

Report to Congress

**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, 2018 - December 31, 2018

U.S. Department of Health and Human Services

Food and Drug Administration

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 ensure that mammography facilities meet standards for performing high-quality mammography. The Food and Drug Administration (FDA or the Agency) administers the MQSA (section 354 of the Public Health Service Act (42 U.S.C. 263b)). Among other things, the MQSA provides for FDA-approved accreditation bodies (ABs) to evaluate and accredit mammography facilities based upon quality standards. Only facilities that either are accredited by ABs or undergoing accreditation by ABs may receive certificates from FDA or an FDA-approved state certifying agency to legally perform mammography. The MQSA requires FDA to annually report to Congress on the performance of ABs. This 23rd annual report covers the period from January 1, 2018, through December 31, 2018.

To implement the MQSA, FDA issued final regulations (21 CFR part 900) that became effective on April 28, 1999. These final regulations (specifically, 21 CFR 900.5) require that the Agency's evaluation of ABs shall include the following:

- (a) an assessment of the reports of FDA or state inspections of facilities accredited by the AB, as well as any additional information deemed relevant by FDA that has been provided by the AB or other sources or has been required by FDA as part of its oversight initiatives; and
- (b) a 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 21 CFR 900.6.

Status of ABs

Currently, there are four ABs: the American College of Radiology (ACR, a private nonprofit organization) and the respective state ABs of Arkansas, Iowa, and Texas. The terms of FDA approval are for a period of 7 years, and all ABs are approved through April 28, 2020. FDA continues to annually review each AB's performance to determine the AB's compliance with the MQSA regulations.

Evaluation of ABs

To assess overall performance, FDA evaluates ABs in the following areas:

- resource analysis (staffing, funding, information technology capability);
- data management (process/errors);
- data security;
- reporting and record-keeping processes (serious consumer complaint and appeal mechanisms);
- accreditation review and decision-making processes (clinical image review, phantom image review, equipment requirements);

- onsite visits of ABs to facilities (random and for-cause visits);
- random clinical image reviews (RCIRs) of facilities;
- additional mammography reviews; and
- accreditation revocations and suspensions.

FDA evaluates the performance of each AB in the areas listed above through the following:

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

Findings from Calendar Year (CY) 2018 AB Performance Evaluations

The following items are the highlights of FDA's CY 2018 report to Congress:

- Each AB adequately funded its program.
- Each AB took appropriate measures to secure and maintain its accreditation data.
- Each AB administered 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.
- Each AB exceeded the required number of RCIRs for the facilities it accredits.
- Each AB used acceptable procedures to review phantom images submitted by facilities and had adequate audit procedures for its phantom image reviewers.
- Two ABs exceeded the required number of annual onsite visits to facilities they accredit, one AB met its regulatory requirement, and one AB failed to meet the minimum requirement. The AB that failed to meet the minimum requirement will conduct additional onsite visits in CY 2019 to compensate for its deficiency in CY 2018.
- Three ABs' rates for mammography units that were denied accreditation remained the same, and one AB's rate increased.
- At the beginning of CY 2018, there were 8,651 accredited mammography facilities. Only 0.8 percent of the 8,471 facilities inspected had a violation of the MQSA characterized as "most serious." This percentage is the same percent reported in CY 2017.
- Of accredited facilities, 82.6 percent had no violations of the MQSA. This is a decrease in the percentage reported compared to CY 2017.
- Facilities' phantom image scores showed no significant differences across the ABs, and these scores improved from those reported in CY 2017.
- All dose measurements at facilities accredited by the ABs remained well below the dose limit of 3.0 milligray (or 0.3 rad) mandated by the MQSA regulations (21 CFR 900.12(e)(5)(vi) and (e)(6)). The average radiation dose (measured at the facility by a

medical physicist) for all ABs decreased slightly or remained the same from those previously reported and remained well below the dose limit mandated by the MQSA final regulations.

