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

January 1, 2000 through December 31, 2000

A Report to Congress

Purpose

The Mammography Quality Standards Act (MQSA) of 1992 (P.L. 102-539), as amended by the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998 (P.L. 105-248), establishes standards for high quality mammography and requires all facilities to be accredited by a Food and Drug Administration (FDA) approved accreditation body in order to demonstrate that they meet these standards. The FDA may approve either private non-profit organizations or State agencies to serve as accreditation bodies. The MQSA also requires that the FDA submit an annual performance evaluation of the approved accreditation bodies to the Committee on Health Education, Labor and Pension of the U.S. Senate and the Committee on Energy and Commerce of the U.S. House of Representatives under 42 USC 263b(e)(6). This report covers the performance of accreditation bodies under the MQSA during the period from January 1, 2000 through December 31, 2000.

Scope

To implement the MQSA (Public Health Service Act section 354, 42 USC section 263b), FDA issued final regulations that were effective on April 28, 1999 (21 CFR Part 900). The final regulations state that FDA's evaluation of accreditation bodies shall include a(n):

(a) Assessment of the reports of FDA or State inspections of facilities accredited by the body as well as any additional information deemed relevant by FDA that has been provided by the accreditation body or other sources or has been required by FDA as part of its oversight initiatives;

(b) Determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the approval of the accreditation body under the provisions of Section 900.6.

This report is based on the evaluations of the following accreditation bodies (ABs): the American College of Radiology (ACR), a private non-profit organization, and the State accreditation bodies of Arkansas (SAR), California (SCA), Iowa (SIA), and Texas (STX).

Methodology

The FDA's general approach to conducting AB performance evaluations consists of (1) examination of accreditation bodies' responses to questionnaires developed by the FDA addressing performance indicators, (2) analysis of quantitative accreditation and inspection information, (3) review of selected files, as well as clinical and phantom images, and (4) interviews with AB staff and management to answer questions or clarify issues. In order to make an assessment of the ABs' performance, the Agency evaluates the information it gathers against the following performance indicators: administrative resources, reporting and record keeping processes, accreditation review and decision-making processes, accreditation body onsite visits to facilities, random clinical image reviews, additional mammography reviews, and accreditation revocations and suspensions. Additionally, the FDA's evaluations are conducted using AB onsite visits, as well as ongoing written and verbal communications with accreditation bodies.

FDA reviewed important components of AB administrative resources. These elements included professional staffing levels, personnel responsibilities and commensurate qualifications, funding, and information systems and support services. FDA also evaluated major aspects of the accreditation review and decision-making processes, including the implementation of policies and procedures to ensure high-quality review of the medical physicist's survey, phantom images, clinical images, facility personnel qualifications, and reporting and record keeping. FDA monitored each AB for its compliance with the regulatory requirements of facility onsite visits and random clinical image reviews.

The FDA reviewed the ABs' methods of evaluating clinical and phantom images because these image evaluations are critical components of the ABs'responsibilities. FDA staff interpreting physicians reviewed and discussed the ABs' clinical image review procedures. The interpreting physicians also evaluated mammograms from facilities accredited by the ABs and compared their own assessment of these mammograms with those of the ABs'clinical image reviewers. FDA staff evaluated phantom images from facilities accredited by the ABs and compared their own assessment of these phantom images with those of the ABs' phantom image reviewers.

FDA also used unit accreditation pass/fail data and data describing reasons for failure from each accreditation body as performance indicators because they may reflect the consistency or inconsistency in how different ABs applied accreditation standards. Significant differences in pass/fail rates or reasons for accreditation denial among accreditation bodies could, for example, indicate that one AB is interpreting the significance of a particular quality control standard more or less strictly than another.

The Agency analyzed accredited facility performance during inspections, as measured by average phantom image scores, average radiation dose values, and average processor speeds, and used this information as additional performance indicators. Collectively, these measures reflect the overall functioning of all components of the mammography system. FDA collected this information its Mammography Program Reporting and Information System database of annual facility inspections performed between January 1, 2000 and December 31, 2000.

Results

Renewal of Accreditation Body Approval

FDA approved all ABs under the Mammography Quality Standards Act of 1992 and its interim regulations (with the exception of Texas which did not apply until the final regulations became effective). The final MQSA regulations became effective on April 28, 1999 and required all current ABs to apply for renewal. An AB's term of approval is for a period not to exceed 7 years.

FDA approved the ACR, the SIA, and the STX as ABs under the MQSRA of 1998 and the final regulations. The SAR applied for renewal and its application approval is currently pending until the State's mammography regulations go into effect, which is expected to occur in the Fall of 2001 (See Action Items). The SCA also applied for renewal and approval of its application is currently pending until efforts to remedy deficiencies in the application are completed and its mammography standards are final (See Action Items).

Administrative Resources

All AB staff members have proper qualifications for their respective positions. The Agency believes staffing levels are not uniformly adequate, as discussed in the recommendations section. All ABs continue to maintain adequate funding for their respective programs.

