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, 2006

A Report to Congress

Purpose

The Mammography Quality Standards Act (MQSA, the Act) of 1992 (Pub .L. No. 102-539), as amended by the Mammography Quality Standards Reauthorization Acts (MQSRA) of 1998 and 2004 (Pub. L. No. 105-248 and Pub. L. No. 108-365), establishes standards for high quality mammography and requires all facilities to be accredited by a Food and Drug Administration (FDA) approved accreditation body (AB) in order for them to demonstrate that they meet these 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, 2006 through December 31, 2006.

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). 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 annually review 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. 263(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

To assess overall performance, FDA evaluates the AB's in the following areas (as outlined in the MQSA regulations):

- 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, 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, FDA analyzes information from its Mammography Program Reporting and Information System (MPRIS) database of annual facility inspections. MQSA inspectors assess accredited facility performance during inspections by measuring average phantom image scores, average radiation dose values, 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 2006, 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 decreased from 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 an established appropriate serious consumer complaint mechanism. In CY 2006, only two ABs (ACR and STX) received complaints from a total of 14 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 2006, only the ACR received appeals to its accreditation decisions. The ACR received two appeals and it 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 2006, the ACR granted interim accreditation to 3 of its facilities; the SAR granted interim accreditation to 1 of its facilities; and the STX granted interim accreditation to 10 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 MQSA-qualified 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. A summary of FDA clinical image reviews follows.

American College of Radiology AB

FDA performed its evaluation of ACR's clinical image review process on October 30, 2006. FDA found that there was good 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 the cases.

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. Overall, the clinical image reviewers are providing adequate feedback to facilities as an educational tool to aid the facilities in improving film quality.

State of Arkansas AB

FDA performed its evaluation of SAR's clinical image review process in October 2006. FDA indicated that the quality of clinical image review performed by SAR remains high and has not deviated from past performance. FDA made the following observations: (1) since the 2005 FDA evaluation, the use of the two questions that deal with whether the reviewer believes the exam to be of diagnostic quality and whether an AMR should be considered are now being appropriately addressed by the AB reviewers; (2) in general, SAR provided good feedback to the facility on ways to improve image quality although,

in one exam, FDA reviewers felt that SAR reviewers could have given additional feedback to the facility; (3) in one exam, the boxes used to check-off whether the breast was of acceptable density were not properly filled in; and (4) in one exam, the first AB reviewer failed the exam due to the position on the right medial lateral oblique. This reviewer appeared to have made a mistake in filling out the assessment form when he/she stated that the films were of diagnostic quality but that an AMR should be considered. The second AB reviewer passed the exam, but the tie-breaker failed it, stating that the exam was of diagnostic quality and an AMR was not indicated.

During the SAR's clinical image reviewer committee meeting in November 2006, FDA clinical image reviewer discussed these errors with SAR reviewers using the clinical image review forms. FDA clinical image reviewer reviewed examples and clarified the significance of checking each box. FDA will check on this during the next annual review.

State of Iowa AB

In October 2006, 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 the SIA AB remains high and has not deviated from past performance. FDA made the observation that the forms used for clinical image evaluation provided additional space for the reviewer's comments but did not specifically ask whether the images were of such quality that further image evaluation should be considered. Thus, FDA reviewers recommended that the SIA AB add a question to the form to address this issue. Since FDA made this observation in previous years, SIA AB must address this issue as an action item in its 2006 Performance Evaluation.

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. The ABs use audit results to enhance reviewer training by emphasizing any performance issues. In 2006, 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. For any reviewer that shows poor performance, the AB requires that individual to undergo remedial 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 for phantom image review. Two FDA staff, working independently, review approximately 10 to 20 randomly selected phantom images from each of the ABs that perform phantom image review. FDA evaluates all test objects (fibers, specks, masses) on these images as part of the review. Scores for these test objects should fall within the acceptable limit of $\pm$ 0.5.

ACR, SAR, and SIA (STX contracts with ACR to conduct its phantom image reviews) have their own phantom image reviewers to evaluate their facilities' phantom images. A summary of FDA phantom image reviews follows.

American College of Radiology AB

FDA reviewed the ACR's phantom images on October 30, 2006 and determined that the quality of the phantom image review performed by ACR remains high and has not deviated from past performance.

State of Arkansas AB

FDA reviewed SAR's phantom images in November 2006 and determined that the quality of phantom image review performed by the SAR remains high and has not deviated from past performance.

State of Iowa AB

In October 2006, FDA reviewed SIA's phantom images and determined that the quality of phantom image review performed by SIA remains high and has not deviated from past performance.

