

**PERFORMANCE EVALUATION OF ACCREDITATION BODIES
UNDER THE
MAMMOGRAPHY QUALITY STANDARDS ACT OF 1992
as amended by the
MAMMOGRAPHY QUALITY STANDARDS REAUTHORIZATION ACTS OF 1998 and 2004**

January 1 to December 31, 2007

A Report to Congress

Executive Summary

The goal of the Mammography Quality Standards Act (MQSA) of 1992, as amended by the Mammography Quality Standards Reauthorization Acts of 1998 and 2004, is to assure that facilities meet standards for performing high quality mammography. The Food and Drug Administration (FDA) administers MQSA. Among other things, MQSA provides for FDA-approved accreditation bodies (ABs) to evaluate and accredit mammography facilities based upon quality standards. Only facilities that are accredited by ABs or undergoing accreditation by ABs may receive certificates from the FDA (or state certifying agency) so that they can legally perform mammography. MQSA requires annual reports to Congress on AB performance. This twelfth annual report covers the period from January 1, 2007, through December 31, 2007.

To implement the MQSA (Section 354q of the Public Health Service Act, (42 United States Code (U.S.C.) 263b)), FDA issued final regulations that became effective on April 28, 1999 (21 Code of Federal Regulations (CFR) Part 900). The final regulations (21 CFR 900.5) state that the FDA's evaluation of ABs shall include a(n):

- (a) Assessment of the reports of FDA or State inspections of facilities accredited by the body as well as any additional information deemed relevant by FDA that has been provided by the accreditation body or other sources or has been required by FDA as part of its oversight initiatives;
- (b) Determination of whether there are major deficiencies in the AB's performance that, if not corrected, would warrant withdrawal of the approval of the AB under the provisions of Section 900.6.

Status of Accreditation Bodies

Currently, there are four ABs: the American College of Radiology (ACR), a private nonprofit organization, and the state ABs of Arkansas (SAR), Iowa (SIA), and Texas (STX). FDA renewed its approval of each of these ABs under the MQSA regulations in 2005. The term of approval is for a period of 7 years. Although the expiration for renewal is April 28, 2013, FDA will continue to review annually each AB's performance to determine its compliance with the MQSA regulations.

Evaluation of Accreditation Bodies

To assess overall performance, FDA evaluates the AB's in the following areas:

- resource analysis (staffing, funding, information technology capability);
- reporting and record keeping processes (serious consumer complaint and appeals mechanisms);

- accreditation review and decision making processes (clinical image review, phantom image review, equipment requirements);
- AB onsite visits to facilities (random and for-cause visits);
- random clinical image reviews of facilities;
- additional mammography reviews (AMRs); and
- accreditation revocations and suspensions

FDA evaluates AB performance in the areas listed above through:

- examination of the ABs' responses to FDA questionnaires that address the performance areas;
- analysis of quantitative accreditation and inspection information;
- review of selected accreditation files, as well as clinical and phantom images;
- interviews with AB staff and management to answer questions or clarify issues;
- analysis of information from FDA's Mammography Program Reporting and Information System;
- onsite visits to the ABs; and
- ongoing written and oral communications with the ABs throughout the year

Findings from Calendar Year (CY) 2007 AB Performance Evaluations

The following items are the highlights of FDA's CY 2007 Report to Congress:

- All ABs adequately funded their respective programs.
- All ABs took appropriate measures to secure and maintain their accreditation data with no increase in the error rate since 2006.
- Each AB had a satisfactory serious consumer complaint process.
- Each AB used acceptable procedures to review clinical images submitted by facilities, and had adequate audit procedures for its clinical image reviewers. However, for two ABs, FDA recommended that each AB provide additional review feedback to its facilities.
- Each AB used acceptable procedures to review phantom images submitted by facilities, and had adequate audit procedures for its phantom image reviewers.
- Three ABs exceeded the required number of AB onsite visits to facilities they accredit.
- All ABs exceeded the required number of random clinical image reviews of the facilities they accredit.
- The ABs performed AMRs when indicated.
- One AB revoked the accreditation of two facilities in CY 2007.
- Facilities' phantom image scores showed no significant differences across the ABs and these scores improved slightly from those reported in the 2006 report.
- Overall, the rates for units denied accreditation remained about the same as those in the last reporting period.

