DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1350 Piccard Drive
Rockville MD 20850

March 20, 2008

MAMMOGRAPHY FACILITY ADVERSE EVENT AND ACTION REPORT - 2007

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, 2007, there were 8,859 fully certified MQSA mammography facilities operating in the United States.

As part of MQSA, Congress mandated there be annual reporting of adverse actions taken against mammography facilities and that the report be made available to physicians and the general public. The report 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 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 under their own authority against mammography facilities.

The following are adverse events and corrective actions taken in 2007.

MEDICARE/MEDICAID

The HHS Inspector General lists no conviction data under **Medicare** or **Medicaid** for cases related to mammography facilities in 2007. There were no prosecutions or convictions of mammography facilities under Federal or State laws relating to fraud, abuse, false billings or kickbacks.

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 2007.

The American College of Radiology (ACR)

Bay Imaging
2626 East 14th Street
Brooklyn, NY 11235
Facility ID 102632

Bay Imaging
9201 4th Avenue
Brooklyn, NY 11209
Facility ID 209767

Adverse Event:	An MQSA inspection was performed by FDA as a follow up to patient complaints concerning the failure of these facilities to provide reports and mammogram films within 30 days of the examination. The inspection found that mammography was performed when the facilities had no interpreting physician to read or interpret the mammograms. The inspection found other serious problems with the facilities' quality assurance program.
Action Taken:	On August 16 and 18, 2006, the New York City Bureau of Radiological Health sealed the mammography units at the Bay Imaging facilities.
Corrective Action:	August 28, 2007, ACR revoked the facilities' accreditations.
Status of Facility:	Facilities are closed

** *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 and South Carolina certifying agencies reported no actions against mammography facilities in 2007. The State of Iowa certifying agency reported an action against one mammography facility in 2007.

State of Iowa (SIA) Certifying Agency

Belmond Medical Center
403 1st Street S.E.
Belmond, IA 50421
FDA Facility ID: 189357

Adverse Event: On February 19, 2007, an annual MQSA inspection found suspected quality control (QC) testing fraud by a radiologic technologist.

Action Taken: The SIA certifying agency requested the SIA accreditation body perform an additional mammography review (AMR), which was conducted April 17, 2007. The facility passed the full AMR.

On the basis of QC testing fraud, the State of Iowa suspended the radiologic technologist's Permit to Practice all diagnostic x-ray procedures, including mammography, for a period of 90 days.

Corrective Action: The radiologic technologist is no longer working at the facility.

Status of Facility: Performing mammography

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

The FDA reported three occasions when actions were taken against mammography facilities in 2007.

Bay Imaging
2626 East 14th Street
Brooklyn, NY 11235
Facility ID 102632

Bay Imaging
9201 4th Avenue
Brooklyn, NY 11209
Facility ID 209767

Bay Imaging
1620 Caton Avenue
Brooklyn, NY 11226
Facility ID 102640

Adverse Event: An MQSA inspection was performed by FDA as a follow up to patient complaints concerning the failure of these facilities to provide reports and mammogram films within 30 days of the examination. The inspection found that mammography was performed when the facilities had no interpreting physician to read or interpret the mammograms. The inspection found other serious problems with the facilities' quality assurance program.

Based on this information, FDA required an additional mammography review (AMR) to assess the quality of mammography. The facilities passed the AMRs.

Action Taken: Following the ACR revocation of the facilities' accreditations, FDA revoked the MQSA certificates for two of the Bay Imaging facilities (Facility ID 102632 and Facility ID 209767) on December 5, 2007. *The MQSA facility certificate for Facility ID 102640 had expired.*

Corrective Action: All three facilities are closed and the owner of the facilities may not legally own or operate another mammography facility for two years from the date of the certificate revocations.

Status of Facility: Facilities are closed

*** In addition to the above action taken against Bay Imaging, FDA 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.*

Baltimore Imaging Center
724 Maiden Choice Lane, Suite 102
Baltimore, MD 21228
FDA Facility ID: 110957

Adverse Event: As a follow-up to previous compliance issues, ACR conducted an onsite visit. The clinical image reviewer found serious problems with the quality of the mammography. Based on the results of the image review, FDA found that the quality of mammography at this facility represented a serious risk to human health.

The ACR denied the facility accreditation. However, the facility applied for reinstatement of its certificate.

Action Taken: On February 27, 2007, FDA required the facility to notify all patients and their referring physicians (PPN) that there was a serious risk to human health. On June 29, 2007, the facility completed the PPN.

On September 12, 2007, FDA denied the facility's application for reinstatement of its MQSA certificate. The denial was based on a history of failures to comply with FDA requirements.

Corrective Action: The facility is not currently certified and FDA has denied its request for a new certificate.