FDA and its approved ABs, working in partnership with certified mammography facilities and state partners, are helping to ensure quality mammography across the United States.

Table of Contents

I. Purpose	1
II. Status of AB Approvals.....	1
III. Standards.....	1
IV. Methodology.....	1
V. Performance Indicators	2
A. Administrative Resources and Funding	2
B. Data Management	2
C. Reporting and Record-Keeping Practices	3
1. Serious Consumer Complaints.....	3
2. Appeals	3
3. Interim Accreditation.....	3
D. Accreditation Reviews and Decision-Making Processes.....	4
1. Clinical Image Reviews (CIRs).....	4
2. Phantom Image Reviews (PIRs).....	6
3. Mammography Equipment Evaluations and Medical Physicist Survey Report Reviews ..	7
E. AB Onsite Visits to Facilities	7
F. RCIRs	8
G. AMRs.....	8
H. Accreditation Revocation and Suspension.....	8
I. Quantitative Accreditation and Inspection Information	9
1. Unit Accreditation Pass/Fail Data for CY 2018 Sorted by AB	9
2. Reasons for Mammography Unit Denial	10
3. Facility Inspection Performance Sorted by AB	10
VI. Action Items.....	12
VII. Conclusion.....	12

I. Purpose

The Mammography Quality Standards Act (MQSA) of 1992 (Pub. L. 102-539), as amended by the Mammography Quality Standards Reauthorization Acts of 1998 and 2004 (Pub. L. 105-248 and Pub. L. 108-365), authorizes the Food and Drug Administration (FDA or the Agency) to ensure that mammography facilities meet standards for performing high-quality mammography. FDA administers the MQSA, which, among other things, provides for FDA-approved accreditation bodies (ABs) to evaluate and accredit mammography facilities based on quality standards. The Agency 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 Pensions 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, 2018, through December 31, 2018.

II. Status of AB Approvals

Currently, there are four ABs: the American College of Radiology (ACR, a private nonprofit organization) and the respective state ABs of Arkansas (SAR), Iowa (SIA), and Texas (STX). The term of approval for the ABs, under the MQSA regulations (21 CFR 900.3(g)), is for a period of 7 years, and each AB is approved until April 28, 2020. At the beginning of calendar year (CY) 2018, there were 8,651 fully accredited mammography facilities, of which 8,256 facilities were accredited by ACR, 62 were accredited by SAR, 130 were accredited by SIA, and 203 were accredited by STX. FDA continues to annually review each AB's performance to determine its compliance with the MQSA regulations.

III. Standards

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

IV. Methodology

For each AB, FDA evaluates the following performance indicators:

- administrative resources and funding;
- data management;
- reporting and record keeping;
- accreditation review and decision-making processes;
- onsite visits of ABs to facilities;
- random clinical image reviews (RCIRs);
- additional mammography reviews (AMRs); and
- accreditation revocations and suspensions.

FDA evaluates the performance indicators listed above through the following:

- examining the responses of ABs to questionnaires developed by FDA addressing performance indicators;
- analyzing quantitative accreditation and inspection information;
- reviewing select accreditation files (including clinical and phantom images);
- interviewing ABs' staff and management to answer questions or clarify issues;
- analyzing information from FDA's Mammography Program Reporting and Information System database of annual facility inspections;
- performing onsite visits to the ABs; and
- reviewing communications that occur with the ABs throughout the year.

FDA analyzes the ABs' 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 the performance of the facilities that the ABs accredit by collecting average radiation dose values, reviewing quality control data, and reviewing personnel qualification documentation during MQSA inspections. Collectively, these measures reflect the overall quality of important aspects of the provision of mammography services.

V. Performance Indicators

A. Administrative Resources and Funding

An AB's staff generally includes managers, mammography or other radiologic technologists, former MQSA inspectors, health physicists, information technology program application specialists, and administrative assistants. Fees collected from mammography facilities for accreditation services support accreditation program activities. All AB program fee schedules must be approved by the Agency. On an ongoing basis, FDA monitors the ABs' levels of efficiency and productivity to ensure that the ABs dedicate adequate resources to their accreditation programs. All ABs continue to maintain adequate funding and staffing for their respective programs.