Accreditation data are secure and appropriately maintained in each AB's information system. All the ABs electronically transmit their data to the FDA's Certification/Accreditation Support System (CASS). CASS generates an acknowledgement of receipt, as well as feedback on the processing status for each data set transmitted. The data transmission error rates for each AB have decreased significantly from those of the previous year as follows:

The ACR error rate for 2000 was 17% as compared to a rate of 33.6% in 1998 – 99.
The SAR error rate for 2000 was 16% as compared to a rate of 23.4% in 1998 – 99.
The SCA error rate for 2000 was 16% as compared to a rate of 23.8% in 1998 – 99.
The SIA error rate for 2000 was 8% as compared to a rate of 16.67% in 1998 – 99.
The STX error rate for 2000 was 17% with no rate reported for 1998 – 99 since the State did not become an AB until mid 1999.

In 2000, all ABs transmitted data to FDA on a daily basis with the exception of the ACR. FDA instructed the ACR to increase its transmission schedule from three times a week to daily transmissions. ACR accomplished this task in the Spring/Summer of 2001. However, transmissions sent from ACR regarding the "address field" were inconsistent. These inconsistencies can result in CASS issuing an inappropriate (replacement) facility certificate unless this process is manually monitored (See Action Items).

In the 1998 – 99 AB Performance Evaluation Action Items, FDA asked all of the ABs to develop and implement a procedure for transmission of data that includes the reason(s) for a mammography unit being denied accreditation. The ACR, the SAR, and the SIA have all implemented this procedure into their data transmission processes. To date, the SCA has transmitted the reason for denial to FDA only one time (See Action Items). During the year 2000, the STX did not transmit the reason(s) a unit was denied accreditation (See Action Items).

For FDA to maintain the current certification status of all mammography facilities, it is important that the ABs report facility accreditation status to FDA in a timely manner. In 2000, the SAR, the SIA, and the STX reported accreditation status in a timely manner. The ACR improved its reporting of accreditation status from the previous year. At the end of 1999, there were 31 facilities with an expired certificate for which FDA had not received any accreditation updates from ACR. For the same time period in 2000, that number had decreased to 6. The SCA also improved significantly its reporting of accreditation status. At the end of 1999, there were 9 SCA facilities listed on FDA's "Expired Facilities Listing," and only 1 for the same time period in 2000.

The FDA and the ABs continue to work together to improve the accuracy and timeliness of electronic data transmissions.

Reporting and Record Keeping

(1) Serious Consumer Complaints

MQSA requires ABs to develop and administer a consumer complaint mechanism. This mechanism provides that all facilities which the AB accredits file serious unresolved complaints with the accreditation body. All ABs have a serious consumer complaint mechanism. 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 submitted their serious consumer complaint report for the year 2000. The ACR received 30 complaints, the SAR received 2, the SCA received 3, the SIA received 0 and the STX received 6. All complaints were successfully resolved with the exception of 3 that were received by the ACR. Those complaints were still under investigation as of the writing of this report.

(2) Appeals

Each AB is required to have an appeals process for facilities contesting adverse accreditation status decisions. All ABs have an appeals process. The State ABs (SAR,

SCA, SIA, and STX) received no appeals from facilities during the year 2000. The ACR received 54 appeals. In 17 of these cases, upon further review, the ACR agreed with the facilities' appeals. Thirty-six cases were denied their appeal and 1 appeal is pending as of the writing of this report.

Standards

The Mammography Quality Standards Act requires that each AB develop (or adopt by reference) standards that are substantially the same as the quality standards established by FDA under subsection (f) of the Act to assure the safety and accuracy of mammography. Regarding State laws, nothing in the Act limits the authority of any State to enact and enforce laws relating to the matters covered by the Act that are at least as stringent as the Act or the regulations issued under the Act.

The ACR adopted the final MQSA standards when they became effective on April 28, 1999 and incorporated them into its accreditation processes.

In October of 2000, the SAR submitted changes to its State Board of Health that will adopt by reference the final MQSA standards. FDA is withholding AB renewal approval until the SAR's mammography standards are final (See Action Items).

The present SCA mammography standards are not comparable to the MQSA standards. The SCA is currently in the process of revising their Draft State mammography standards. FDA is withholding AB renewal approval until the SCA's mammography standards are final (See Action Items).

The SIA adopted the final MQSA standards by reference and thus incorporated them into its State standards on July 1, 2000.

FDA determined that the STX mammography standards are substantially the same as the MQSA final standards. FDA approved the STX on April 28, 1999, the day the MQSA final standards became effective.

All ABs require their facilities to comply with the final MQSA standards.

Accreditation Review and Decision-Making Processes

(1) Clinical Image Review

FDA's MQSA qualified staff interpreting physicians reviewed clinical images from facilities that had submitted cases to the accreditation bodies for clinical image review. (Note: the States of California and Texas each have a contract with the ACR to conduct their clinical image reviews).

