DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 15, 2003

Dear Mammography Quality Advocate:

Under the Mammography Quality Standards Act (MQSA) of 1992, the Food and Drug Administration (FDA) is required to prepare and publish an annual report to assist health professionals and consumers in evaluating the performance of their mammography facilities. The document (attached) is titled "**Mammography Facility Adverse Event and Action Report - 2002."** We encourage you to make this information available to your constituents, especially physicians and the general public.

The report includes the following:

- background information
- a list of facilities that had adverse events for which actions were taken in 2002
- the name of a State that submitted incomplete adverse event and action information and an address to contact them directly

You will find this report, along with other MQSA related documents, on our mammography web site, www.fda.gov/cdrh/mammography/. Under the Reports heading, select *Mammography Facility Adverse Event and Actions Reports* from the list of choices.

If you have any questions about this report, please send them to Patti Hoage at pah@cdrh.fda.gov.

Sincerely yours,

John L. McCrohan, M.S.
Director
Division of Mammography Quality
and Radiation Programs
Office of Health and Industry Programs
Center for Devices and Radiological Health

Enclosures

MAMMOGRAPHY FACILITY ADVERSE EVENT AND ACTION REPORT 2002

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 toughen the 1994 interim standards for personnel, equipment, quality assurance and quality control activities, and reporting of exam results as well as requirements for accreditation bodies.

To help patients understand how MQSA affects them, FDA developed and widely distributed a brochure titled "*Mammography Today – Questions and Answers for Patients on Being Informed Consumers*." You can find the brochure on our web site at www.fda.gov/cdrh/mammography/. Under the Consumer Information heading, select 'About Consumer Information' and then select the brochure.

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

As of April 30, 2003, there were 9,184 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 five MQSA accreditation bodies for reports of revocation of accreditation and cease and desist orders.

- FDA's Office of Health and Industry Programs, Division of Mammography Quality and Radiation Programs, Inspection and Compliance Branch for actions taken against mammography facilities.

- FDA's Office of Criminal Investigations 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 2002:

MEDICARE/MEDICAID ACTIONS

The HHS Inspector General lists no conviction data under **Medicare** or **Medicaid** for cases related to mammography facilities in 2002. There were no prosecutions or convictions of mammography facilities under Federal or State laws relating to fraud, abuse, false billings or kickbacks.

ACCREDITATION BODY ACTIONS

Each year, we ask all of the accreditation bodies to report if they revoked the accreditation of facilities accredited by them. Revocation means withdrawal of a facility's accreditation prior to the expiration date for reasons other than voluntary withdrawal by the facility. Currently, there are five FDA-approved accreditation bodies – the American College of Radiology (ACR) and the States of Arkansas, California, Iowa and Texas.

The American College of Radiology and the States of Arkansas, Iowa, and Texas, and reported no revocations of accreditation in 2002.

The State of California does not currently revoke accreditation, but rather issues cease and desist orders under State regulations. California issued no cease and desist orders during 2002.

FDA ACTIONS

MQSA Actions

Midwest Health Center, P.C.
5050 Schaefer Road
Dearborn, MI 48126

FDA facility ID:	125609
Adverse event:	Phantom image failure (Level 1).
Action taken:	FDA required a Validation Film Check. The facility happened to be undergoing a random Validation Film Check by the accreditation body; therefore, FDA was able to use the accreditation body results.
Corrective action:	The facility was reinspected by FDA on November 6, 2002 and found to be in compliance with MQSA regulations.
Status of facility:	Performing mammography.

In addition to the above action, FDA also works closely with States to investigate adverse events and assist in actions taken under State laws. Some of these adverse events are currently under investigation and will be reported in calendar year 2003.

FDA's Office of Criminal Investigations

Medical Diagnostics
2736 East Florence Avenue
Huntington Park, CA 90255

FDA Facility ID:	168187
Adverse event:	Submitting false statements to a government official about qualifications to interpret mammography findings.
Action taken:	Criminal prosecution of Dr. Terry Alan Dichter, a former employee of Medical Diagnostics, under Title 18 USC, Section 1001, False statements.
Corrective action:	Dr. Dichter was arraigned on January 14, 2002, before the U.S. District Court where he pled guilty to violation of Title 18 USC, Section 1001, False Statements, and was released on bond pending sentencing. On June 11, 2002, Dr. Dichter was sentenced to ten months incarceration (5 months in a Bureau of Prisons facility, and five months home detention), followed by 36 months supervised release. Dr. Dichter was also ordered to pay a $3,000 criminal fine and $29,740.00 in restitution.
Status of facility:	Not performing mammography.

STATE'S ACTIONS

MQSA does not preclude a State or U.S. territory from having stricter mammography requirements. 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 here were taken by States. Only those cases that compare to those that could be the subject of actions under MQSA are reported. A total of four States reported adverse events and subsequent actions for calendar year 2002.

