to human health. On December 28, 2006, FDA suspended the facility's certificate based on the fact that the ACR revoked the facility's accreditation. The facility did not perform mammography from October 2, 2006 – April 5, 2007.

Corrective Action: The patient and physician notification is complete. The facility successfully completed a corrective action plan, and its accreditation was reinstated on April 5, 2007. FDA reactivated the facility's MQSA certificate on that same date.

Status of Facility: Performing mammography

FDA'S OFFICE OF CRIMINAL INVESTIGATIONS (OCI)

The Office of Criminal Investigations reported two criminal prosecution or conviction information cases related to mammography facilities in 2006.

Diagnostic Medical Group of Southern California
1129 S. San Gabriel Blvd.
San Gabriel, CA 91776

FDA Facility ID: 202002

Adverse Event: During an annual MQSA inspection, it was found that an interpreting physician provided a falsified American Board of Radiology certificate as proof that she met the MQSA requirements.

Action Taken: Referred to Medical Board of California for appropriate action against Andrea Mallet-Reese, M.D.

Corrective Action: Effective October 13, 2006, Dr. Mallet-Reese was sentenced to 36 months probation and 15 day suspension of her physician's and surgeon's certificate commencing January 1, 2007, for violations of California Business and Professions Codes, sections 2261, 2234(e), 651, and 2234

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.

Action Taken: Prosecution and conviction of radiologic technologist Josephine M. Latini, a former employee of Geisinger Clinic Lock Haven. In 2005, FDA had suspended the facility's certificate and the State had required patient and physician notification (this action was reported in the 2005 edition of this report).

Corrective Action: On December 6, 2006, Ms. Latini was sentenced by U.S. District Judge to three years probation, ordered to pay $21,782 in restitution, and to perform 577 hours of community service for violating 18 USC 1035 (False Statements Relating to Healthcare Matters).

Status of Facility: Not 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. Four (4) States reported adverse events and subsequent actions for calendar year 2006.

California

Paradise Valley Hospital
2400 East Fourth Street
National City, CA 91950

FDA Facility ID: 151449

Adverse Event: During an annual MQSA inspection, it was found that the facility performed mammography without current State certification.

Action Taken: The State of California required the facility to notify all affected patients and their referring physicians and levied a fine of $299,000 against the facility.

Corrective Action: The patient and physician notification is complete.

Status of Facility: Performing mammography

New Jersey

St. Mary's Hospital
211 Pennington Ave.
Passaic, NJ 07055

FDA Facility ID: 139931

Adverse Event: During a State inspection conducted as the result of a complaint, it was found that the facility performed

mammography when the quality assurance program did not meet State requirements.

Action Taken: The State levied administrative penalties with a corrective action of "Notice of Prosecution for $2500."

Corrective Action: The facility paid the administrative penalty.

Status of Facility: Not performing mammography

New York City

Bay Imaging
2626 East 14th Street,
Brooklyn, NY 11235

Bay Imaging
1620 Caton Ave.
Brooklyn, NY 11226

Bay Imaging
9201 4th Avenue.
Brooklyn, NY 11209

FDA Facility ID: 102632, 102640, and 209767

Adverse Event: New York City Bureau of Radiological Health, the New York State Health Department, and FDA received complaints from patients stating they had not received the results of their mammogram within 30 days of having their mammogram.

Action Taken: On August 16 and 18, 2006, the New York City Bureau of Radiological Health sealed the mammography units at the three facilities.

Corrective Action: The facilities stopped performing mammography.

Status of Facilities: Not performing mammography

In addition to the above action taken against Bay Imaging, FDA has also worked closely with New York City and State to investigate this adverse event and assist in actions taken under the

City and State laws. FDA continues to investigate and any FDA actions will be reported in calendar year 2007.

Astoria Medical Imaging
27-47 Crescent St, Suite 107
Astoria, NY 11102

FDA Facility ID: 237627

Adverse Event: During a State inspection, it was found that the facility was operating without valid New York City registration.

Action Taken: On August 9, 2006, the City of New York sealed the mammography unit and issued a "Notice of Violation" to the facility with a monetary penalty of $1000.

Corrective Action: On August 24, 2006, the facility paid a $1000 fine. The facility obtained a valid New York City registration.

Status of Facility: Performing mammography

Pennsylvania

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 and FDA suspended its certification. The State required patient and physician notification (this action was reported in the 2005 edition of this report).

Action Taken:	On February 28, 2006, Pennsylvania Department of Environmental Protection (DEP) fined Geisinger Health Systems $900,000 for violating MQSA.
Corrective Action:	The technologist surrendered her National Radiography and Mammography licenses. The facility paid the civil money penalty on March 21, 2006.
Status of Facility:	Not performing mammography

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

The following states missed reporting for three or more months for actions they may have taken against mammography facilities under State laws for the time period of January 1 – December 31, 2006.

State of Connecticut

Department of Environmental Protection
Division of Radiation
79 Elm Street
Hartford, CT 06106-5127
Attention: Denny Galloway
(860) 424-3029

State of Delaware

Office of Radiation Control
Division of Public Health
417 Federal Street
Dover, DE 19903
Attention: Robert Brinsfield, Sr.
(302) 744-4546

State of Wyoming

Mammography Program
Department of Health
2300 Capital Avenue
Hathaway Bldg., Room 482
Cheyenne, WY 82002

Attention: Dewey Long
(307) 777-6057

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.