

**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, 2017 - December 31, 2017**

**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 facilities meet standards for performing high-quality mammography. The Food and Drug Administration (FDA or the Agency) administers the MQSA. Among other things, the MQSA provides for FDA-approved accreditation bodies (AB) 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 FDA or an FDA-approved state certifying agency to legally perform mammography. The MQSA requires annual reports to Congress on AB performance. This 22<sup>nd</sup> annual report covers the period from January 1, 2017, through December 31, 2017.

To implement the MQSA (section 354 of the Public Health Service Act (42 U.S.C. 263b)), FDA issued final regulations that became effective on April 28, 1999 (21 CFR Part 900). The final regulations (21 CFR 900.5) require that the Agency's evaluation of ABs shall include:

- (a) an 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 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 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). The terms of FDA approval are for a period of 7 years, and all ABs are approved through April 28, 2020. FDA continues to review each AB's performance annually to determine its compliance with the MQSA regulations.

### Evaluation of Accreditation Bodies

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);
- AB onsite visits to facilities (random and for-cause visits);

- random clinical image reviews (RCIR) of facilities;
- additional mammography reviews (AMR); 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;
- biennial onsite visits to the ABs; and
- written and oral communications with the ABs throughout the year.

#### Findings from Calendar Year (CY) 2017 AB Performance Evaluations

The following items are the highlights of FDA's CY 2017 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 random clinical image reviews 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.
- Each AB exceeded the required number of annual onsite visits to facilities they accredit.
- Overall, the rates for mammography units denied accreditation remained about the same as those in the last reporting period.
- At the beginning of CY 2017, there were 8,662 accredited mammography facilities. Only 0.8 percent of these had a violation of the MQSA characterized as "most serious." This percentage is comparable to the 0.7 percent reported in CY 2016.
- Of accredited facilities, 87 percent had no violations of the MQSA. This is the same percentage reported in CY 2016 and continues to demonstrate that mammography facilities, as a whole, are a highly compliant regulated entity.
- Facilities' phantom image scores showed no significant differences across the ABs, and these scores improved from those reported in CY 2016.
- 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.

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## **I. Purpose**

The Mammography Quality Standards Act (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 the Food and Drug Administration (FDA or the Agency) to ensure that 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, 2017, through December 31, 2017.

## **II. Status of Accreditation Body Approvals**

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). The term of approval of each AB under the MQSA regulations is for a period of 7 years (21 CFR 900.3(g)), and all ABs are approved until April 28, 2020. At the beginning of calendar year (CY) 2017, there were 8,662 fully accredited mammography facilities, of which 8,263 facilities were accredited by ACR, 61 were accredited by SAR, 130 were accredited by SIA, and 208 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 facilities 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 incorporated the standards into its accreditation processes.

## **IV. Methodology**

FDA evaluates the following AB performance indicators:

- administrative resources and funding;
- data management;
- reporting and record keeping;
- accreditation review and decision-making processes;
- AB onsite visits to facilities;
- Random Clinical Image Reviews (RCIRs);
- Additional Mammography Reviews (AMRs); and
- accreditation revocations and suspensions.

FDA evaluates performance in these areas through:

- examining AB responses to questionnaires developed by FDA addressing performance indicators;
- analyzing quantitative accreditation and inspection information;
- reviewing selected accreditation files (including clinical and phantom images);
- interviewing AB 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 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 the performance of facilities 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:

- 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 documenting corrective actions.

### C. Reporting and Record-Keeping

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

#### *1. Serious Consumer Complaints*

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

In CY 2017, ABs investigated all serious complaints they received—13 for ACR and 1 for SIA. Each AB submitted its serious consumer complaint report to FDA. FDA's review determined that each AB 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). In CY 2017, the ACR, which accredits approximately 95 percent of facilities, was the only AB that received appeals. ACR handled its six denial of accreditation appeals per its FDA-approved procedures. The facilities' appeals contested six adverse accreditation decisions. 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, four adverse accreditation decisions were upheld, and two adverse accreditation decisions were overturned.

#### *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 the facility remains certified pending the accreditation renewal decision.

