DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 27, 2004

MAMMOGRAPHY FACILITY ADVERSE EVENT AND ACTION REPORT - 2003

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, 2003, there were 9,117 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 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 Health and Industry Programs (OHIP), Division of Mammography Quality and Radiation Programs (DMQRP), Inspection and Compliance Branch 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 2003:

MEDICARE/MEDICAID

The HHS Inspector General lists no conviction data under **Medicare** or **Medicaid** for cases related to mammography facilities in 2003. There were no prosecutions or convictions of mammography facilities under Federal or State laws relating to fraud, abuse, false billings or kickbacks.

ACCREDITATION BODIES

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), although California (SCA) was an approved accrediting body during the 2003 reporting period.

The ACR reported one revocation of accreditation and the State of Texas reported one suspension of accreditation.

The American College of Radiology (ACR)

Caribbean Imaging & Radiation Treatment Center, Inc.
Edificio Parra
2225 Ponce By Pass, Ste. 102-105
Ponce, PR 00717

FDA facility ID:	184200
Adverse event:	During an annual inspection, it was found that the facility operated from September 17, 2002 and March 5, 2003 with no documented processor quality control testing being performed and from August 19, 2002 – March 5, 2003 with no documented phantom image quality control testing being performed. Based on this information, 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 considered to pose a serious risk to human health.
Action taken:	Based on the fact that the facility failed the additional mammography review, the ACR revoked the facility's accreditation on November 17, 2003. The facility ceased performing mammography at this 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 February 20, 2004. The facility resumed performing mammography on March 12, 2004.
Status of facility:	Performing mammography.

***See actions under **FDA's Office of Health and Industry Programs** and **States and U.S. Territories** for further information.*

State of Texas

Karnes County Hospital District
dba Otto Kaiser Memorial Hospital
3349 South Highway 181
Kenedy, TX 78119

FDA facility ID:	225072
Adverse event:	Based on previous failed attempts at accreditation, the State of Texas accreditation body performed an unannounced inspection at the facility and found no quality assurance or quality control program in place.
Action taken:	The State of Texas accreditation body suspended the facility's accreditation on May 29, 2003. The facility ceased performing mammography at this time.
Corrective action:	The facility successfully completed a corrective action plan and its suspension of accreditation was lifted on September 22, 2003. The facility resumed mammography services on September 22, 2003.
Status of facility:	Performing mammography.

The **States of Arkansas** and **Iowa** accrediting bodies reported no revocations or suspensions of accreditation in 2003.

The **State of California** accrediting body does not currently revoke or suspend accreditation, but rather issues cease and desist orders under State regulations. California issued no cease and desist orders during 2003.

STATES AS CERTIFIERS

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 2003.

FDA'S OFFICE OF HEALTH AND INDUSTRY PROGRAMS

Maryland

Baltimore Imaging Center
724 Maiden Choice Lane, Suite 102

Baltimore, MD 21228

FDA facility ID: 110957

Adverse event: During an annual inspection, it was found that the facility failed to perform weekly phantom image 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. Testing records were missing for the time period of June 23 -July 28, 2002. Additionally, personnel qualifications for the interpreting physician and mammography technologist were missing. The facility also operated without a valid MQSA certificate from May 6 – July 26, 2002.

Action taken: On March 3, 2003, FDA required the facility to implement a Directed Plan of Correction which allows the facility an opportunity to correct violative findings in a timely manner. The plan is currently being monitored by FDA.

Corrective action: Directed Plan of Correction ongoing and being monitored by FDA.

Status of facility: Performing mammography.

Puerto Rico

Caribbean Imaging & Radiation Treatment Center, Inc.
Edificio Parra
2225 Ponce By Pass, Ste. 102-105
Ponce, PR 00717

FDA facility ID: 184200

Adverse event 1: During an annual inspection, it was found that the facility operated from September 17, 2002 and March 5, 2003 with no documented processor quality control testing being performed and from August 19, 2002 – March 5, 2003 with no documented phantom image quality control testing being performed.

Action taken 1:	On August 21, 2003, FDA required the facility to implement a Directed Plan of Correction which allows the facility an opportunity to correct violative findings in a timely manner. The plan is currently being monitored by FDA.
Corrective action 1:	Directed Plan of Correction ongoing and being monitored by FDA.
Adverse event 2:	Based on the missing processor and phantom image quality control testing, the facility was required to submit mammography images for an additional mammography review. 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.
Action taken 2:	On December 8, 2003, the facility was required to notify all affected referring physicians and patients of possible compromise of mammography quality. The notification is currently being monitored by FDA. 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 November 17, 2003 – March 12, 2004.
Corrective action 2:	The Patient and Physician Notification is ongoing. The facility successfully completed a corrective action plan, and its accreditation was reinstated on February 20, 2004. FDA reactivated the facility's MQSA certificate on March 4, 2004. The facility resumed performing mammography on March 12, 2004.
Status of facility:	Performing mammography.