- The average radiation doses measured at the facilities of all the ABs remained about the same as those in the previous report and remain well below the dose limit mandated by the MQSA final regulations.
- Nearly 76 percent of the accredited mammography facilities had no MQSA violations. This percentage is an improvement from the 75 percent reported in 2006.
- Only 1.7 percent of facilities had a violation characterized as “most serious.” This percentage is an improvement from the 2 percent reported in 2006. FDA actively works with these facilities on corrective measures, and takes regulatory actions as indicated.
- The one AB with action items from CY 2006 successfully resolved both items.

FDA and ABs, working in partnership with the certified mammography facilities in the United States, and with the states participating in inspections and other MQSA activities, are ensuring quality mammography across the Nation.

Purpose

The MQSA of 1992 (P .L. 102-539), as amended by the Mammography Quality Standards Reauthorization Acts of 1998 and 2004 (P. L. 105-248 and P. L. 108-365), authorizes FDA to assure that facilities meet standards for performing high quality mammography. FDA administers the MQSA. Among other things, the MQSA provides for FDA-approved ABs to evaluate and accredit mammography facilities based on quality standards. FDA may approve either private nonprofit organizations or state agencies to serve as ABs. The MQSA also requires FDA to submit an annual performance evaluation of the approved ABs to the Senate Committee on Health, Education, Labor and Pension and the House Committee on Energy and Commerce under 42 U.S.C. 263b(e)(6). This report covers the performance of the ABs under the MQSA from January 1, 2007 through December 31, 2007.

Status of Accreditation Body Approvals

Currently, there are four ABs: ACR, a private nonprofit organization; and SAR, SIA, and STX. FDA renewed its approval of each of these ABs under the MQSA regulations in 2005. The term of approval is for a period of 7 years. Although the expiration for renewal is April 28, 2013, FDA will continue to review annually each AB's performance to determine its compliance with the MQSA regulations.

Standards

Under the MQSA, each AB must require facilities it accredits to meet standards that are substantially the same as the quality standards established by FDA under 42 U.S.C. 263b(f) to assure the safety and accuracy of mammography. All ABs have either adopted the MQSA standards by reference or have developed standards that are substantially the same as the quality standards established by FDA. Each AB incorporated the standards into its own accreditation processes.

Methodology

As outlined in MQSA regulations, FDA evaluates the AB's in the following areas:

- resource analysis;
- reporting and record keeping processes;
- accreditation review and decision-making processes;
- AB onsite visits to facilities;
- random clinical image reviews (RCIRs) of facilities;
- additional mammography reviews (AMRs); and
- accreditation revocations and suspensions.

FDA evaluates performance in these areas through:

- examination of the ABs' responses to questionnaires developed by FDA addressing performance indicators;
- analysis of quantitative accreditation and inspection information;
- review of selected accreditation files (including clinical and phantom images);
- interviews with AB staff and management to answer questions or clarify issues;
- analysis of information from FDA's Mammography Program Reporting and Information System database of annual facility inspections; and
- onsite visits to the ABs.

FDA staff analyzes unit accreditation pass and fail data, along with data that describe the reasons for each accreditation failure decision. Significant differences in pass and fail rates or reasons for accreditation denial among ABs could, for example, indicate that one AB is interpreting the significance of a particular quality standard more or less strictly than another.

To complement the information submitted by the ABs, MQSA inspectors assess accredited facility performance during inspections by collecting average radiation dose values and by measuring average phantom image scores and average processor speeds. Collectively, these measures reflect the overall functioning of all components of the mammography system.

Performance Indicators

(1) Administrative Resources and Funding

AB staffs generally include management, mammography radiologic technologists, MQSA inspectors, health physicists, information technology program application specialists, and administrative assistants. In 2007, all ABs continued to maintain adequate funding and staffing for their respective programs.