In CY 2017, ACR granted interim accreditation to 11 facilities (0.1 percent of facilities it accredited in CY 2017), and SIA granted interim accreditation to 2 facilities (1.5 percent of facilities it accredited in CY 2017). Overall, the ABs granted interim accreditation to 0.2 percent of the facilities accredited in CY 2017. Interim accreditation is evaluated as 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 as the previous reporting period. Each AB followed its approved procedures for granting interim accreditation.

#### D. Accreditation Review and Decision-Making Processes

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

- 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 Review (CIR)*

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

To evaluate the ABs' performance in the clinical image review 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 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 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 AB CIR reviews, FDA has found the ABs to be significantly stable in following their CIR procedures, as well as providing reliable results of those CIRs. Additionally, the ABs themselves are seasoned, with the newest having served as an AB for 19 years. Based on these findings, FDA has changed the frequency of the CIR review to a biennial review while continuing to evaluate certain criteria throughout the year to determine whether annual CIR review 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 CIR; or other issues identified by FDA as part of its oversight of the AB. FDA has determined that biennial CIR review from alternating ABs, in combination with evaluating these criteria throughout the year, is sufficiently

appropriate and relevant to evaluate an AB's performance. (See 42 USC 263b(e)(6)(A)(ii); 21 CFR 900.5.)

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

### ACR AB

There were no criteria present that would cause annual CIR review to be appropriate. The ACR's CIR will be conducted in CY 2018.

### SAR AB

FDA performed its evaluation of the SAR AB's CIR process in November 2017. A total of 10 clinical cases and summary evaluation forms from seven facilities were reviewed. FDA reviewers agreed with the SAR reviewers' overall scores for eight cases, for an 80 percent agreement rate (an improvement from the CY 2016 rate of 70 percent). FDA provided detailed feedback to the SAR reviewers on the reasons for these disagreements. FDA generally agreed with reviewer comments on image quality, but determined that more extensive comments could have been provided as an educational tool to aid facilities in improving overall image quality. FDA provided feedback to SAR reviewers as a model for educational feedback to facilities.

### SIA AB

FDA performed its evaluation of the SIA AB's CIR process in November 2017. A total of 20 clinical cases and summary evaluation forms from 10 facilities were reviewed. FDA reviewers agreed with the SIA reviewers' overall scores for all but two cases, for a 90 percent agreement rate, which remains stable compared to the 90 percent rate in CY 2016. FDA provided detailed feedback to the SIA reviewers on the reasons for these disagreements. FDA generally agreed with reviewer comments on image quality, but determined that more extensive comments could have been provided as an educational tool to aid facilities in improving overall image quality. FDA provided feedback to SIA reviewers as a model for educational feedback to facilities.

#### *a) 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 2017, the ABs that perform CIR, 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 2017, three ACR reviewers (6.1 percent of the total number of ACR clinical image reviewers)

required remediation. The other two ABs reported no remediation activities. ACR's percentage is a decrease from the 7.2 percent reported in CY 2016. All reviewers with performance issues completed remediation by attending a refresher course or by reviewing clinical image review protocols and guides. Their post-remediation performance is being monitored.

### Training

The ABs that perform CIR, 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 at which clinical image reviewers evaluate clinical images that have been submitted to the AB for various reasons; the reviewers discuss their findings, including how to apply AB clinical image review evaluation criteria.

## *2. Phantom Image Review (PIR)*

A breast phantom is a test object used to simulate radiographic characteristics of compressed breast tissue that contains components that 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. 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 medical physicists, working independently, review randomly selected phantom images from each AB. A third reviewer is used when there is a need for a tie-breaker. 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 the results of FDA's phantom image reviews.

### ACR AB

FDA reviewed 10 phantom images from ACR in December 2017. FDA reviewers agreed with ACR's pass/fail assessment in all the cases. FDA determined that the quality of the phantom image reviews performed by the ACR AB remains high and has not deviated from past performance.

### SAR AB

FDA reviewed 10 phantom images from SAR in November 2017. FDA reviewers agreed with SAR's pass/fail assessment in all the cases. FDA concluded that the quality of the phantom image reviews performed by the SAR AB remains high and has not deviated from past performance.

### SIA AB

FDA reviewed 10 phantom images from SIA in November 2017. FDA reviewers agreed with SIA's pass/fail assessment in all the cases. FDA concluded that the quality of the

phantom image reviews performed by the SIA AB remains high and has not deviated from past performance.