The two FDA interpreting physicians independently conducted the ACR clinical image review on July 12, 2000. FDA found that there was agreement between the FDA

interpreting physicians and the ACR clinical image reviewers on the final overall pass/fail assessments in all the cases reviewed. This spot review of cases indicated that the quality of clinical image review by the ACR remains high and has not deviated from past performance.

On September 18 and September 22, 2000, respectively, the two FDA interpreting physicians independently conducted the SAR clinical image review. The review indicated that the quality of the clinical image review by the SAR remained acceptable but that there were areas that could be improved (See Recommendations).

One FDA interpreting physician conducted the SIA clinical image review on September 15, 2000 during the SIA onsite visit. In all the cases reviewed, the FDA interpreting physician agreed with the overall pass/fail assessment given by the Iowa reviewers. The review indicated that the SIA continues to maintain appropriate quality standards concerning clinical image review. However, FDA believes there are some improvements that could be made to SIA's Annual Clinical Image Review In-Service and to its clinical image review protocol (See Recommendations).

Clinical image review quality control activities, which promote consistency among the various clinical image reviewers, exist at ACR, the SAR and the SIA. Each of these ABs conduct training sessions at which clinical image reviewers evaluate clinical images and discuss findings, including the application of AB clinical image review evaluation criteria. In addition, each AB, to ensure uniformity and to identify potential problems, analyzes agreement and non-agreement rates of all individual clinical image reviewers to provide the reviewer with the necessary data to compare his/her results to the rest of the review group.

(2) Phantom Image Review

FDA staff reviewed phantom images that had been submitted from facilities to the accreditation bodies for phantom image review. (Note: the State of Texas has a contract with the ACR to conduct its phantom image review).

FDA conducted a review of ACR's phantom images on July 12, 2000. FDA reviewers independently reviewed 10 phantom images. Average scores of the FDA reviewers were within 0.5 of the average scores of the ACR reviewers for all objects in all images reviewed. This spot review of the phantom images indicates that the quality of phantom image review by the ACR remains high and has not deviated from past performance.

In March 2000, FDA reviewers independently performed the SAR's phantom image review. FDA concluded that the SAR reviewers underscored the fiber score in 3 of the 10 phantoms reviewed by FDA. In these cases, the SAR reviewers' average scores differed by > 0.5 from the FDA reviewers' scores. However, in all 3 cases, the SAR and FDA reviewers passed the phantom image. FDA will monitor the phantom image reviewers scoring and provide additional consultation and assistance to address this difference (See Recommendations).

FDA conducted the last phantom image review on the SCA was on December 8, 1999. Ten phantom images were selected randomly and scored independently by two FDA reviewers. Nine of the images were within 0.5 of the scores of the FDA reviewers while one image was > 0.5 from the FDA reviewers' scores. The FDA reviewers failed the image while the SCA reviewer gave the phantom image a passing score. This difference in scoring has been resolved through a detailed discussion between FDA and the SCA. An area of concern for FDA is that only one phantom image reviewer is used to score phantom images under the SCA accreditation application process. In contrast, the other ABs utilize at least two reviewers when reviewing phantom images. Because SCA uses only one phantom image reviewer, FDA is unable to determine the consistency of reviewer scoring for phantom images used for accreditation purposes. FDA expects the SCA to implement the required quality assurance program for phantom image reviewers in 2001, including the requirement that the SCA will use two phantom image reviewers to score phantom images with a tie break reviewer when necessary (See Action Items).

FDA reviewers performed the SIA's phantom image review in October 2000. They concluded that there was one instance in which the scoring by FDA differed by more than 0.5 from the scoring of the SIA reviewers. However, the reviewers from both SIA and FDA passed the phantom image.

The ACR and the SAR conducted an audit of their phantom image reviewers in order to collect statistics regarding agreement/non-agreement reviewer rates. This type of audit ensures uniformity, identifies any potential problems, and provides all individual phantom image reviewers the necessary data to compare his/her results to the rest of the review group.

The SIA and the SCA did not compile phantom image reviewer statistics for 2000 but state they are developing a process of evaluation to be utilized in 2001 (See Action Items).

(3) Medical Physicist Survey Review

The ACR, the SAR, and the SIA have an appropriate process to review the medical physicist survey report of the facilities that apply for accreditation and reaccreditation. These ABs verify that all MQSA required tests are completed and that the results are acceptable and meet the appropriate standards. For any tests in the medical physicist's report that are not acceptable, the facility must supply documentation of appropriate corrective action which is reviewed and approved by the accreditation body.

The SCA uses a Physicist Report Checklist to review the medical physicist survey report section for each facility accreditation application it receives. In the 1998 – 99 SCA AB Performance Evaluation, FDA identified some questions and concerns regarding the checklist. Since that time, the SCA has submitted a revised checklist but the FDA still has some questions and concerns (See Action Items).

The STX's policies and procedures state that the AB staff reviews the medical physicist survey reports that facilities submit with their accreditation application. However, the STX has not provided to date procedures and tools used during the review (See Action Items).