(2) Data Management (Process/Errors)

All ABs provide FDA with electronic transmissions of accreditation data in a secure and appropriately maintained manner. Overall, the percentage rate of data management errors remained about the same as the rate noted in the previous year. FDA continues to work individually with the ABs to:

- further minimize the number of data errors;

- emphasize the importance of routinely performing quality assurance and quality control practices to correct errors before transmitting the data; and
- provide reports that outline errors and the frequency with which they occur.

(3) Reporting and Recordkeeping

FDA's review of the ABs' reporting and recordkeeping practices includes examining procedures for handling serious consumer complaints, appeals for accreditation decisions, and granting interim accreditation.

(a) Serious Consumer Complaints

The regulations require ABs to develop and administer a consumer complaint mechanism whereby all facilities that an AB accredits must file serious unresolved complaints with their AB. By regulation, each AB must submit to the agency an annual report summarizing all serious complaints received during the previous calendar year, their resolution status, and any actions taken in response to them.

All ABs have established an appropriate serious consumer complaint mechanism. In CY 2007, 3 ABs (ACR, SAR and SIA) received complaints from a total of 9 consumers. Each of the ABs submitted its serious consumer complaint report to FDA which indicated that the ABs followed their approved procedures when resolving these complaints.

(b) Appeals

Each AB must have an appeals process for facilities to contest an AB's adverse accreditation decision. In CY 2007, only the ACR received two appeals to its accreditation decisions. The ACR reviewed those appeals and upheld the original adverse decision for both.

(c) Interim Accreditation

An AB may grant a 45-day interim accreditation to a fully accredited facility whose MQSA certificate will expire prior to the AB making a renewal decision. The facility must be fully accredited and meet certain criteria in order to obtain interim accreditation. Once the AB grants the facility interim accreditation, FDA (or state certifying agency) may grant the facility a 45-day interim certificate. Each AB has an approved interim accreditation policy and procedure.

In CY 2007, the ACR granted interim accreditation to 9 of its facilities and the STX granted interim accreditation to 13 of its facilities. Each AB followed its approved procedure for granting interim accreditation.

(4) Accreditation Review and Decision-Making Processes

Review of the ABs' accreditation and decision-making processes includes evaluating procedures for clinical image review, phantom image review, and mammography equipment evaluation and medical physicist annual survey review.

(a) Clinical Image Review

As part of the accreditation process, mammography facilities must submit clinical images to their ABs for review. To evaluate the ABs' performance in the clinical image review area, FDA's interpreting physicians (IPs) annually review clinical images from a sample of facilities that submit cases to the ABs for clinical image review. Generally, two FDA IPs independently conduct clinical image reviews for each facility in the sample from each of the ABs that perform clinical image review by evaluating each examination on the eight attributes listed in the MQSA regulations.

ACR, SAR, and SIA (the STX contracts with the ACR to conduct its clinical image reviews) have their own clinical image reviewers to evaluate their facilities' clinical images. Below is a summary of FDA clinical image reviews.

ACR AB

FDA performed its evaluation of ACR's clinical image review process on October 29, 2007. FDA found that there was a favorable agreement between ACR reviewers at the attribute evaluation level. In reviewing the images and summary evaluation forms, FDA agreed with the final overall assessments (pass and fail) in all of the cases reviewed.

FDA determined that this review of cases indicates that the quality of clinical image review by ACR remains high and has not deviated from past performance. In general, the clinical image reviewers are providing adequate feedback to facilities on ways to improve image quality. FDA did, however, encourage the ACR to provide additional feedback for one element during its review process.

SAR AB

FDA performed its evaluation of SAR's clinical image review process in September 2007. In reviewing the images and summary evaluation forms, FDA agreed with the final overall assessments (pass and fail) in all of the cases reviewed. FDA indicated that the quality of clinical image review performed by SAR remains high and has not deviated from past performance. The clinical image reviewers provided adequate feedback to

those facilities that failed the review. FDA encouraged SAR to also provide feedback to those facilities that passed the review.