### STX AB

FDA reviewed 10 phantom images from STX in October 2017. FDA reviewers agreed with STX's pass/fail assessment in all the cases. FDA concluded that the quality of the phantom image review performed by the SIA AB remains high and has not deviated from past performance.

#### *a) Summary of Audits and Training of Phantom Image Reviewers by the ABs*

##### Audits

An audit of phantom image reviewers helps to ensure consistency among reviewers, identify potential problems, and provide phantom 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 2017, 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 2017, one ACR reviewer (3.3 percent of the total number of AB phantom image reviewers) required remediation, an improvement from the 5.0 percent reported in CY 2016. 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 phantom image review quality assurance activities that promote consistency among their phantom image reviewers. Each AB conducts training sessions at which phantom image reviewers evaluate and score phantom images and discuss findings, including the application of AB phantom image review evaluation criteria.

#### *3. Mammography Equipment Evaluation and Medical Physicist Survey Report Reviews*

MQSA regulations 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 (21 CFR 900.4(e)). In CY 2017, 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 5 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 5 facilities must 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:

- 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 selected randomly, 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). All ABs met or exceeded the required number of facility visits.

AB	Number of Accredited Facilities	Number of Random Onsite Visits	Number of Targeted Onsite Visits	Total Onsite Visits	Regulatory Requirement*
ACR	8,263	47	4	51	50
SAR	61	3	2	5	5
SIA	130	14	0	14	7
STX	208	10	2	12	10

\* The requirement is 5 percent of accredited facilities, with a minimum of 5 facilities and a maximum of 50 facilities.

#### F. Random Clinical Image Review

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. All ABs exceeded the requirement for RCIRs.

AB	Number of Accredited Facilities	Regulatory Requirement	Total RCIRs	Percentage of Facilities*
ACR	8,263	248	345	4.2%
SAR	61	2	9	14.8%
SIA	130	4	18	13.8%
STX	208	6	24	11.5%

\* The requirement is at least 3 percent of accredited facilities.

## G. Additional Mammography Review

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, as 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 healthcare 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 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 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 determination that the facility's certificate shall no longer be in effect, suspension or revocation of a facility's certificate, or seeking injunction to enjoin continuation of a facility's activity .

The table below shows the CY 2016 and CY 2017 accreditation revocations and suspensions by AB. The rates of these actions remained relatively stable over the two reporting periods.

	ACR		SAR		SIA		STX	
	2016	2017	2016	2017	2016	2017	2016	2017
Number of Revocations/ Suspensions of Accreditation	7	10	1	1	0	0	0	2
Percentage of Accredited Facilities with Revocation/ Suspension of Accreditation	0.08%	0.12%	1.54%	1.64%	0	0	0	0.96%

## 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 2017 Sorted by AB*

The table below displays the number of units that passed accreditation, the number of units denied accreditation, and the total number of unit applications for accreditation in CY 2016 and CY 2017.

	ACR		SAR		SIA		STX	
	2016	2017	2016	2017	2016	2017	2016	2017
Units Passed Accreditation	4,204 (99.9%)	4,848 (99.9%)	35 (100%)	31 (100%)	40 (100%)	104 (100%)	118 (100%)	68 (100%)
Units Denied Accreditation *	2 (0.01%)	1 (0.02%)	0	0	0	0	0	0
Total Number of Unit Applications for Accreditation	4,206	4,449	35	31	40	104	118	68

\* Units that were still denied accreditation as of December 31, 2016.

The accreditation pass rate of mammography units among the ABs was 99.9 percent. The percentage of units that were denied accreditation in CY 2017 remained essentially the same as those reported in CY 2016.

