

# MQSA PROGRAM ACCOMPLISHMENTS

June 1993 through September 2003

## **FDA's Division of Mammography Quality and Radiation Programs**

After Congress passed the Mammography Quality Standards Act of 1992 (MQSA), the Food and Drug Administration (FDA) received authority from the Department of Health and Human Services to implement MQSA. As a result, the Agency established the Division of Mammography Quality and Radiation Programs (DMQRP) in the Center for Devices and Radiological Health.

(Besides implementing MQSA, the Division also directs other radiation program activities.)

On October 9, 1998, the Mammography Quality Standards Reauthorization Act of 1998 (MQSRA) was enacted, extending the program through September 2002. Congress is currently evaluating certain elements of the standards as it considers reauthorizing the program.

## **Key Milestones**

- MQSA enacted – October 1992
- FDA delegated responsibility – June 1993
- Interim regulations published – December 1993
- National Mammography Quality Assurance Advisory Committee – First meeting February 1994.
- All mammography facilities certified and must meet interim regulations – October 1994
- Mammography Program Reporting and Information System (MPRIS) – implemented October 1994
- Annual inspections began – January 1995
- Implemented a comprehensive compliance and enforcement strategy to ensure that noncompliances are successfully corrected
- Final regulations published – October 1997
- States-As-Certifiers (SAC) pilot program initiated – August 1998
- MQSRA enacted – October 1998
- Final regulations effective – April 1999
- SAC proposed regulations published for comment – March 2000
- Screen/film facility certification extended to include Full Field Digital Mammography (FFDM) – March 2000
- Inspection Demonstration Program initiated – May 2002
- SAC final regulations effective - May 2002
- Approved two Accreditation Bodies to accredit FFDM units:  
1) the American College of Radiology for General Electric (12/18/02), Fischer (7/24/03) and Lorad (9/4/03); and 2) the

- State of Iowa for General Electric and Lorad (8/28/03).  
➤ New enforcement strategy implemented - Oct.1, 2003

**The Program Director**

John L. McCrohan, M.S., is the Director of the Division. Before this appointment, he served as the Division's Deputy Director and was previously involved with mammography through the "Breast Exposure: Nationwide Trends (BENT)" and the Nationwide Evaluation of X-ray Trends (NEXT)" programs.

**Standards Development**

On December 21, 1993, FDA published interim regulations for mammography facilities and accreditation bodies. Development of the final regulations began with the first meeting of the National Mammography Quality Assurance Advisory Committee in February 1994. Proposed rules were published on April 3, 1996, with a 90-day comment period. FDA analyzed over 1,900 letters and considered approximately 8,000 comments during this development process. On October 28, 1997, FDA issued the more comprehensive final regulations which became effective on April 28, 1999.

Since 1994, FDA has provided guidance documents designed to help facilities comply with the regulations. The Agency has had these documents incorporated into the Policy Guidance Help System (a computerized search engine) that is available on our website at [www.fda.gov/cdrh/mammography/guidance-rev.html#pghs](http://www.fda.gov/cdrh/mammography/guidance-rev.html#pghs). FDA continues to update its guidance in response to facility and consumer inquiries.

**Accreditation Bodies**

FDA has approved five accreditation bodies under MQSA: the American College of Radiology (ACR), and the States of Arkansas, California, Iowa and Texas. The agency reports annually to Congress about the performance of these accreditation bodies.

**Facility Certification**

The total number of certified facilities at the end of FY-03 was 9,114. Facilities that fail accreditation and are not MQSA certified must stop performing mammograms. However, once a facility has corrected the problem(s) that caused the failure, it may apply for reinstatement to reenter the accreditation process. Facility certification can now be extended to include FDA-approved Full Field Digital Mammography (FFDM) units. To track certification activities and other aspects of the MQSA program, FDA uses the Mammography Program Reporting and Information System (MPRIS), a state-of-the-art information management system.

**States as Certifiers (SAC)**

In June 1996, FDA formed a States as Certifiers (SAC) Working Group to help develop procedures and regulations so that States could

certify facilities as provided for by MQSA. In August 1998, FDA started a SAC Demonstration Program with the States of Iowa and Illinois. The demonstration program was in effect for approximately three years. FDA published proposed regulations for the program on a nationwide basis on March 30, 2000, with a 90-day comment period. It published the Final Regulations on Feb. 6, 2002, effective on May 7, 2002. Responsibilities delegated to the participating States include:

- Issuance, renewal, suspension, and revocation of certificates for mammography facilities within the State;
- Annual facility inspections; and
- All compliance actions for any violation(s) identified during inspections or otherwise.