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. The ABs use audit results to enhance reviewer training by emphasizing any performance issues. In 2006, ACR (and STX via its contract with ACR), SAR, and SIA conducted audits of their phantom image reviewers to collect statistics on reviewer agreement and nonagreement rates. For any

reviewer that shows poor performance, the AB requires that individual to undergo remedial action.

Training

ACR, SAR, and SIA (STX contracts with ACR for phantom image review) 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 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. During such visits, the AB is required to evaluate 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).

American College of Radiology AB

In CY 2006, ACR accredited 8,504 facilities. It conducted 65 onsite visits (56 random, 9 for cause), thus exceeding the minimum of 50 onsite visits required by regulation.

State of Arkansas AB

In CY 2006, SAR accredited 58 facilities. It conducted 6 onsite visits (4 random, 2 for cause), thus exceeding the minimum of 5 onsite visits required by regulation.

State of Iowa AB

In CY 2006, SIA accredited 139 facilities. It conducted 52 onsite visits (51 random, 1 for cause), thus exceeding the minimum of 7 onsite visits required by regulation.

State of Texas AB

In CY 2006, STX accredited 166 facilities. It conducted 9 onsite visits (6 random, 3 for cause), thus exceeding the minimum of 8 onsite visits required by regulation.

(6) Random Clinical Image Review

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.

American College of Radiology AB

During CY 2006, ACR conducted 306 RCIRs (3.6 percent), thereby exceeding the 255 required by regulation.

State of Arkansas AB

SAR conducted 4 RCIRs (6.9 percent) in CY 2006, thus exceeding the minimum of the 2 required by regulation.

State of Iowa AB

SIA conducted 55 RCIRs (39.5 percent) in CY 2006, thus exceeding the minimum of the 4 required by regulation.

State of Texas AB

STX conducted 6 RCIRs (3.6 percent) in CY 2006, thus exceeding the minimum of the 5 required by regulation.

(7) Additional Mammography Review

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 it 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 2006:

AB	Number of AMRs Conducted or Initiated*	Number With Serious Risk to Human Health	Number That Completed Notification
ACR	29	3	3
SAR	3	1	1
SIA	2	0	0
STX	2	1	1

*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.

State of Arkansas AB, State of Iowa AB, and State of Texas AB

SAR, SIA, and STX did not revoke or suspend any facility's accreditation in 2006.

American College of Radiology AB

ACR revoked the accreditation of two facilities during 2006. After ACR performed an AMR on each facility, it issued each a letter of revocation when its clinical image reviewers found the facilities' practices to possibly pose a serious risk to human health.

Subsequently, under 21 CFR 900.13(a), FDA determined that the certificates at both facilities were no longer in effect and required the facilities to notify affected patients and their referring physicians. Each facility completed its corrective action plan (CAP) and ACR is currently waiting for both facilities to submit their documentation in order to be reinstated.

(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	5,064	24	69	123
Passed Accreditation	5,054 (99.8%)	24 (100%)	69 (100%)	122 (99.2%)
Denied Accreditation*	10 (0.2%)	0	0	1 (0.8%)

*Units that were still denied accreditation as of December 31, 2006.

At the conclusion of the reporting period, the accreditation pass rate of mammography units among the ABs ranged from 99.2 - 100 percent. The rates for units that were denied accreditation remained about the same as those in the last reporting period.

(b) Reasons for Mammography Unit Denial

In 2006, 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 CAP 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 2006, 74.3 percent of the accredited mammography facilities had no MQSA violations. This is an increase from the 2005 report. Also, in CY 2006, only 2 percent of the facilities had a violation characterized as "most serious." This is the same percentage

as in the 2005 report. FDA actively works with these facilities on corrective measures, or takes regulatory measures if a facility cannot improve its performance.

	ACR	SAR	SIA	STX
Average Phantom Image Score*	12.5	12.2	11.4	13.0
Average Dose (in millirads)	177	173.2	157.6	178.4
Average Processor Speed	96.7	105.5	98.7	101.6

*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.

There were no significant differences in average phantom image scores among the facilities accredited by the four ABs. In general, average phantom image scores remained about the same as those reported in the 2005 Report.

In general, the average doses remained the same as those reported in the 2005 report and remain well below the dose limit of 300 millirads mandated by the MQSA regulations. This dose limit has the advantage of permitting flexibility for the optimization of technique factors used during examinations to achieve improved image quality.

The average processing speeds among the facilities of all the ABs decreased slightly from those reported in the 2005 report 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.

Status of the Action Items From the 2005 Report to Congress

The one AB with two action items from its 2005 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 the states participating in inspection and other MQSA activities are ensuring quality mammography across the nation.