AB Onsite Visits to Facilities

The final MQSA regulations require that each AB annually visit at least 5% of the facilities the body accredits to monitor and assess the facility's 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. At least 50% 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, inspectors, or FDA (i.e., targeted visits).

(1) Random Onsite Visits

ACR performed 25 random onsite visits in the year 2000. Two of the visits found unacceptable results. Both facilities submitted acceptable corrective action. ACR also performs Scheduled Onsite Surveys (SOSS) of those facilities that require extensive corrective action (after their second failure) in order for the facility to reinstate and continue the accreditation process. During 2000, ACR performed 27 SOSS's. The 25 random onsite visits combined with the 27 SOSS's meet ACR's obligation to perform random onsite visits in the year 2000. As of the writing of this report, one facility failed after reinstatement, one unit was withdrawn from accreditation, 15 facilities were reinstated and 10 actions are still pending for completion of corrective action by the facility or completion of the accreditation process after reinstatement.

The SAR performed 36 random onsite visits between January 1, 2000 and December 31, 2000. One facility received an overall poor evaluation. The facility performed follow-up action that resulted in a passing review of their clinical image. The SAR met its obligation to perform random onsite visits in the year 2000.

In 2000, the SIA performed 97 random onsite visits. SIA found one facility to have significant quality control (QC) problems. The facility performed corrective action and the SIA determined that the problems had been resolved during its follow-up visit to the facility. The SIA met its obligation to perform random onsite visits in the year 2000.

The SCA states that annual MQSA inspections can be considered random onsite visits because they are conducted on an annual routine basis. However, the MQSA final regulations regarding random onsite facility visits require, at a minimum, eight areas for review and the SCA has not included all the required elements in its AB onsite visit plan. Of particular concern is the SCA's current understanding of the random onsite visits requirement in the area of review regarding the selection of a sample of clinical images for clinical image review by the AB. FDA does not train its MQSA inspectors in the review of clinical images, nor do the annual MQSA inspection procedures include review

of clinical images. Rather, FDA requires the ABs to perform clinical image review as part of the accreditation of their facilities. Therefore, the annual MQSA inspection procedures must be supplemented with procedures for reviewing clinical images if the inspection is to meet requirements for an AB onsite facility visit. SCA performed no clinical image reviews during inspections in 2000; thus, it did not perform complete random onsite visits. The SCA is expected to implement the required AB onsite visit plan in 2001 (See Action Items).

As of December 31, 2000, the STX had not instituted an onsite visit plan to facilities. Therefore, during the year 2000, the STX did not perform any random onsite visits. During FDA's visit to the STX in March 2001, STX provided a copy of its "procedures for routine onsite visits." FDA expects the STX to implement the AB onsite visit process in 2001 (See Action Items).

(2) Targeted Onsite Visits

The ACR met its obligation to perform targeted onsite visits in the year 2000. ACR conducted 2 targeted onsite visits in 2000. ACR found both of the facilities to be deficient. One facility completed acceptable corrective action. The other facility had not yet completed its corrective action as of the writing of this report.

In 2000, the SAR conducted 3 targeted onsite visits and thus met its obligation to perform targeted onsite visits. SAR found one facility to be deficient. SAR performed a random clinical image review on this facility and the clinical images passed the review. This facility also performed acceptable corrective action on its deficient policies and procedures.

The SCA met its obligation to perform targeted onsite visits in the year 2000. Between January 1, 2000 and December 31, 2000, the SCA conducted 6 targeted onsite visits. All 6 facilities failed their clinical images during the reinstatement process and were required to complete a directed plan of correction. Upon completion of the corrective plan, SCA conducted follow-up visits and the facilities passed the subsequent reinstatement process.

The SIA conducted 2 targeted onsite visits in the year 2000 and thus met its obligation to perform targeted onsite visits. One facility closed. The AB noted that it had been over 14 months since the closed facility performed a medical physicist's survey (these are required every 12 months). The AB performed a targeted visit to ensure that the facility met all requirements of the mammography program. The facility opened under a new name and the SIA performed an annual scheduled visit and found the facility to be in compliance. The other facility's annual visit revealed significant QC problems, and therefore the AB conducted a targeted onsite visit. The facility performed corrective action and the SIA determined that the facility resolved its problems.

Random Clinical Image Review

The final MQSA regulations require that each AB annually conduct random clinical image reviews of at least 3% of the facilities the body accredits to monitor and assess the facility's compliance with the standards established by the body for accreditation.

Between January 1, 2000 and December 31, 2000, the ACR conducted a random clinical image review of 153 facilities or 1.7% of the facilities the AB accredits. This percentage does not meet the ACR's obligation to conduct a review of at least 3% of the facilities the body accredits. ACR did not meet its obligation in 2000 because the majority of the image reviews were initiated in the latter part of the year due to the replacement of its old accreditation software with a new, updated version. ACR anticipates fulfilling its 2000 requirement by the end of 2001 (See Action Items). As of the writing of this report, 9 of the 153 facilities reviewed were deficient, 27 passed, and 117 are pending (i.e. the facility's review has not been completed and a report has not been written). The facilities that were found deficient to date have subsequently performed acceptable corrective action.