SIA AB

In October 2007, FDA performed its evaluation of SIA's clinical image review process. In reviewing the clinical images and summary evaluation forms, FDA agreed with the SIA reviewers' final overall assessments (pass/fail) in all of the cases reviewed. The review indicated that the quality of clinical image review performed by SIA remains high and has not deviated from past performance. Overall, the clinical image reviewers are providing adequate feedback to facilities as an educational tool to aid the facility in improving image quality.

Summary of Audits and Training of Clinical Image Reviewers by the ABs

Audits

An audit of clinical image reviewers ensures uniformity, identifies any potential problems, and provides all individual clinical image reviewers with the necessary data to compare his/her results to the rest of the review group. ABs use audit results to enhance reviewer training by emphasizing any performance issues. In 2007, ACR (and STX via its contract with ACR), SAR, and SIA conducted audits of their clinical image reviewers to collect statistics on reviewer agreement and nonagreement rates. The rates are used to identify performance issues that require corrective action.

Training

ACR, SAR, and SIA (STX contracts with ACR for clinical image review) have clinical image review quality control activities that promote consistency among the various clinical image reviewers. Each of these ABs conducts training sessions at which clinical image reviewers evaluate clinical images and discuss findings, including the application of AB clinical image review evaluation criteria.

(b) Phantom Image Review

As part of the accreditation process, mammography facilities must submit phantom images to their ABs for review. To evaluate the ABs' performance in the phantom image review area, FDA's MQSA expert staff annually reviews phantom images from facilities that submit cases to the ABs. Two FDA staff, working independently, review 10 randomly selected phantom images from each AB. The FDA reviewers evaluate all test objects (fibers, specks, masses) on these images to determine whether they agree or disagree with the AB's pass/fail decisions. Below is a summary of FDA phantom image reviews.

ACR AB

FDA reviewed the ACR's phantom images on October 29, 2007. FDA reviewers agreed with the ACR in all 10 cases (100 percent agreement) and determined that the quality of the phantom image review performed by the ACR remains high and has not deviated from past performance.

SAR AB

FDA reviewed SAR's phantom images in November 2007. FDA reviewers agreed with SAR's pass/fail assessment in 9 out of 10 cases. In the one case of disagreement, FDA's reviewers agreed that this was a borderline case that fell within acceptable limits of variability. FDA concluded that the quality of the phantom image review performed by the SAR remains high and has not deviated from past performance.

SIA AB

FDA reviewed SIA's phantom images in October 2007. FDA reviewers agreed with SIA in 8 out of 10 cases. In the two cases of disagreement, FDA's reviewers agreed that these were borderline cases that fell within acceptable limits of variability. FDA concluded that the quality of the phantom image review performed by the SIA remains satisfactory and has not deviated from past performance.

STX AB

In the past, STX AB contracted with the ACR AB to review its phantom images. However, in January 2007, STX AB developed and implemented its own FDA-approved phantom image review program. FDA reviewed phantom images from STX's program in October 2007. FDA agreed with STX in all 10 cases (100 percent agreement) and determined that the quality of the phantom image review performed by STX is high.

Summary of Audits and Training of Phantom Image Reviewers by ABs

Audits

An audit of phantom image reviewers ensures uniformity, identifies any potential problems, and provides all individual phantom image reviewers with the necessary data to compare his/her results to the rest of the review group. ABs use audit results to enhance reviewer training by emphasizing any performance issues. In 2007, all of the ABs conducted audits of their phantom image reviewers to collect statistics on reviewer agreement and nonagreement rates. The rates are used to identify performance issues that require corrective action.

Training

All of the ABs have phantom image review quality control activities that promote consistency among the various phantom image reviewers. Each of these ABs conducts training sessions at which phantom image reviewers evaluate phantom images and discuss findings, including the application of AB phantom image review evaluation criteria.