B. Data Management

All ABs provide FDA with electronic transmissions of accreditation data in a secure, timely, and appropriately maintained manner. FDA continues to work individually with the ABs to accomplish the following:

- minimize the number of data errors;
- ensure the timeliness and reliability of the data;

- emphasize the routine performance of quality assurance and quality control practices to correct errors before transmitting the data; and
- emphasize the importance of producing and analyzing reports that outline errors, the frequency with which they occur, and corrective actions.

C. Reporting and Record-Keeping Practices

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

1. Serious Consumer Complaints

MQSA implementing regulations (21 CFR 900.4(g)) require ABs to develop and administer a consumer complaint mechanism. All facilities are required to file serious unresolved complaints with their AB. By regulation (21 CFR 900.4(h)(4)), each AB must submit to FDA an annual report summarizing all serious complaints received during the previous calendar year, the resolution status of these complaints, and any actions taken in response to them.

Each AB must investigate serious consumer complaints and submit its serious consumer complaint report to FDA (see 21 CFR 900.4(f), (g), and (h)). In CY 2018, ACR was the only AB that received serious consumer complaints. ACR investigated serious complaints from four consumers. FDA's review determined that ACR followed its approved procedures when investigating and resolving serious consumer complaints.

2. Appeals

Each AB must have a process for facilities to appeal an adverse accreditation decision, including either a denial of accreditation or a revocation of accreditation (or an application for accreditation) (21 CFR 900.3(b)(3)(iii)(K) and 900.4(a)(6)). In CY 2018, ACR, which accredits approximately 95 percent of facilities, was the only AB that received appeals. These appeals contested two denial of accreditation decisions. ACR handled these appeals per its FDA-approved procedures. Since the appeals were related to denials of accreditation, the images were forwarded to one of the AB's senior clinical image reviewers for an additional independent review. Based on this additional review, the two adverse accreditation decisions were upheld.

3. 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 an accreditation renewal decision. The facility must be fully accredited and meet certain criteria to obtain interim accreditation at the time of accreditation renewal. Once the AB grants the facility interim accreditation, FDA (or an FDA-approved state certifying agency) may grant the facility a 45-day interim certificate so that the facility remains certified pending the accreditation renewal decision (42 U.S.C. 263b(c)(2)).

In CY 2018, ACR granted interim accreditation to nine facilities (0.1 percent of facilities it accredited in CY 2018), and STX granted interim accreditation to one facility (0.5 percent of facilities it accredited in CY 2018). Overall, the ABs granted interim accreditation to 0.1 percent of the facilities accredited in CY 2018. Interim accreditation is evaluated because it is a measure of how often an AB is unable to make a timely accreditation decision. The need for interim accreditation remained the same for CY 2018 as the previous reporting period. Each AB followed its approved procedures for granting interim accreditation.

D. Accreditation Reviews and Decision-Making Processes

FDA's review of the ABs' accreditation and decision-making processes includes the following:

- evaluating procedures for clinical image review and evaluating a sample of clinical images;
- evaluating procedures for phantom image review and evaluating a sample of phantom images;
- reviewing mammography equipment evaluations; and
- reviewing medical physicist annual surveys.

1. Clinical Image Reviews (CIRs)

As part of the accreditation process, mammography facilities must submit clinical images (mammograms) to their ABs for review (21 CFR 900.4(c)). ACR, SAR, and SIA have their own clinical image reviewers to evaluate their facilities' clinical images. ACR performs the CIRs for STX under contract.

To evaluate the ABs' performance in the CIR area, FDA's breast imaging physicians review clinical images from a sample of facilities that submit cases to the ABs for accreditation and other clinical image review purposes. Two FDA radiologists conduct a CIR of images from each facility in the sample for each of the ABs that performs clinical image review. Each examination, which is given a pass or fail, is evaluated on the following eight attributes listed in the MQSA regulations (21 CFR 900.4(c)(2)): positioning, compression, exposure level, contrast, sharpness, noise, artifacts, and examination identification. FDA's results are then compared to the AB clinical image reviewer results.

