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 - 2004

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.

FDA has been conducting inspections under the final regulations since July 1999. Since that time, the number of citations at all levels has decreased, particularly for serious and moderate non-compliant findings.

As of December 31, 2004, there were **8,979** fully certified MQSA mammography facilities operating in the United States.

In order to gather data for this report, FDA consulted with and received reports from the following entities:

- 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 2004:

MEDICARE/MEDICAID

The HHS Inspector General lists no conviction data under **Medicare** or **Medicaid** for cases related to mammography facilities in 2004. 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, we ask 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, there are four FDA-approved accreditation bodies – the American College of Radiology (ACR) and the States of Arkansas (SAR), Iowa (SIA) and Texas (STX). The State of California (SCA) voluntarily withdrew its application seeking status as an AB under the Mammography Quality Standards Act (MQSA) Final Regulations on May 5, 2004.

The ACR reported two revocations of accreditation, the State of Iowa reported two suspensions of accreditation, and the State of Texas reported one suspension of accreditation.

The American College of Radiology (ACR)

Cascade Medical Center
817 Commercial St.
Leavenworth, WA 98826

FDA Facility ID: 198002

Adverse Event: During an annual MQSA inspection, it was found that processor quality control testing was missing on 15 days and phantom image quality control testing was missing on 9 days. Based on this information and the history of other violations at the facility, an additional mammography review was performed to assess the quality of mammography at the facility. The facility failed the additional mammography review. 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 additional mammography review, the ACR revoked the facility's accreditation on April 9, 2004. 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 July 23, 2004.

Status of Facility: Performing mammography.

See additional actions under ***FDA's* Office of Communication, Education, and Radiation Programs *for further information.*

Baltimore Imaging Centers
4000 Old Court Rd., Ste. 103
Pikesville, MD 21208

FDA Facility ID: 106401

Adverse Event: During an annual MQSA inspection, it was found that the facility operated 23 days with processor quality control testing being out of limits and on 3 occasions with no

documented phantom image quality control testing being performed. Based on this information and the history of other violations at the facility, an additional mammography review was performed to assess the quality of mammography at the facility. The facility failed the additional mammography review. 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 additional mammography review, the ACR revoked the facility's accreditation on May 20, 2004. 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 November 23, 2004.

Status of Facility: Performing mammography.

See additional actions under **FDA's Office of Communication, Education, and Radiation Programs *for further information.*

State of Iowa (SIA)

Community Memorial Hospital
909 West First Street
Sumner, IA 50674

FDA facility ID: 168153

Adverse event: The facility failed three phantom images submitted for re-accreditation.

Action taken: On April 7, 2004, after three failed attempts of passing the phantom image, the facility was required to immediately cease providing mammography services until the additional mammography review was completed and the phantom image passed accreditation.

Corrective action: The facility improved the phantom image quality and submitted clinical images for the additional mammography

review. The facility passed the additional mammography review on June 8, 2004 and passed the phantom image on June 16, 2004.

Status of facility: Performing mammography

Montgomery County Memorial Hospital
2301 Eastern Avenue
Red Oak, IA 51566

FDA facility ID: 160796

Adverse event: During the annual MQSA inspection, the facility received violations related to the phantom image quality testing which is a test that utilizes a test object to simulate radiographic characteristics of compressed breast tissue and contains objects that radiographically model aspects of breast disease and cancer. Also, during two subsequent visits to the facility, it failed the phantom image testing.

Action taken: The facility voluntarily stopped providing mammography services. The facility was required to submit mammography images for an additional mammography review due to the numerous phantom image failures.

Corrective action: During follow up inspections of the facility, it passed the phantom image test. On June 8, 2004, the facility passed the additional mammography review.

Status of facility: Performing mammography

State of Texas (STX)

Big Spring Hospital Corporation
1601 West 11th Place
Big Spring, TX 79720

FDA Facility ID: 176701

Adverse Event: Based on the results of a random evaluation of two clinical images, the State of Texas accreditation body performed a thirty image additional mammography review. The facility failed the additional mammography review. The quality of

mammography at the facility was determined to pose a serious risk to human health.

Action taken: The State of Texas accreditation body suspended the facility's accreditation on June 21, 2004. The facility ceased performing mammography at that time.

Corrective Action: The facility successfully completed a corrective action plan and its suspension of accreditation was lifted on September 16, 2004. The facility resumed mammography services on September 16, 2004.

Status of Facility: Performing mammography.

STATES AS CERTIFIERS (SAC)

Each year, we ask all of the FDA-approved certification agencies to report whether they took any actions against mammography facilities that they certify. Currently, there are two FDA-approved certification agencies–the States of Illinois and Iowa.

The **States of Illinois and Iowa** reported no actions against mammography facilities in 2004.

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

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

FDA facility ID: 224455

Adverse event: During an unannounced FDA MQSA inspection of the facility, it was found that the facility was performing mammography without a valid MQSA certificate. Because of the uncertified operation, an additional mammography review 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.

Action taken: On January 7, 2004, the facility was required to notify all affected referring physicians and patients of possible compromise of mammography quality. The facility failed to notify patients and their referring physicians. On August 23, 2004, the FDA notified all affected referring physicians and patients of possible compromise of mammography quality through media outlets.

Corrective action: The Patient and Physician Notification is complete. The facility has not applied for reaccreditation.

Status of facility: Not performing mammography.