(c) Mammography Equipment Evaluation (MEE) and Medical Physicist Survey Report Reviews

The MQSA regulations state that ABs shall require every facility applying for accreditation to submit an MEE with its initial accreditation application and prior to accreditation to submit a medical physicist survey on each mammography unit at the facility (21 CFR 900.4(e)). All of the ABs have established FDA-approved policies and procedures for the review of both the MEE and the medical physicist survey report.

(5) AB Onsite Visits to Facilities

The MQSA regulations (21 CFR 900.4(f)(1)(i)) require that each AB annually conduct onsite visits to at least 5 percent of the facilities the body accredits to monitor and assess facility compliance with the standards established by the body for accreditation. However, a minimum of 5 facilities shall be visited, and visits to no more than 50 facilities are required except in limited circumstances. During such visits, the AB is required to evaluate the following eight core elements:

- assessment of quality assurance activities;
- review of mammography reporting procedures;
- clinical image review;
- review of medical audit system;
- verification of personnel duties;
- equipment verification;
- verification of consumer complaint mechanism; and
- other identified concerns.

At least 50 percent of the facilities visited shall be selected randomly and the other facilities visited shall be selected based on problems identified through state or FDA inspections, serious complaints received from consumers or others, a previous history of noncompliance, or other information in the possession of the AB, the MQSA inspectors, or the FDA (i.e., visits for cause).

ACR AB

In CY 2007, ACR accredited 8,348 facilities. It conducted 60 onsite visits (55 random, 5 for cause), thereby exceeding the minimum of 50 onsite visits required by regulation.

SAR AB

In CY 2007, SAR accredited 61 facilities. It conducted 5 onsite visits (3 random, 2 for cause) which equals the minimum that is required by regulation.

SIA AB

In CY 2007, SIA accredited 139 facilities. It conducted 39 onsite visits (39 random, 0 for cause), thereby exceeding the minimum of 7 onsite visits required by regulation.

STX AB

In CY 2007, STX accredited 177 facilities. It conducted 10 onsite visits (6 random, 4 for cause), thereby exceeding the minimum of 9 onsite visits required by regulation.

(6) RCIR

The MQSA regulations (21 CFR 900.4(f)(2)(i)) require that each AB annually conduct RCIRs of at least 3 percent of the facilities the body accredits to monitor and assess facility compliance with the standards established by the body for accreditation.

ACR AB

During CY 2007, ACR conducted 309 RCIRs (3.7 percent), thereby exceeding the minimum of the 250 required by regulation.

SAR AB

SAR conducted 6 RCIRs (9.8 percent) in CY 2007, thereby exceeding the minimum of the 2 required by regulation.

SIA AB

SIA conducted 42 RCIRs (30.3 percent) in CY 2007, thereby exceeding the minimum of the 4 required by regulation.

STX AB

STX conducted 6 RCIRs (3.4 percent) in CY 2007, thereby exceeding the minimum of the 5 required by regulation.

(7) AMR

If FDA has reason to believe that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility must provide clinical images and other relevant information, as specified by FDA (or certifying agency), for review by its AB (21 CFR 900.12(j)). This AMR helps the agency to determine whether there is a need to notify affected patients, their physicians, or the public that the quality of mammograms may have been compromised. The request for an AMR may also be initiated by an AB or a state certifying agency. When an AB initiates an AMR, FDA encourages the AB to discuss the case with the agency prior to performing the AMR.

The following chart summarizes the number of AMRs conducted by each AB during CY 2007:

AB	Number of AMRs Conducted or Initiated*	Number With Serious Risk to Human Health	Number That Completed Notification
ACR	20	1	1
SAR	4	0	0
SIA	1	0	0
STX	1	0	0

*Note: STX has a contract with ACR to conduct its clinical image reviews during an AMR. The remaining three ABs have their own clinical image reviewers to evaluate their facilities' clinical images.

(8) Accreditation Revocation and Suspension

The MQSA regulations (21 CFR 900.3(b)(3)(iii)(I)) require that each AB have policies and procedures for suspending or revoking a facility's accreditation. If a facility cannot correct deficiencies to ensure compliance with the standards or if a facility is unwilling to take corrective actions, the AB shall immediately notify FDA and shall suspend or revoke the facility's accreditation.