In evaluating the results of past CIRs by ABs, FDA has found the ABs to be significantly stable in following their CIR procedures, as well as in providing reliable results of those CIRs. Additionally, the ABs themselves are seasoned, with the newest AB having served as an AB for 20 years. Based on these findings, in CY 2017, FDA changed the frequency of the CIRs to a biennial review, but FDA continues to evaluate certain criteria throughout the year to determine whether an annual CIR is appropriate, including whether the AB is new; more than 10 percent of the AB's CIR reviewers are new; the AB has been approved to accredit a technology new to its accreditation program; the AB has an action item the previous year related to the CIR; or other issues identified by FDA as part of its oversight of the AB. FDA has determined that biennial CIRs from alternating ABs, in combination with evaluating

these criteria throughout the year, are sufficiently appropriate and relevant to evaluate an AB's performance. (See 42 U.S.C. 263b(e)(6)(A)(ii) and 21 CFR 900.5.)

Below is a summary of the results of FDA's review of clinical images.

a. ACR

FDA evaluated ACR's CIR process in February 2019. Fifty clinical cases and summary evaluation forms from 21 facilities were reviewed. For 45 cases, FDA reviewers agreed with ACR reviewers' overall pass or fail scores and reviewer comments (i.e., a 90 percent agreement rate), including ACR-provided feedback to facilities on ways to improve quality. For the five cases in which FDA disagreed with the ACR reviewers' overall pass or fail scores, FDA provided detailed feedback to ACR on the reasons for these disagreements. FDA encouraged ACR to incorporate FDA feedback into ACR's internal assessment of its CIR process.

b. SAR

SAR's CIR was conducted in CY 2017. During CY 2018, there were no criteria present that would warrant an annual CIR. Therefore, based on the biennial CIR schedule, SAR's CIR will be conducted in CY 2019.

c. SIA

SIA's CIR was conducted in CY 2017. During CY 2018, there were no criteria present that would warrant an annual CIR. Therefore, based on the biennial CIR schedule, SIA's CIR will be conducted in CY 2019.

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

Audits

An audit of clinical image reviewers helps to ensure consistency among reviewers, identify potential problems, and provide individual clinical image reviewers with the necessary data to compare their results to the rest of the review group. ABs use audit results to enhance reviewer training by emphasizing any performance issues. In CY 2018, the ABs that performed CIRs (i.e., ACR, SAR, and SIA) also conducted audits of their clinical image reviewers to collect statistics on reviewer agreement and non-agreement rates. The ABs utilize these rates to identify performance issues that may require corrective action. In CY 2018, three ACR reviewers (5.5 percent of the total number of ACR clinical image reviewers) required remediation. The other two ABs reported no remediation activities. ACR's CY 2018 percentage is a decrease from the 6.1 percent reported in CY 2017. All reviewers with performance issues completed remediation by attending a refresher course or by reviewing clinical image review protocols and guides. The post-remediation performance of these reviewers is being monitored.

Training

The ABs that perform CIRs (i.e., ACR, SAR, and SIA) also perform clinical image review quality assurance activities that promote consistency among the various clinical image reviewers. These activities include conducting training sessions during which clinical image reviewers evaluate clinical images that have been submitted to the AB for various reasons and the reviewers discuss their findings, including how to apply CIR evaluation criteria.