FDA'S OFFICE OF CRIMINAL INVESTIGATIONS

The Office of Criminal Investigations reported no criminal prosecution or conviction data for cases related to mammography facilities in 2003.

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 three States reported adverse events and subsequent actions for calendar year 2003.

Florida

RX Cardiovascular Specialties, Inc.
9280 Sunset Drive Bldg #1
Miami, FL 33173

FDA facility ID:	230136
Adverse event:	An anonymous caller notified the State that the facility was operating without a valid MQSA certificate. The State investigated and found that the facility operated without a valid certificate from September 16 - December 11, 2002.
Action taken:	State assessed administrative penalties in the amount of $1,000 against the facility.
Corrective action:	Facility obtained provisional accreditation on December 30, 2002 and then voluntarily withdrew its accreditation on October 13, 2003.
Status of facility:	Not performing mammography.

New York

Park Avenue Mammography
200 Park Avenue South, Suite 1103
New York City, NY 10003

FDA facility ID:	129825
Adverse event:	The facility failed a quality assurance review conducted by the New York State Department of Health Cancer Services

	Program that assessed the clinical image quality at the facility.
Action taken:	On November 5, 2003, the New York State Department of Health held a press conference to notify referring physicians and patients of possible compromise of mammography quality at the facility.
Corrective action:	The facility voluntarily withdrew as a mammography provider for the New York State Department of Health Cancer Services Program.
Status of facility:	Performing mammography.

Michigan

Northland Radiology / Seven Mile
15521 West Seven Mile Road
Detroit, MI 48075

FDA facility ID:	165167
Adverse event:	During the annual 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. The received also received violation related to processor artifacts.
Action taken:	The facility was required to immediately cease performing mammography until the artifacts were eliminated and acceptable phantom image quality was established.
Corrective action:	The facility reduced the artifacts and improved the phantom image quality. However, the facility voluntarily withdrew its accreditation and the facility certificate was inactivated on June 27, 2003.
Status of facility:	Not performing mammography.

Texas

Smithville Hospital Authority
Smithville Regional Hospital
800 East Highway 71
Smithville, TX 78957

FDA facility ID:	136564
Adverse Event:	During an annual inspection, it was found that the facility failed to include an overall final assessment of findings in several randomly selected mammography reports.
Action Taken:	The State assessed administrative penalties in the amount of $1,000 against the facility.
Corrective Action:	The facility obtained a computer based mammography tracking program that requires the transcriptionist to select an overall final assessment of finding before the record can be completed and printed.
Status of facility:	Performing mammography.

Karnes County Hospital District
dba Otto Kaiser Memorial Hospital
3349 South Highway 181
Kenedy, TX 78119

FDA facility ID:	225072
Adverse event:	Based on previous failed attempts at accreditation, the State of Texas accreditation body performed an unannounced inspection at the facility and found that the mammography technologist at the facility was not adequately performing the quality control program, the medical audit program, or the phantom quality control testing.
Action taken:	The State assessed administrative penalties in the amount of $7,500 against the technologist.
Corrective action:	The facility terminated the employment of the radiology administrator and mammography technologist. The facility's accreditation was suspended on May 29, 2003. The facility successfully completed a corrective action plan and

the state lifted suspension of the facility's accreditation on September 22, 2003.

Status of facility: Performing mammography.

Texas Tech University Health Sciences Center- Mobile
3601 4th Street
Lubbock, TX 79752

FDA facility ID: 211474

Adverse event: During an annual inspection, it was found that the facility had repeated violations for quality control testing and in the medical audit program for its mobile unit.

Action taken: The State assessed administrative penalties in the amount of $15,000 against the facility. The facility was required to notify referring physicians and patients of possible compromise of mammography quality.

Corrective action: The facility terminated the mammography technologist and voluntarily suspended mobile mammography services on July 22, 2003.

Status of facility: Not performing mobile mammography.

Weslaco Radiology Center, Inc.
913 South Airport Drive
Weslaco, TX 78596

FDA facility ID: 170050

Adverse event: The facility voluntarily closed and the medical records were abandoned on or about November 30, 2001. The facility's owner failed to comply with an Emergency Order issued on February 6, 2002 by the Texas Department of Health, to maintain all mammography records associated with its facility in a safe and secure manner. As of July 31, 2003, no attempts to comply with the order had been observed.

Action taken: The State assessed administrative penalties in the amount of $10,000 against the facility.

Corrective action: State actions ongoing.

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 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, 2003.

State of North Carolina
Radiation Protection Section
Division of Environmental Health
Department of Environment & Natural Resources
3825 Barrett Drive
Raleigh, NC 27609-7221
Attention: Robin J. Haden
(919) 571-4141 Ext. 217

New York City, NY
Bureau of Radiological Health
New York City Department of Health
2 Lafayette Street, 11th Floor
New York, New York 10007
Attention: Martin Schnee
(212) 676-1580

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

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 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 1-800-363-2068. The NTIS order number is SUB-5386/Code D01.