During 2000, the SAR conducted random clinical image reviews of 9 facilities or 12.5% of the facilities the AB accredits. All 9 facilities passed the review, and therefore no follow-up actions were required.

In the year 2000, the SIA conducted random clinical image reviews of 97 facilities or 72% of the facilities the AB accredits. The SIA found three of the facilities to be deficient. Each facility submitted an acceptable plan of correction and a second set of clinical images that passed review.

As of December 31, 2000, the SCA had not instituted a random clinical image review procedure. Therefore, during the year 2000, the SCA did not perform any random clinical image reviews. FDA understands that the SCA plans on instituting random clinical image reviews in 2001 (See Action Items).

As of December 31, 2000, the STX had not instituted a random clinical image review procedure. Therefore, during the year 2000, the STX did not perform any random clinical image reviews. The STX reports that it will institute random clinical image reviews in 2001 (See Action Items).

Additional Mammography Review

When 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, for review by the accreditation body. This additional mammography review (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 initiate from the accreditation body or a State Certifying Agency. All AMRs initiated by an accreditation body are discussed with the FDA prior to implementation.

Between January 1, 2000 and December 31, 2000, the ACR completed 5 AMRs. The results of 3 of the AMRs suggested a serious risk to human health while 2 were determined not to pose a serious risk to human health. ACR required the three facilities in which a serious risk to human health was found to perform a patient/physician notification. All three of these facilities are no longer performing mammography.

The SCA conducted 2 limited AMRs during 2000 (Note: a limited AMR consists of 5 clinical cases as opposed to a full AMR that consists of 30 clinical cases). One facility elected to cease operations permanently and completed the process of notification to patients and physicians. The other facility elected to withdraw its certification after being ordered to undergo a directed plan of correction action.

The STX conducted 3 AMRs in 2000. The result of one of these was found to pose a serious risk to human health and, subsequently, the STX denied the facility's accreditation. At present, the facility is not performing mammography nor has the facility applied for reinstatement.

During 2000, the SAR and the SIA did not perform any AMRs.

Accreditation Revocation and Suspension

The MQSA final regulations require that each accreditation body have policies and procedures for suspending or revoking a facility's accreditation. If a facility's deficiencies cannot be corrected to ensure compliance with the standards or if a facility is unwilling to take corrective actions, the accreditation body shall immediately so notify the FDA, and shall suspend or revoke the facility's accreditation.

Between January 1, 2000 and December 31, 2000, the ACR revoked the accreditation of two facilities after the State suspended the medical licenses of the facilities' interpreting physicians.

During 2000, the SCA did not revoke or suspend any facility's accreditation. However, the SCA placed two facilities under order to suspend mammography operations by authority of State law. One of these facilities elected to cease operations permanently and completed the process of notification of patients and physicians. The second elected to withdraw after being ordered to undergo a directed plan of corrective action.

The SAR, the SIA, and the STX did not revoke or suspend any facility's accreditation in 2000.

Quantitative Accreditation and Inspection Information

As additional performance indicators, FDA analyzed quantitative accreditation and inspection information as it relates to unit accreditation pass/fail data, reasons for failure of accreditation, and accredited facility performance during inspections. In so doing, it

took into consideration and recognized that **because of the relatively small number of State-accredited facilities compared to ACR-accredited facilities, small variations in State-accredited facility performance may lead to differences across accreditation bodies that do not reflect actual differences in accreditation body performance.**

At the conclusion of the reporting period, the accreditation pass rate of mammography units among the accreditation bodies ranged from 71.5% - 95.8% (see Table 1, p.20). In general, the rates for facilities that failed accreditation decreased since the last reporting period while the rates for facilities that did not complete the accreditation process, withdrew from the process, or whose accreditation expired increased.

There was a difference between the ACR and State accreditation bodies with regard to unit denial in the accreditation process (see Table 2, p.21). State accreditation bodies have interactive relationships with their facilities that enable them to be proactive in resolving potential problems. Therefore, the overall denial rate among the State ABs is lower than the ACR's denial rate. Since the last reporting period, the number of units denied accreditation by ACR decreased 40% while the number of units denied accreditation by SAR and SCA decreased 100% and 74%, respectively. The SIA remained the same with no units being denied accreditation in either reporting period. Since the STX was not in the last reporting period, there are no data available for comparison to this reporting period.

Most of the facilities that receive a denial in the accreditation process complete rigorous corrective action plans under the reinstatement protocol and, with the technical expertise provided by their accreditation body, can successfully achieve the levels of quality needed for accreditation.

Table 3 (p.22) gives the inspection results of facilities accredited by each accreditation body with respect to average phantom image score, average dose, and average processor speed. In 2000, there were a total of 9,445 facility inspections. ACR was the AB for 92% of the facilities inspected; SAR was the AB for 0.7%; SCA was the AB for 5%; SIA was the AB for 1.4%; and STX was the AB for 0.9%.