2. *Phantom Image Reviews (PIRs)*

A breast phantom is a test object used to simulate radiographic characteristics of compressed breast tissue that contains components that may radiographically model mammographic signs of breast cancer. As part of the accreditation process, mammography facilities must submit images of breast phantoms (phantom images) to their ABs for review (21 CFR 900.4(d)). To evaluate the ABs' performance in the PIR area, FDA's MQSA expert staff annually reviews phantom images from facilities that submit cases to the ABs. Two FDA medical physicists, working independently, review randomly selected phantom images from each AB. A third reviewer is used when there is a need for a tiebreaker. FDA reviewers evaluate all test objects (fibers, specks, and masses) on these images to determine whether they agree or disagree with an AB's pass/fail decision. Below is a summary of the results of FDA's PIRs.

a. ACR

FDA reviewed 10 phantom images from ACR in December 2018. FDA reviewers agreed with ACR's pass/fail assessment in all the cases. FDA determined that the quality of the PIRs performed by ACR remains high and has not deviated from past performance.

b. SAR

FDA reviewed 10 phantom images from SAR in January 2019. FDA reviewers agreed with SAR's pass/fail assessment in all the cases. FDA concluded that the quality of the PIRs performed by SAR remains high and has not deviated from past performance.

c. SIA

FDA reviewed 10 phantom images from SIA in October 2018. FDA reviewers agreed with SIA's pass/fail assessment in all the cases. FDA concluded that the quality of the PIRs performed by SIA remains high and has not deviated from past performance.

d. STX

FDA reviewed 10 phantom images from STX in December 2018. FDA reviewers agreed with STX's pass/fail assessment in all the cases. FDA concluded that the quality of the PIRs performed by STX remains high and has not deviated from past performance.

i. Summary of Audits and Training of Phantom Image Reviewers by the ABs

Audits

An audit of phantom image reviewers helps to ensure consistency among them, identify potential problems, and provide them with the necessary data to compare their results to the rest of the review group. ABs use audit results to enhance reviewer training by emphasizing any performance issues. In 2018, each AB conducted audits of its phantom image reviewers to collect statistics on reviewer agreement and non-agreement rates. The ABs use these rates to identify performance issues that may require corrective action. In CY 2018, no phantom image reviewers required remediation, an improvement from the 3.3 percent reported in CY 2017. All reviewers with performance issues completed remedial action by attending a refresher course or reviewing phantom image review protocols and guides.

Training

All ABs perform PIR quality assurance activities that promote consistency among their phantom image reviewers. Each AB conducts training sessions during which PIRs evaluate and score phantom images and discuss findings, including the application of the AB's PIR evaluation criteria.

3. Mammography Equipment Evaluations and Medical Physicist Survey Report Reviews

MQSA regulations (21 CFR 900.4(e)) state that ABs shall require every facility applying for accreditation to submit a Mammography Equipment Evaluation (MEE) with its initial application and, prior to accreditation, to submit a medical physicist survey report on each mammography unit at the facility. In CY 2018, the ABs followed their FDA-approved policies and procedures for the review of both the MEE and the medical physicist survey reports.

E. AB Onsite Visits to Facilities

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

- quality assurance/quality control activities;
- mammography reporting procedures;
- clinical images;
- medical audit system;
- personnel duties;
- equipment present;
- consumer complaint mechanism; and
- any identified concerns.

At least 50 percent of the facilities visited must be randomly selected, and the other facilities visited must be selected based on problems identified through state or FDA inspections, such as serious consumer complaints, a previous history of noncompliance, or other information in the possession of the AB, the MQSA inspectors, FDA, or a state certifying body (i.e., visits for cause). Three ABs met or exceeded the required number of annual onsite visits to the facilities they accredit, and one AB failed to meet the minimum requirement. (Please see section VI.)

AB	Number of Accredited Facilities	Number of Random Onsite Visits	Number of Targeted Onsite Visits	Total Onsite Visits	Regulatory Requirement*
ACR	8,256	44	4	48	50
SAR	62	5	0	5	5
SIA	130	10	0	10	7
STX	203	11	0	11	10

* The requirement is five percent of accredited facilities, with a minimum of five facilities and a maximum of 50 facilities.