SAR AB, SIA AB, and STX AB

SAR, SIA, and STX did not revoke or suspend any facility's accreditation in 2007.

ACR AB

During 2007, the ACR revoked the accreditation of two facilities as a result of FDA revoking each facility's MQSA certificate. To date, neither facility has chosen to begin the reinstatement process and therefore remain closed.

(9) Quantitative Accreditation and Inspection Information

As additional performance indicators, FDA analyzed quantitative accreditation and inspection information related to unit accreditation pass/fail data; reasons for denial of accreditation; and accredited facility performance during inspections.

Note: There are a relatively small number of state-accredited facilities compared to ACR-accredited facilities. Therefore, small variations in state-accredited facility performance may lead to differences across ABs that do not reflect actual differences in AB performance.

(a) Unit Accreditation Pass/Fail Data Sorted by AB

Number of Units	ACR	SAR	SIA	STX
Total	4,890	42	66	94
Passed Accreditation	4,881 (99.8%)	42 (100%)	66 (100%)	94 (100%)
Denied Accreditation*	9 (0.2%)	0	0	0

*Units that were still denied accreditation as of December 31, 2007.

At the conclusion of the reporting period, the accreditation pass rate of mammography units among the ABs ranged from 99.8 - 100 percent. The rates for units that were denied accreditation remained similar to those in the last reporting period.

(b) Reasons for Mammography Unit Denial

In CY 2007, clinical image review failure was the major reason for denial of unit accreditation. Phantom image review failure and failure to submit the required materials were the other reasons for mammography units being denied accreditation. Most of the facilities that receive a denial in the accreditation process complete a corrective action plan under the ABs' reinstatement protocols and eventually successfully achieve the levels of quality needed for accreditation.

(c) Facility Performance During Inspections Sorted by AB

In CY 2007, 75.8 percent of the accredited mammography facilities had no MQSA violations. This is an improvement from the 74.3 percent reported in 2006. Also, in CY 2007, only 1.7 percent of the facilities had a violation characterized as "most serious." This is an improvement from the 2 percent reported in 2006. FDA actively works with these facilities on corrective measures, or takes regulatory measures if a facility cannot improve its performance.

There were no significant differences in average phantom image scores among the facilities accredited by the four ABs. In general, average phantom image scores improved slightly from those reported in the 2006 Report.

In general, the average doses remained similar to those reported in the 2006 report and remain well below the dose limit of 300 millirads mandated by the MQSA regulations.

The average processing speeds among the facilities of all the ABs remained similar to those previously reported and remain well within the range to produce satisfactory clinical images. The evaluation of the mammography facility’s film processing speed is an important quality assurance measure. The speed of film processing impacts directly not only on the resulting image quality of the mammogram, but can also impact on the dose administered to the patient. If a mammography facility is processing film in accordance with the film manufacturer’s recommendations, then the processing speed should be close to 100 (80 – 120 is considered normal processing speed for standard cycle processing). If the processing speed falls significantly below the acceptable level, then the clinical image is not completely developed and may appear too light, and the quality of the mammographic image can be significantly compromised. Moreover, the facility may not realize its film processor is the source of the problem and may compensate by increasing the dose administered to the patient.

	ACR	SAR	SIA	STX
Average Phantom Image Score*	12.6	12.4	11.8	13.0
Average Dose (in millirads)	175.4	170.9	168.4	183.9
Average Processor Speed	110.3	108.6	108.5	108.7

*The maximum possible phantom image score is 16. Four fibers, three masses, and three speck groups must be visible on the image for a minimum passing score.

Status of the Action Items From the 2006 Report to Congress

The one AB with two action items from its 2006 Performance Evaluation successfully resolved both items.

Conclusion

FDA's AB oversight program promotes collaboration and cooperation. Therefore, each AB, in concert with FDA, addresses any action items that may arise during the year. FDA and the ABs, working in partnership with the certified mammography facilities in the United States and with the states participating in inspection and other MQSA activities, are ensuring quality mammography across the nation.