There were no significant differences in average phantom image scores among the facilities accredited by the five bodies. The averages ranged from 11.6 to 12.1 (Table 3, p.22 explains phantom image scoring for accreditation). Average phantom image scores remained the same as those reported in the 1998 – 99 report. The 0.5 difference in the range of scores suggests that phantom image quality is consistent throughout the facilities in the U.S.

Average doses ranged from 147.9 to 169.3 millirads per image (see Table 3, p.22). In general, the average doses remained the same as those reported in the 1998 – 99 report and range from 44% - 49% lower than the dose limit of 300 millirads mandated by the MQSA final regulations. The MQSA limit is a low exposure level compared to the exposure levels that were used in earlier years of mammography. This dose limit has the advantage of permitting more flexibility for the optimization of the technical factors used during examinations in order to achieve improved image quality.

Average processing speeds ranged from 99.9 to 111.9 (see Table 3, p.22). Generally, the average processing speeds among the facilities of all the accreditation bodies remained about the same as those reported in the 1998 – 99 report, in the range to produce satisfactory clinical images. The evaluation of the mammography facility's film processing speed is an important quality assurance measure. The quality 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). If the processing speed falls significantly, then the clinical image is not completely developed, appears lighter, and the quality of the image on the mammogram 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 administered dose to the patient.

Status of Action Items from the previous Report to Congress

As part of its accreditation body evaluation, the FDA cites action items that the AB must implement to comply with MQSA regulations and improve accreditation body performance.

ACR and the SIA have implemented all required action items from their 1998 – 99 AB Performance Evaluation Report.

The SCA's 1998 – 99 AB Performance Evaluation Report included six action items. The responses to these action items did not meet MQSA final regulations and therefore have been carried forward to the 2000 Report and are described in the Action Items Section below.

Action Items from the 2000 AB Performance Evaluation Reports

The due date for the accreditation bodies action items is February 15, 2002, unless otherwise indicated. All information must be submitted to FDA on or before that date.

American College of Radiology (ACR):

- Complete the revisions to the Clinical Image Review Protocol and finalize the Additional Mammography Review Protocol.

- Increase the data transmission schedule from three times a week to daily transmissions. When possible, transmissions should occur prior to a facility's accreditation expiration date.

- Institute a procedure that allows for consistent data transmissions of the facility's address field.

- Complete the balance of the required random clinical image reviews for 2000 in order to meet ACR's obligation of reviewing "at least 3% of the facilities the body accredits."

STATUS:

ACR met all action items by the due date.

State of Arkansas (SAR):

- As noted in the 1998 – 99 AB Performance Evaluation, SAR must obtain approval of its mammography quality standards (which will adopt by reference the final MQSA standards). FDA is withholding accreditation body renewal approval under the final MQSA regulations until the SAR's mammography standards are final.

STATUS:

On March 6, 2002, SAR reported to FDA that it anticipates the Governor will sign-off on its mammography standards by late April, 2002.

State of California (SCA): The due date for the following action items is October 31, 2001:

- Complete a draft of the SCA mammography standards that is acceptable to FDA.

- Develop a quality assurance program approved by FDA for the phantom image review process. This process must include provisions for the facility to produce the phantom image using its own phantom and a mechanism for each phantom image to be scored by 2 reviewers with a tie break reviewer when necessary. Implement the quality assurance process for phantom image review within 30 days of FDA approval.

- Complete development and obtain FDA approval of the checklist used for the medical physicist survey report review and mammography equipment evaluation and of instructions for the use of the checklist. The checklist must include all required items in the MQSA final regulations and provide guidance to the reviewer on the acceptable compliance ranges and action limits for each of the required items. Additionally, reference materials identifying acceptable compliance ranges and action limits for each of the required items reviewed must be provided to reviewers. Implement use of the checklist within 30 days of FDA approval.

- Develop and obtain FDA approval for a plan for random onsite visits to facilities that includes all of the required areas for review (e.g., clinical image review). Implement the random onsite visit plan within 30 days of FDA approval.

- Develop and obtain FDA approval for a SOP for random clinical image reviews that meets all applicable requirements in the final MQSA regulations. Implement the random clinical image review SOP within 30 days of FDA approval.

- Develop and obtain FDA approval for a quality assurance program to minimize data transmission errors and to assure that denial/failure reasons are provided whenever a facility is denied reaccreditation or fails initial accreditation. Implement the quality assurance program within 30 days of FDA approval.

STATUS:

FDA held a two-day meeting with SCA in Rockville, MD, in August 2001 during which many issues with the SCA standards were resolved. Based on the resolution of these issues, FDA granted SCA a preliminary approval of their draft mammography standards on September 30, 2001. The FDA approval allowed SCA to begin its State regulatory process for publishing their standards as final. FDA granted preliminary approval to ensure that SCA did not change these standards in a way that would be unacceptable to FDA as they underwent the State process.