Maryland
Baltimore Imaging Center
4000 Old Court Road, Ste. 103
Baltimore, MD 21208

FDA facility ID: 106401

Adverse event: During an annual MQSA inspection, it was found that the facility processed mammograms for 23 days when processor quality control testing was out of limits and on 3 occasions with no documented phantom image quality control testing being performed. Based on this information and the history of other violations at the facility, an additional mammography review 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 May 20, 2004.

Action taken: On June 21, 2004, the facility was required to notify all affected referring physicians and patients of possible compromise of mammography quality. The FDA also declared the facility's certificate no longer valid 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 May 20, 2004 – September 27, 2004.

Corrective action: The Patient and Physician Notification is ongoing. The facility successfully completed a corrective action plan, and its accreditation was reinstated on November 23, 2004. FDA reactivated the facility's MQSA certificate on November 29, 2004. The facility resumed performing mammography on December 3, 2004.

Status of facility: Performing mammography.

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

FDA facility ID: 110957

Adverse event: During an annual MQSA inspection, it was found that the facility operated without a valid MQSA certificate from May 6 – July 26, 2002.

Action taken: On September 15, 2003, FDA issued an administrative penalty order against the facility for performing mammography without a valid MQSA certificate.

Corrective action: On December 17, 2004, the Administrative Law Judge issued an order for a total civil money penalty of $1,158,000. The facility has appealed the judge's ruling and the Health and Human Services (HHS) Departmental Appeals Board is currently reviewing it.

Status of facility: Performing mammography.

New York City
Union Square Medical Imaging & Mammography
(Formerly known as Park Avenue Mammography)
200 Park Avenue South, Suite 1103
New York City, NY 10003

FDA facility ID: 129825

Adverse event: Based on a failed additional mammography review performed by the State of New York, an additional mammography review 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.

Action taken: On December 2, 2003, the facility was required to notify all affected referring physicians and patients of possible compromise of mammography quality.

Corrective action: The Patient and Physician Notification is complete.

Status of facility: Performing mammography.

Washington

Cascade Medical Center
817 Commercial Street
Leavenworth, WA 98826

FDA facility ID: 198002

Adverse event: During an annual MQSA inspection, it was found that processor quality control testing was missing on 15 days and phantom image quality control testing was missing on 9 days. Based on this information and the history of other violations at the facility, an additional mammography review 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 April 9, 2004.

Action taken: On May 7, 2004, the facility was required to notify all affected referring physicians and patients of possible compromise of mammography quality. The FDA also declared the facility's certificate no longer valid 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 April 9, 2004 – August 6, 2004.

Corrective action: The Patient and Physician Notification is complete. The facility successfully completed a corrective action plan, and its accreditation was reinstated on July 23, 2004. FDA reactivated the facility's MQSA certificate on July 30, 2004.

The facility resumed performing mammography on August 6, 2004.

Status of facility: Performing mammography.

FDA'S OFFICE OF CRIMINAL INVESTIGATIONS (OCI)

The Office of Criminal Investigations reported no criminal prosecution or conviction data for cases related to mammography facilities in 2004.

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.

Adverse events and subsequent actions reported below were taken by States. 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 States reported adverse events and subsequent actions for calendar year 2004.

New Jersey

Bayonne Medical Center
29th Street & Avenue E
Bayonne, NJ 07002

FDA facility ID: 141754

Adverse Event: During the annual MQSA inspection, it was found that the x-ray field at the edge of the image-receptor support designed to be adjacent to the chest wall extended beyond the edge of the image receptor support by more that 2% of the source to image distance (SID).

Action taken: On April 20, 2004, an administrative order was issued which gave the facility 30 days to correct the alignment problem.

Corrective Action: On April 28, 2004, the facility notified the state that the problem had been corrected.

Status of Facility: Performing mammography

New York City

Central Brooklyn Medical Group, P.C. - Downtown Center
345 Schermerhorn Street
Brooklyn, New York 11217

FDA facility ID: 186783

Adverse event: Facility failed to produce documents demonstrating that a radiologic technologist had a valid state license from an FDA approved body.

Action taken: On June 18, 2004, a hearing was held to determine the monetary penalty for the facility. The Radiology administrator of this facility provided a valid New York State license for the radiologic technologist involved.

Corrective action: Per the Administrative Tribunal Judge, the evidence produced met the requirement that the radiologic technologist be properly licensed and therefore this facility was not fined.

Status of facility: Performing mammography

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

The following States missed reporting for 3 or more months for actions they may have taken against mammography facilities under State laws. You may contact them directly if you have questions about facilities in their State for the time period of January 1 – December 31, 2004.

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 Kentucky
Radiation Health and Toxic Agents Branch
Cabinet for Health Services
275 East Main Street
Frankfort, KY 40621-0001
Attention: Dewey Crawford
(502) 564-7818 Ext. 3695

State of Mississippi
Division of Radiological Health
State of Department of Health
3150 Lawson Street
P.O. Box 1700
Jackson, MS 39215-1700
Attention: Herman Gaines
(601) 987-6893

State of Puerto Rico*
Radiological Health Division
Department of Health
P. O. Box 70184
San Juan, PR 00936-8184
Attention: Raul Hernandez
(787) 274-7815

State of South Carolina
Bureau of Radiological Health
Department of health and Environmental Control
2600 Bull Street
Columbia, SC 29201
Attention: Aaron Gantt
(803) 545-4420

State of Tennessee
Division of Radiological Health
L & C Annex, Third Floor
401 Church Street
Nashville, TN 37243-1532
Attention: Mary Helen Short
(615) 532-0363

**Failed to report for greater than 3 months for the second year in a row*

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 FDA-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 FDA certified facilities by selected State (or U.S. territory) and zip code.

National Technical Information Service

A list of all FDA-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

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