### **Inspections and Inspector Training**

Under MQSA, facilities may be inspected by FDA inspectors, State or local agency inspectors under FDA contract, or inspectors from States that are certifying agencies. Only FDA performs annual inspections of federal facilities. As of September 30, 2003, 47 States and local agencies have contracts. Since 1995, these inspectors combined have conducted more than 78,646 annual facility inspections.

In May of 2002, as part of MQSRA, FDA began a demonstration program to inspect, less frequently, those facilities that had excellent inspection records. Results of this program are expected in late 2004.

FDA qualifies MQSA inspectors who meet specific qualifications and who must maintain this qualification by meeting continuing education and experience requirements. Inspectors receive specialized training in radiation physics, physics related to mammography equipment and inspecting mammography facilities' compliance with MQSA regulations. All inspectors must pass a series of hands-on tests prior to independently performing inspections. Since 1994, FDA has trained a total of 401 inspectors. Currently, there are 249 active qualified inspectors. Of those, 215 are State inspectors and the remaining 34 are FDA inspectors. In addition, FDA has an audit program to assure that quality inspections are being performed by the contracting States.

### **State-of-the-Art Equipment Used During Inspections**

Inspectors perform science-based inspections, using a patient-equivalent mammography phantom to determine patient dose and evaluate image quality. Inspectors evaluate the quality of film processing which can impact on dose. Inspectors also evaluate the facility's mammography reports, letters to patients, and medical outcomes audit. The facility's quality assurance and quality control records are also reviewed. Inspectors test each facility's darkroom for

high light levels that may affect mammography films. FDA annually calibrates the testing equipment used during inspections by FDA in a state-of-the-art laboratory to ensure the accuracy of measurements made during inspections. To record inspection information, inspectors use laptop computers that connect to the FDA MPRIS database, giving them access to the most current facility information available. After the inspection, the inspectors send this information directly to the FDA MPRIS database.

## **Inspection Fees**

MQSA requires FDA to collect fees from facilities to cover the cost of annual facility inspections. Effective October 1, 2003, the fee is \$1,749 for the first mammography unit and \$204 for each additional unit. The fee for a follow-up inspection, if needed to assure that violations from a previous inspection have been corrected, is \$991.

MQSA exempts governmental entities from fees. Governmental entities include any facility operated by any federal department, State, district, territory, possession, city, county, town, village, municipality, or federally recognized Native American tribe. In addition, facilities that have at least 50% of their screening mammograms funded under the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Title XV of the Public Health Service Act) are considered governmental entities under MQSA. The costs of inspecting governmental entities are paid through federal funding appropriated to FDA. Every two years, FDA performs an audit of facilities claiming the governmental entity status to ensure that it exempts only those facilities that are truly eligible.

## **Compliance and Enforcement**

FDA has classified each adverse inspection into one of three category levels:

- A **Level 1** observation indicates a failure to meet a key MQSA requirement that may compromise the quality of mammography performed at the facility.
- A **Level 2** observation indicates that the facility meets all key MQSA requirements but fails to meet a significant mammography quality item.
- A **Level 3** observation indicates that the facility meets all major MQSA requirements with only minor problems. Adverse inspection observations are placed into a category level based on FDA's assessment of how the observation may affect the quality of mammography. The category level is also used to determine how the facility should respond to the observation. Identical

observations found during two consecutive inspections are identified as repeats.

The following table summarizes FDA's inspection results over the course of the program:

<b>Fiscal Year*</b>	<b>Facilities Inspected</b>	<b>No Violations</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
1995	4851	30.0	2.6	19.9	47.6
1996	8803	42.7	1.6	12.5	42.3
1997	9448	55.9	0.9	12.5	30.7
1998	9297	58.2	1.1	18.9	21.9
1999	9537	58.4	1.7	23.5	16.2
2000	9443	53.0	3.9	32.7	10.3
2001	9277	58.3	3.4	28.2	10.1
2002	8986	61.4	2.6	27.1	8.9
2003	8681	65.5	2.0	23.3	9.1

\*FDA fiscal year, starts on October 1<sup>st</sup> and ends on September 30<sup>th</sup>.