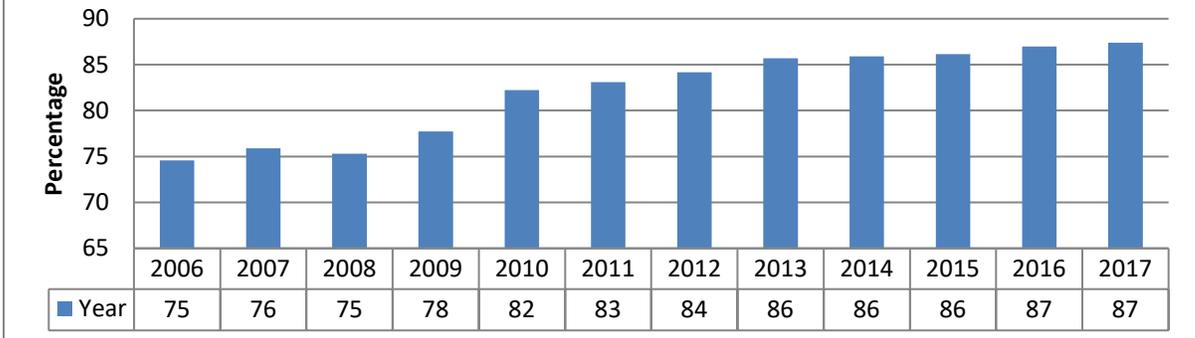
*2. Reasons for Mammography Unit Denial*

In CY 2017, clinical image review 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 the ABs’ reinstatement protocols and successfully achieved the level of quality needed for accreditation.

*3. Facility Inspection Performance Sorted by AB*

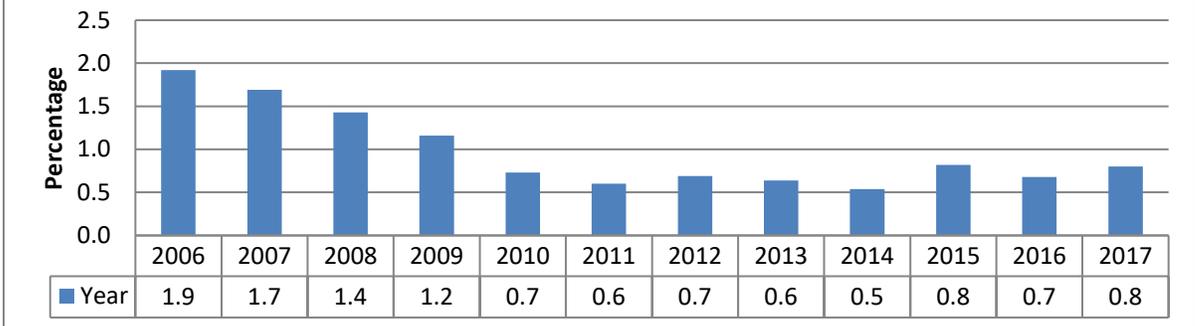
In CY 2017, 87 percent of certified mammography facilities had no violations of the MQSA. This is the same percentage reported in CY 2016. The graph below displays the percentage of inspections with no violations for the last 11 calendar years. That percentage has exceeded 80 percent every year since 2010.

### Inspections with No Violations, as a Percent of Total MQSA Inspections, 2006 - 2017



In CY 2017, 0.8 percent of facilities had a violation of the MQSA that may have seriously compromised the quality of mammography services offered at the facility. This percentage is comparable to the percentage (0.7 percent) reported in CY 2016. 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 2006.

### Inspections with Serious Violations, as a Percent of Total MQSA Inspections, 2006 - 2017



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 2016.

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 2016 (see table below).

	ACR		SAR		SIA		STX	
	2016	2017	2016	2017	2016	2017	2016	2017
Average Phantom Image Score*	13.5	13.4	13.3	13.5	13.2	13.2	13.6	13.2
Average Dose (in milligray)+	1.4	1.4	1.5	1.3	1.3	1.3	1.5	1.4

\* The maximum possible phantom image score is 16. The minimum passing score is 10.  
+ MQSA regulations require that the dose not exceed 3.0 milligray (0.3 rads) (21 CFR 900.12(e)(5)(vi) and (e)(6)).

## 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. There were no action items during this reporting period.

During the previous reporting period, in CY 2016, the combined disagreement rate between FDA reviewers and SAR AB reviewers for CIR oversight for CY 2015 and CY 2016 was 36 percent compared to an average of 7.5 percent for the other ABs who perform clinical image reviews. The SAR AB was required to provide a written plan that addressed possible reasons and mitigations for this finding. The SAR AB provided FDA with its written plan and FDA approved the SAR AB's corrective action.

## 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 inspection and other MQSA activities, are helping to ensure quality mammography across the United States.