Status of Facility: Not performing mammography

Hackensack Medical and Molecular Imaging
155 State Street
Hackensack, NJ 07601
FDA Facility ID: 236454

Adverse Event: FDA required this facility to undergo an additional mammography review (AMR) after receiving a complaint from an interpreting physician at another

	facility about the clinical image quality at Hackensack Medical and Molecular Imaging. Based on the results of the AMR, FDA found that the quality of mammography at this facility represented a serious risk to human health.
Action Taken:	On April 25, 2007, FDA required the facility to notify all patients and their referring physicians (PPN) that the AMR found a serious risk to human health. On August 21, 2007, the facility completed the PPN.
Corrective Action:	The facility is not accredited or certified. The facility has not applied for reinstatement of its MQSA certificate.
Status:	Not performing mammography

FDA'S OFFICE OF CRIMINAL INVESTIGATIONS (OCI)

The Office of Criminal Investigations reported one criminal prosecution and conviction case related to mammography facilities in 2007.

Name / address of individual:	Percival Norman Fenton, Wintergreen, Virginia
Adverse Event:	Mr. Fenton fraudulently performed services as a certified medical physicist for numerous hospitals and medical facilities in the States of Virginia, North Carolina, Kentucky, West Virginia and Tennessee based on falsification of undergraduate and other academic credentials. Mr. Fenton also committed perjury during testimony about his academic credentials.
Action Taken:	Criminal prosecution of Mr. Fenton under crimes for violation of 18 USC 1341 - MAIL FRAUD (48 counts) and 18 U.S.C. 1623 - Lying to a Grand Jury or a Court (one count).
Corrective Action:	On May 4, 2007, Mr. Fenton pled guilty to 48 separate counts of mail fraud and one count of perjury. On

September 4, 2007, Mr. Fenton was sentenced to 54 months incarceration in federal prison, 3 years probation, and required to pay $400,000 in restitution.

FDA believes that no women were harmed by Mr. Fenton's actions because there are numerous safeguards in place for mammography equipment. Under FDA's MQSA regulations, the equipment is regularly tested by radiologic technologists who use the equipment.

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 that reported adverse events and subsequent actions are 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. Three States reported adverse events and subsequent actions for calendar year 2007.

New York City

Bay Imaging
2626 East 14th Street
Brooklyn, NY 11235
Facility ID 102632

Bay Imaging
9201 4th Avenue
Brooklyn, NY 11209
Facility ID 209767

Bay Imaging
1620 Caton Avenue
Brooklyn, NY 11226
Facility ID 102640

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 examination. Mammography was performed when the facilities had no interpreting physician to read or interpret the mammograms.

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

Corrective Action: Registration was withdrawn by New York City for all three Bay Imaging facilities in 2007.

Status of Facility: Facilities are closed

** *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.*

Pennsylvania

Heart of Lancaster Regional Medical Center
1500 Highlands Drive
Lititz, PA 17543
FDA Facility ID: 107466

Adverse Event: On January 8, 2007, a State inspection found that the facility performed mammography when it had failed phantom image testing for four consecutive months.

Action Taken: The State of Pennsylvania required the facility to re-read all of the patient's mammograms that had been performed during the time of the phantom image testing failures. This internal review found that quality had not been compromised for any of the patient's mammograms and no mammograms needed to be repeated.

On October 5, 2007, the Pennsylvania Department of Environmental Protection fined Heart of Lancaster Regional Medical Center a civil penalty of $21,250.

Corrective Action: As required under State authority, the facility revised its policies and quality control testing procedures, and QC personnel received additional training in the quality control process.

On November 28, 2007, the facility paid the Commonwealth of Pennsylvania a $15,000 fee settlement.

Status of Facility: Performing mammography

Texas

Diagnostic Image Plus
3022 Motley Drive
Mesquite, TX 75150
FDA Facility ID 236524

Adverse Event: A joint State of Texas and FDA investigation was initiated when a complaint was received from a temporary mammography technologist that the facility was performing sub-optimal quality mammography. The inspection found serious problems with the facility's quality assurance program.

Action Taken: The State of Texas required an additional mammography review (AMR) to assess the quality of mammography. The AMR failed with a serious risk to human health.

Corrective Action: The facility was required to notify all patients and their referring physicians (PPN) that the AMR found a serious risk to human health. The facility completed the PPN.

Additionally, the facility was fined administrative penalties in the amount of $45,500 for violations found during the investigation. The fine was probated on the agreement that the owner would not provide mammography services or be involved with

any organization that provided mammography services for a period not less than 5 years.

Status of Facility: Not performing mammography

*** In addition to the above action taken against Diagnostic Image Plus, FDA worked with the State to investigate this adverse event and assist in actions taken under the State laws.*

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 – December 31, 2007.

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.