# MQSA PROGRAM ACCOMPLISHMENTS

June 1993 through September 2002

## 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.

## 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

## 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 web site at 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-02 was 9,306. 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 3 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, 2002, 46 States and local agencies have contracts. Since 1995, these inspectors have conducted more than 69,600 facility inspections.

In May of 2002, as part of MQSRA, FDA began a demonstration program to inspect facilities with excellent inspection records less frequently.

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 388 inspectors. Currently, there are 237 active qualified inspectors. Of those, 205 are State inspectors and the remaining 32 are FDA inspectors. In addition, FDA has an audit program to assure quality inspections.

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

Inspectors perform science-based inspections to evaluate the radiation dose for a standard breast, image quality using a special mammography phantom, and the performance of the facility's film processing. 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 February 13, 1998, the fee is $1,549 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 the first inspection have been corrected, is $878.

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 government entities under MQSA. The costs of inspecting government entities are paid through federal funding appropriated to FDA.

## 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:

| Fiscal Year* | Facilities Inspected | No Findings | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|---|
| 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 |

*FDA fiscal year, starts on October 1st and ends on September 30th.

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.

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 web site at www.fda.gov/cdrh/mammography that provides general MQSA information as well as facility guidance issued by FDA containing a policy search engine;
- a newsletter, *Mammography Matters*, for facilities and other interested parties. Published from Winter 1994 through Fall 2000. Those issues are available electronically on the mammography web site at http://www.fda.gov/cdrh/mammography/newsletter.html. With the Fall 2000 issue, the *Mammography Matters* newsletter was officially suspended. Instead, FDA now uses the entire website to publicize key mammography news as it emerges (see the "From the Director" column in the Fall 2000 issue). We will continue to carry previous issues, back to Winter 1998, on our website. 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 web site for MQSA-certified facilities;
- a live, inter-active teleconference for all MQSA facilities was broadcast on February 18, 1999, focusing on the final regulations.

## 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. Less than 3% of facilities have non-compliances at the most serious level. Currently, over 98% of all mammography facilities pass the phantom image test during their facility inspection. In 1993, only 64.5% of mammography units applying for accreditation passed on their first attempt. In 2002, 87% of units

applying for (or renewing) accreditation passed on their first attempt. This clearly illustrates the positive impact of the Mammography Accreditation Program and the MQSA 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 are being published incrementally at http://www.fda.gov/cdrh/mammography/reports.html#5.

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