Executive Summary

The goal of the Mammography Quality Standards Act (MQSA) of 1992, as amended by the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998, is to assure that facilities meet standards for performing high quality mammography. The Food and Drug Administration (FDA) administers MQSA. Among other things, MQSA provides for FDA-approved accreditation bodies (ABs) to evaluate and accredit mammography facilities against quality standards. Based on successful completion of this process, FDA then issues certificates to the facilities so that they can legally operate. MQSA requires annual reports to Congress on AB performance. This eighth annual report covers the period from January 1, 2003, through December 31, 2003.

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

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

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

Status of Accreditation Bodies

FDA approved the American College of Radiology (ACR), a private, nonprofit organization, as well as the States of Arkansas, Iowa, and Texas under the MQSRA of 1998 and the final regulations. FDA approved the State of California (SCA) under the interim regulations. While reviewing the SCA's application under the MQSRA and the final regulations, the SCA withdrew its application (on May 5, 2004) for status as an accreditation body. Through this withdrawal, the SCA relinquished its authority and responsibilities under the MQSRA. As a result, SCA-accredited facilities are in the process of transitioning their accreditation to the ACR.

Core Functions of the Accreditation Bodies

The ABs review documentation and clinical[1] and phantom[2] images that are submitted by mammography facilities for accreditation purposes. On determining that facilities meet

[1] Clinical image review: the facility must submit to the AB two cases (one fatty breast and one dense breast) to be reviewed and scored by an AB panel of trained interpreting physicians. Each case consists of four views, two craniocaudal and two mediolateral oblique views.

[2] Phantom images are x-ray films of plastic objects that contain various simulated abnormalities of breast tissues. Phantom images are used to test the ability of the equipment to discriminate abnormalities.

specific requirements, the ABs make a positive accreditation decision. The FDA then certifies the facilities based on that accreditation.

FDA evaluates the ABs on a number of elements, but concentrates on these core AB functions:

- Clinical Image Review
- Phantom Image Review
- Random Clinical Image Review
- Onsite Visits
- Equipment Requirements
- Consumer Complaint Mechanism
- Additional Mammography Review

Performance Indicators

FDA evaluates the performance of its ABs through:

- examination of their responses to FDA questionnaires that address performance indicators;
- analysis of quantitative accreditation and inspection information;
- review of selected files, as well as clinical and phantom images;
- interviews with staff and management to answer questions or clarify issues;
- analysis of information from its Mammography Program Reporting and Information System; and
- on-site visits

To assess overall performance of the ABs, the agency evaluates information in various areas: administrative processes, reporting and record keeping processes, accreditation review and decision-making processes, AB on-site visits to facilities, random clinical image reviews, additional mammography reviews, and accreditation revocations and suspensions. FDA's evaluation includes on-site visits to the ABs and ongoing written and oral communications with the ABs.

Findings from CY 2003 AB Performance Evaluations

The following items are the highlights of FDA's CY 2003 report to Congress. Where FDA found that an AB did not meet established requirements, it noted action items for these areas in the individual 2003 AB Performance Evaluations:

- All ABs adequately fund their respective programs.
- All ABs take appropriate measures to secure and maintain their accreditation data. Overall, the data management error rates for each AB decreased from those in the previous year.
- Each AB has a satisfactory serious consumer complaint process.
- All ABs have developed (or adopted by reference) standards that are substantially the same as the quality standards established by FDA under subsection (f) of the MQSA.

However, one AB agreed to incorporate the agency's comments in the future revision of its standards.

- Each AB used acceptable procedures to review clinical images submitted by facilities, and has adequate audit procedures for its clinical image reviewers. FDA's oversight revealed that the quality of clinical image review remains high and has not deviated from past performance.
- The majority of the ABs had an adequate procedure to review phantom images and audit its phantom image reviewers. However, one AB failed to implement its FDA-approved policy for the review of phantom images. This failure was included as an action item in its 2003 performance evaluation.
- All ABs met or exceeded the required number of AB on-site visits to facilities they accredit.
- All ABs met or exceeded the required number of random clinical image reviews of the facilities they accredit.
- The ABs performed additional mammography reviews when indicated.
- One AB revoked facility accreditation and one AB suspended facility accreditation in CY 2003.
- Facilities' phantom image scores showed no significant differences across the ABs. Phantom image scores stayed about the same as those reported in the 2002 report.
- Overall, the rates for units that failed accreditation decreased from those in the last reporting period.
- Generally, the average radiation doses measured at the facilities of all the ABs increased slightly from those in the previous report, but still remain well below the dose limit mandated by the MQSA final regulations.
- Generally, the average x-ray film processing speeds among the facilities of all the ABs slightly increased from those reported in the previous report, within the range to produce satisfactory clinical images.
- In CY 2003, over half (65.5 percent) of the accredited mammography facilities received no violations during their MQSA inspection, while only 2.0 percent of facilities had a violation characterized as "most serious." FDA actively works with these facilities on corrective measures, and takes regulatory actions as indicated.

FDA works with each AB to address all the issues and action items noted in this report and as described in the ABs' CY 2003 Performance Evaluations.

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