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 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 based upon quality standards. Based on successful completion of this process, FDA (or state certifying agency) then issues certificates to facilities so that they can legally operate. MQSA requires annual reports to Congress on AB performance. This eleventh annual report covers the period from January 1, 2006, through December 31, 2006.

To implement the MQSA (Section 354q 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) state that the 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

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.

Evaluation of Accreditation Bodies

To assess overall performance, FDA evaluates the AB's in the following areas:

- resource analysis (staffing, funding, information technology capability);
- reporting and record keeping processes (serious consumer complaint and appeals 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 of facilities;
- additional mammography reviews (AMRs); 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 staff and management to answer questions or clarify issues;
- analysis of information from its Mammography Program Reporting and Information System;
- onsite visits to the ABs; and
- ongoing written and oral communications with the ABs throughout the year

Findings from Calendar Year (CY) 2006 AB Performance Evaluations

The following items are the highlights of FDA's CY 2006 Report to Congress:

- All ABs adequately funded their respective programs.
- All ABs took appropriate measures to secure and maintain their accreditation data. Overall, the percentage rate of data errors decreased from the rate noted in 2005.
- Each AB had 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. However, FDA made some observations and recommendations for modifications to two ABs regarding their review procedures and evaluation forms.
- Each AB used acceptable procedures to review phantom images submitted by facilities, and had adequate audit procedures for its phantom image reviewers.
- All ABs exceeded the required number of AB onsite visits to facilities they accredit.
- All ABs exceeded the required number of random clinical image reviews of the facilities they accredit.
- The ABs performed AMRs when indicated.
- One AB revoked the accreditation of two facilities it reviewed in CY 2006.
- Facilities' phantom image scores showed no significant differences across the ABs and these scores remained about the same as those reported in the 2005 report.
- Overall, the rates for units denied accreditation remained about the same as those in the last reporting period.
- Generally, the average radiation doses measured at the facilities of all the ABs remained the same as those in the previous report and remain well below the dose limit mandated by the MQSA final regulations.
- Nearly 75 percent of the accredited mammography facilities received no violations during their MQSA inspection. This percentage is an increase from the one reported in 2005.

- Only 2 percent of facilities had a violation characterized as “most serious.” This percentage is the same as the one reported in 2005. FDA actively works with these facilities on corrective measures, and takes regulatory actions as indicated.
- The one AB with action items from CY 2005 successfully resolved both items.

The 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.