SCA, therefore, did meet the October 31, 2001 deadline for the first of the action items listed above. On November 1, 2001, SCA sent a letter to FDA detailing its efforts to meet the remaining five Action Items. After reviewing this response, FDA determined that SCA had not met the requirements outlined for these items. FDA notified SCA of these deficiencies and recommended to SCA that they send SCA staff to Rockville for a working meeting, patterned on the successful meeting held in August regarding the SCA standards. FDA offered this opportunity to SCA to resolve these problems and other remaining issues. Because of SCA travel restrictions, FDA staff traveled to Sacramento during the week of February 25, 2002 for a lengthy and intensive working session with SCA staff to cover the issues in the Action Items and others identified since the completion of the CY 2000 Performance Evaluation. During the meeting, the work in several areas, including the fourth and fifth Action Items on the list above, resulted in a final polishing of these materials. FDA thoroughly discussed the other areas of concern, including the remaining Actions Items for the SCA staff to develop a greater understanding of what they needed to do to complete these areas. SCA committed to finishing several of the remaining tasks by mid April, 2002. They will, working with FDA, establish completion dates for the remaining tasks.

The due date for the following action item is January 31, 2002:

- Publish as final SCA mammography regulations that are acceptable to FDA.

STATUS:

Although SCA cleared the process for the publication of their regulations at the end of September 2001, these regulations have not yet been published as final. During the visit by FDA staff to Sacramento in February 2002, the SCA staff expressed the expectation

that the regulations would be published under the SCA Emergency Process by mid-March 2002. The Emergency Process would allow SCA to enforce the regulations while they underwent a public comment period and the remaining steps for publication as final.

To date, SCA has not published its final regulations, and has not been able to offer a revised date for publication.

State of Iowa (SIA):

- Conduct an annual audit of SIA's phantom image reviewers in order to collect statistics regarding agreement/non-agreement rates.

STATUS:

SIA met its action item by the due date.

State of Texas (STX):

- Implement onsite visits to facilities (random and targeted) that meet all applicable requirements in section 900.4(f)(1) of the final MQSA regulations.

- Develop and implement a program for random clinical image reviews that meets all applicable requirements in section 900.4 (f)(2) of the final MQSA regulations.

- Develop and implement the use of an evaluation form, checklist, or tool for use by the accreditation body staff in the review, evaluation and documentation of medical physicist survey reports and medical equipment evaluations. The tool must include all required items in the final MQSA regulations and provide guidance to the user (the reviewer) on the acceptable compliance ranges and action limits for each of the required items. Additionally, reference materials identifying acceptable compliance ranges and action limits for each of the required items reviewed must be provided to reviewers and identified to FDA. These documents must be provided to FDA for review and, upon approval, must be included in the STX policies and procedures documentation.

- Provide FDA copies of the required changes and additions to the STX policies and procedures sections that were identified to the STX AB staff program manager during the March 2001 visit and subsequent correspondence via electronic mail.

- Electronically transmit to FDA the reason(s) for a unit being denied accreditation.

STATUS:

STX has made efforts to fulfill the first two Action Items, but has not been able to complete these tasks. Addressing the first Action Item, STX conducted four on-site visits during CY 2001, identified as random. However, they did not conduct any targeted on-

site visits during CY 2001. The MQSA regulation requires an AB to conduct on-site visits annually of at least five percent of the facilities it accredits (with a minimum of five visits to be conducted). At least 50 percent of these facilities must be at facilities selected randomly. STX completed only four of the six required visits for their State.

For an on-site visit to be completed, an AB must conduct a random clinical image review. Although STX informed the FDA that it conducted these reviews at its four on-site visits, they did not provide FDA with supporting documentation indicating that it developed and implemented a random clinical image review program as required by the second Action Item. Consequently, FDA cannot verify that the clinical images reviewed during the on-site visits were chosen randomly.

Similarly, STX has not provided FDA with supporting documentation to indicate that they met the third and fourth Action Items. The fifth Action Item does not apply since STX did not deny accreditation to any facility unit in 2001.

While in Austin, Texas in March 2001, FDA discussed these and other problems extensively with STX staff. Additionally, FDA discussed these issues again in August, 2001 during a visit by STX staff to Rockville, MD, and subsequent written and oral communications. FDA is considering ways in which to address the lack of progress made by STX in this area and how best to work with them to correct outstanding deficiencies.

Recommendations from the 2000 AB Performance Evaluation Reports

American College of Radiology (ACR):

- FDA recommends that ACR implement the recommendation of its Subcommittees on Clinical Image Review and Mammography Physics that states "individual means for the CIRs [Clinical Image Reviews] and PIRs [Phantom Image Reviews] be compared against the mean fail rate and standard deviation obtained for the previous full calendar year in order to provide a more stable comparison on which to base action and to better evaluate trends."

- FDA recommends that ACR review the ratio of the number of accredited facilities to the number of FTEs to ensure the number of FTEs are adequate to sustain the workload.