Kentucky

Memorial Hospital Inc.
401 Memorial Dr.
Manchester, KY 40962

FDA facility ID:	193912
Adverse event:	A radiologic technologist falsified mammography quality control records.
Action taken:	State requested this facility to voluntarily cease performing mammography examinations on February 27, 2002.
Corrective action:	Facility dismissed the radiologic technologist from employment. The State suspended her radiologic technologist's general operator certification for six months, and permanently revoked her privilege to work as a mammography technologist in Kentucky. The facility was permitted to resume performing mammography examinations on March 11, 2002.
Status of facility:	Performing mammography.

Michigan

Midwest Health Center, P.C.
5050 Schaefer Road
Dearborn, MI 48126

FDA facility ID:	125609
Adverse event:	Phantom image failure (Level 1).

Action taken:	State sent written statements to the facility on August 8, 2002 requiring that improvements in image quality be completed before performing further examinations.
Corrective action:	Facility had mammography unit serviced to meet requirements.
Status of facility:	Performing mammography.

Blue Care Network
1403 South Creyts Road
Lansing, MI 48917

FDA facility ID:	103531
Adverse event:	Phantom image failure (Level 2).
Action taken:	State sent a written statement to the facility on July 11, 2002 requiring that improvements in image quality be completed before performing further examinations.
Corrective action:	Facility reported changing intensifying screens, cassettes, and film.
Status of facility:	Performing mammography.

Suburban Radiology
3723 Fort Street
Lincoln Park, MI 48146

FDA facility ID:	141044
Adverse event:	Phantom image failure (Level 2).
Action taken:	State sent a written statement to the facility on May 20, 2002 requiring that improvements in image quality be completed before performing further examinations.
Corrective action:	Facility ordered new cassettes, screens, and film that were placed in use the week of July 1, 2002. The processor was also serviced. The State reinspected on July 12, 2002. The facility replaced the machine with a new machine on September 1, 2002. Facility and its new machine were inspected by the state on September 27, 2002. Automatic exposure control was out of adjustment. Facility notified

	the State on October 28, 2002 and is in compliance with both state and MQSA requirements.
Status of facility:	Performing mammography.

New Jersey

FUSING- St. Mary's Hospital
308 Willow Avenue
Hoboken, NJ 07030

FDA facility ID:	139816
Adverse event:	Facility operated mammography equipment when the quality assurance program did not meet State requirements.
Action taken:	State issued an administrative order and civil money penalties in the amount of $600.00.
Corrective action:	Facility corrected its quality assurance program to meet State requirements.
Status of facility:	Performing mammography.

Bergenline X-ray Diagnostic Center Corp.
402 43rd Street
Union City NJ 07087

FDA facility ID:	202713
Adverse event:	Facility operated mammography equipment when the quality assurance program did not meet State requirements.
Action taken:	State issued an administrative order and civil money penalties in the amount of $200.00.
Corrective action:	Facility corrected its quality assurance program to meet state requirements.
Status of facility:	Performing mammography.

Virginia

Shenandoah Valley Mobile X-Ray, Inc.
Woodstock, VA 22664

FDA Facility ID	Facility was not issued an FDA facility ID number because it was not accredited or FDA certified.
Adverse event:	Dr. Francis H. G. George performed mammography from February 1996 to February 1998 without accreditation and without certification from the FDA. Dr. George failed to document his qualifications as an interpreting physician and did not provide documentation to an accreditation body or FDA that he met qualifications to interpret mammograms.
Action taken:	The State Board of Medicine concluded that Dr. George is in violation of Section 54.1-2915.A (3), *Refusal; suspension or revocation; other disciplinary actions*, as further defined in Section 54.1-2914.A (7), (8), and (11), *Unprofessional conduct*, of the Code of Virginia.
Corrective action:	Dr. George was ordered to pay a Monetary Penalty in the amount of $5, 000 on May 20, 2002. Dr. George shall pay $2,500 within 60 days from the date of the Order and the remaining $2,500 within 180 days from the date of the Order. Dr. George shall not read any mammogram until his facility has been certified by the FDA and a copy of the certification has been submitted to the State Board of Medicine.
Status of facility:	Not performing mammography.

STATE THAT SUBMITTED NO OR INCOMPLETE ADVERSE EVENT AND ACTION INFORMATION

South Dakota did not submit information for May 2002 about 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 this time period.

State of South Dakota
Office of Health Care Facilities
Licensure and Certification
Systems Development and Regulation
615 East 4th Street
Pierre, SD 57501-1700
Attention: Gary Kaus
(605) 642-6010

HOW TO FIND AN FDA-CERTIFIED FACILITY

Cancer Information Service

To operate legally, a mammography facility must have and prominently display an FDA 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 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 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).

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.