If a facility doesn't correct its problems and continues to violate the law, FDA may use MQSA sanctions including: 1) Directed Plans of Correction; 2) Patient Information (patient and physician notification); 3) Civil Money Penalties; 4) Suspension of facility certificates; 5) Revocation of facility certificates; and 6) Injunctions.

On October 1, 2003, FDA implemented the following revised policy for how facilities should respond to serious inspection observations:

Instead of automatically receiving a Warning Letter, for a Level 1, repeat Level 1, or repeat Level 2 observation, the facility must correct the problem(s) found as soon as possible and the facility should send a written response to FDA within 15 days after the inspection. The facility's response is then evaluated and further actions such as issuing a Warning Letter or follow-up inspection are performed, as necessary. For more detailed information, see article at [www.fda.gov/cdrh/mammography/followup.html](http://www.fda.gov/cdrh/mammography/followup.html)

If FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, it may require an Additional Mammography Review (AMR). Under an AMR, FDA may require the facility to provide clinical images and

other relevant information for review by the accreditation body, or other entity designated by the agency. If this AMR shows a serious risk to human health, FDA may require the facility to notify patients and their referring physicians about this risk, along with what steps the patients and physicians should take.

Since 1995, there have been six criminal convictions involving fraud at mammography facilities. In each case, the criminal activity was related to falsification of records.

Sometimes FDA requires a facility to notify its patients and their referring healthcare providers about problems at that facility that may compromise the quality of their mammograms.

## **Outreach Activities**

Approaches that FDA uses to inform mammography facilities and the public about MQSA requirements include the following:

- a Facility Hotline for responding to questions from facility staff (phone 1-800-838-7715). Over the past five years (from 1998-2002), calls average approximately 14,000 a year;
- a website at [www.fda.gov/cdrh/mammography](http://www.fda.gov/cdrh/mammography) that provides general MQSA information, facility guidance issued by FDA containing a policy search engine, and mammography-related radiation articles; [Subscribe](#) to the electronic listserv to receive e-mail alerts and highlights of new information as it becomes available on our website.
- a brochure for patients, [Mammography Today](#), [PDF] that clarifies patients' rights under MQSA;
- a consumer brochure, *Things to Know About Quality Mammograms* (published in cooperation with the Agency for Healthcare Research and Quality);
- a brochure, *MQSA and You, Making Quality a Reality*, A Resource Guide for Facilities, Health Professionals, Inspectors, and the Public;
- a searchable database on our mammography website for MQSA-certified facilities.

## **Program Evaluation**

According to the General Accounting Office's (GAO's) October 1997 report on the mammography program, MQSA has positively impacted mammography quality. Inspection data continue to show overall facility compliance with the national standards to ensure the quality of x-ray images. Over 60% of facilities have no violations, and only 2% have non-compliances at the most serious level. Currently, over 99% of all mammography facilities pass the phantom image test during their facility inspection. This clearly illustrates the positive impact of the MQSA program on the public health. Experts agree that

improving the quality of images should lead to more accurate interpretation by physicians and, therefore, lead to early detection of breast cancer. Through inspections and data from accreditation bodies, FDA monitors MQSA's impact on mammography quality, including radiation exposure levels.

More information about the impact of MQSA is contained in the following GAO reports:

- "Mammography Services: Initial Impact of New Federal Law Has Been Positive." (October 1995) [[PDF](#)]
- "FDA's Mammography Inspections: While Some Problems Need Attention, Facility Compliance is Growing." (January 1997) [[PDF](#)]
- "Mammography Services: Impact of Federal Legislation on Quality, Access, and Health Outcomes." (October 1997) [[PDF](#)]
- "Mammography: Capacity Generally Exists to Deliver Services." (April 2002) [[PDF](#)]

In April 1997, FDA surveyed facilities to determine the level of satisfaction with the inspection process. Analysis of the results showed general satisfaction with the inspection process and inspector conduct. FDA conducted a similar survey of facility satisfaction under the final regulations in May 2001. The most recent findings were very much the same as the first survey. The results of the 2001 survey and FDA's actions in response to the survey are being published incrementally at <http://www.fda.gov/cdrh/mammography/reports.html#5>.