F. RCIRs

MQSA regulations (21 CFR 900.4(f)(2)(i)) require that each AB annually conduct RCIRs of at least three percent of the facilities they accredit to monitor and assess facility compliance with the standards they have established for accreditation. All ABs exceeded the requirement for RCIRs.

AB	Number of Accredited Facilities	Regulatory Requirement	Total RCIRs	Percentage of Facilities*
ACR	8,256	248	302	3.7%
SAR	62	2	5	8.1%
SIA	130	4	11	8.5%
STX	203	6	22	10.8%

* The requirement is at least three percent of accredited facilities.

G. AMRs

If FDA believes 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 specified by FDA (or a state certifying agency) for review by the facility's AB (21 CFR 900.12(j)). This AMR helps FDA (or a state certifying agency) determine whether there is a need to notify affected patients, their health care providers, or the public that the quality of mammography may have been compromised. The request for an AMR may also be initiated by an AB or a state certifying agency if the requirements in 21 CFR 900.12(j) and 21 CFR 900.22(f) are satisfied. FDA's review showed that all the ABs followed their approved policies and procedures for conducting AMRs.

H. Accreditation Revocation and Suspension

MQSA regulations (21 CFR 900.3(b)(3)(iii)(I)) require that each AB has 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 must immediately notify FDA or the state certifying body and may suspend or revoke the facility’s accreditation. If a facility’s accreditation is revoked by an AB, FDA or a state certifying body may investigate the reasons for the revocation. Following such investigation, FDA or a state certifying body may pursue a combination of actions based on how the Agency decides will best protect the public health, including a determination that the facility’s certificate shall no longer be in effect, a suspension or revocation of a facility’s certificate, or an injunction to enjoin continuation of a facility’s activity. FDA reports adverse actions taken against mammography facilities on the MQSA webpage (<https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program/reports-mqsa>).

The table below shows the CY 2017 and CY 2018 accreditation revocations and suspensions by AB. The rates of these actions remained relatively stable over the two reporting periods.

	ACR		SAR		SIA		STX	
	2017	2018	2017	2018	2017	2018	2017	2018
Number of Revocations/ Suspensions of Accreditation	10	13	1	0	0	0	2	2
Percentage of Accredited Facilities with Revocation/ Suspension of Accreditation	0.12%	0.16%	1.64%	0	0	0	0.96%	0.98%

I. Quantitative Accreditation and Inspection Information

As additional performance indicators, FDA analyzes quantitative accreditation and inspection information related to unit accreditation pass/fail data, reasons for denial of accreditation, and accredited facility inspection performance. Accreditation is a unit-based process, and a facility is considered accredited if it has at least one accredited unit.

1. Unit Accreditation Pass/Fail Data for CY 2018 Sorted by AB

The table below displays the number of units that passed accreditation, the number of units that were denied accreditation, and the total number of unit applications for accreditation in CY 2017 and CY 2018.

	ACR		SAR		SIA		STX	
	2017	2018	2017	2018	2017	2018	2017	2018
Units Passed Accreditation	4,848 (99.9%)	5,529 (99.6%)	31 (100%)	61 (100%)	104 (100%)	93 (100%)	68 (100%)	188 (100%)

Units Denied Accreditation *	1 (0.02%)	21 (0.4%)	0	0	0	0	0	0
Total Number of Unit Applications for Accreditation	4,449	5,550	31	61	104	93	68	188

* Units that were still denied accreditation as of December 31, 2018.

The accreditation pass rate of mammography units among the ABs was 99.9 percent. The percentage of units that were denied accreditation in CY 2018 increased for one AB and remained the same for three ABs, as reported in CY 2017.

2. Reasons for Mammography Unit Denial

In CY 2018, CIR failure was the reason for denials of unit accreditation. Most of the facilities that received a denial in the accreditation process completed corrective action plans under their respective AB's reinstatement protocols and successfully achieved the level of quality needed for accreditation. The facilities that did not complete their corrective action plans were not granted accreditation.