State of Arkansas (SAR):

- The quality of the clinical image review by the SAR remains acceptable, however FDA believes there are areas that could be improved. Many of the clinical images passed by SAR had no comments even though there were aspects of the studies that could have been improved, such as excessive dust artifacts, incomplete visualization of the infra mammary fold, and inadequate pectoral muscle on the medial lateral oblique views. Such comments are useful for facility education. FDA believes that

non-visualization of the pectoralis muscle on the cranio-caudal (CC) view should not be an element that contributes to failure, as in the best of circumstances, the pectoralis muscle is only seen on the CC view approximately 25% of the time. FDA recommends that the SAR review its clinical image review protocol and specifically recommends the standard of the posterior nipple line measurement be used, and that the deficiency of "pectoralis muscle not visualized on the CC view" be removed.

- The SAR phantom image reviewers underscored phantom image fibers in three cases. FDA recommends that the SAR review its phantom image protocol and FDA will monitor the phantom image reviewers' scoring and provide additional consultation and assistance.

- Monitor the phantom image reviewers' scoring and provide additional consultation and assistance.

- SAR has indicated that its accreditation program has initiated the process to add three interpreting physicians to the Clinical Image Review Committee to bring the total to 7 reviewers. FDA recommends that this process be accomplished as soon as possible.

State of Iowa (SIA):

- FDA recognizes that Iowa currently has the highest ratio of FTEs to accredited facilities among the ABs. However, because of the loss of a current staff member, FDA recommends that Iowa proceed with the hiring of another employee to maintain adequate baseline staffing. Another staff member is crucial if the SIA proceeds in the next year with plans to accredit facilities in the State of Wyoming.

- FDA recommends that the following improvements be made to the SIA's Annual Clinical Image Review In-Service and to its clinical image review protocol:
  a. clearly specify, prior to the In-Service, whether the clinical images should be viewed as self-selected or randomly selected images;
  b. as a learning tool, add clinical images that have gone to a tie-breaker review to the In-Service discussion;
  c. accept benign findings on clinical images submitted for accreditation, with proper documentation to substantiate the benign nature of the findings (this submission would be allowed in circumstances where the facility, usually low volume, has difficulty finding clinical images to submit for accreditation in the approved timeframe);
  d. update SIA's clinical image score/evaluation form to include the overall reasons for failure and additional comments as feedback to the facility for learning purposes.

Conclusion

FDA has learned from its approximate six years of experience that some AB performance indicators are a more direct measure of performance than other indicators and, thus,

should be reviewed in greater detail. Therefore, this Report (in contrast to past Reports) reviews in more detail those parameters that FDA believes more accurately reflect the performance and function of an AB.

Given that the AB program promotes collaboration and cooperation, the respective accreditation body, in concert with FDA, is currently addressing all action items cited in this Report. Working in partnership, the FDA and its ABs, together with the certified mammography facilities in the United States, and States participating in inspection and other MQSA activities, are ensuring quality mammography across the nation.

Table 1. Accreditation of Mammography Units by Accreditation Body *

Number of Units	American College of Radiology	State of Arkansas	State of California	State of Iowa	State of Texas
Applications Fully Processed	4,978	34	316	96	93
Passed Accreditation	4,768(95.8%)	29(85.3%)	226(71.5%)	82(85.4%)	73(78.5%)
Failed Accreditation**	43(0.9%)	0	4(1.3%)	0	1(1.1%)
Did Not Complete, Withdrew or Expired	167(3.3%)	5(14.7%)	86(27.2%)	14(14.6%)	19(20.4%)

*Data from January 1, 2000 through December 31, 2000
**Units that were still denied accreditation as of December 31, 2000

Table 2. Reasons for Mammography Unit Denial by Accreditation Body *

Reasons for Failure	American College of Radiology	State of Arkansas	State of California	State of Iowa	State of Texas
Clinical Image Review (CIR)	133(71%)	0	8(100%)	0	1(100%)
Phantom Image Review (PIR)	34(18%)	0	0	0	0
CIR and PIR	13(7%)	0	0	0	0
CIR and Other**	0	0	0	0	0
PIR and Other**	0	0	0	0	0
Other**	7(4%)	0	0	0	0

*Data from January 1, 2000 through December 31, 2000 (includes units that failed and subsequently passed and became accredited)
**Other = Processor or Dose

Table 3. Facilities' Inspection Results by Accreditation Body*

	American College of Radiology	State of Arkansas	State of California	State of Iowa	State of Texas
Number of Inspections	**8,696**	**72**	**457**	**134**	**86**
Average Phantom Image Score**	12.0	11.6	11.8	11.7	12.1
Average Dose (in millirads)	164.5	155.8	147.9	154.4	169.3
Average Processor Speed	99.9	111.9	107.9	99.2	107.2

*Data from January 1, 2000 through December 31, 2000

**The maximum possible phantom image score is 16. Four fibers, 3 masses, and 3 speck groups must be visible on the image for a passing score.

Because of the relatively small number of State-accredited facilities compared to ACR-accredited facilities, small variations in State-accredited facility performance may lead to differences across accreditation bodies that do not reflect actual differences in accreditation body performance.