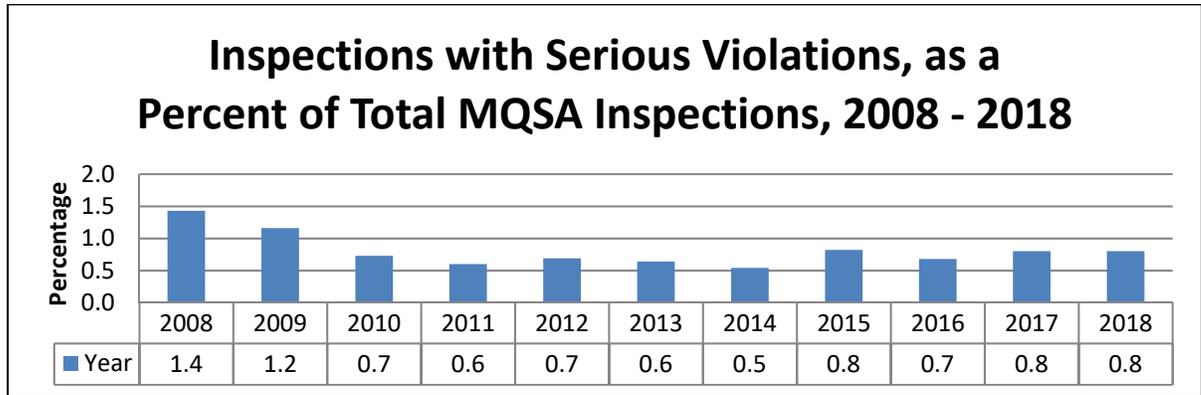
3. Facility Inspection Performance Sorted by AB

In CY 2018, 82.6 percent of certified mammography facilities had no violations of the MQSA. This is a decrease from the percentage reported in CY 2017. The graph below displays the percentage of inspections with no violations for the last 11 calendar years. That percentage has exceeded 80 percent every year since 2010.



In CY 2018, 0.8 percent (68 of the 8,471 facilities inspected) had a violation of the MQSA that may have seriously compromised the quality of mammography services offered at the facility. This percentage is the same percentage reported in CY 2017. FDA actively works with these facilities on corrective measures or takes regulatory action if a facility cannot

improve its performance. The graph below displays the percentage of inspections with serious violations for the last 11 calendar years, showing overall improvement since CY 2008.



There were no significant differences in average phantom image scores among the facilities accredited by the four ABs (see table below). Overall, average phantom image scores were comparable to scores reported in the report covering CY 2017.

All dose measurements at facilities accredited by the ABs remained well below the dose limit of 3.0 milligray (or 0.3 rad) mandated by the MQSA regulations (21 CFR 900.12(e)(5)(vi) and (e)(6)). The average radiation dose (measured at the facility by a medical physicist) for facilities accredited by each AB was comparable to doses reported for CY 2017 (see table below).

	ACR		SAR		SIA		STX	
	2017	2018	2017	2018	2017	2018	2017	2018
Average Phantom Image Score*	13.4	13.4	13.5	13.4	13.2	13.2	13.2	13.2
Average Dose (in milligray)+	1.4	1.3	1.3	1.4	1.3	1.2	1.4	1.4

* The maximum possible phantom image score is 16. The minimum passing score is 10.

+ MQSA regulations (21 CFR 900.12(e)(5)(vi) and (e)(6)) require that the dose not exceed 3.0 milligray (0.3 rads).

VI. Action Items

During a reporting period, if an AB fails to meet any of the performance requirements, it will be required to perform one or more action items that mitigate the deficiency. During CY 2018, ACR conducted 48 onsite visits as opposed to the minimum of 50 required by regulation. In CY 2019, ACR will conduct two additional onsite visits to compensate for its deficiency in CY 2018.

VII. Conclusion

FDA's AB oversight program promotes collaboration and cooperation. FDA and the ABs, working in partnership with the certified mammography facilities in the United States and with the states participating in mammography facility inspections and other MQSA activities, are helping to ensure quality mammography across the United States.