

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 sixth annual report covers the period from January 1, 2001, through December 31, 2001.

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 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, a private, nonprofit organization, as well as the States of Arkansas, Iowa, and Texas under the MQSRA of 1998 and the final regulations. The renewal approval for the State of California is pending until its mammography standards are signed and in effect. FDA approved California's draft standards, which are currently moving through the State's legislative process.

Core Functions of the Accreditation Bodies

The ABs review documentation and clinical¹ and phantom² images that are submitted by mammography facilities for accreditation purposes. On determining that facilities meet the specific requirements, the ABs make a positive accreditation decision. The FDA then certifies the facilities based on that accreditation.

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

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

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

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; 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 evaluations include on-site visits and ongoing written and oral communications with the ABs.

Findings from CY 2001 AB Performance Evaluations

The following items are the highlights of FDA's CY 2001 report to congress. Where FDA found that an AB did not meet established requirements, it notes action items for these areas in the individual 2001 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.
- Overall, each AB had a satisfactory serious consumer complaint process in place.
- Only one AB had not 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, FDA gave preliminary acceptance to the AB's draft standards which are currently proceeding through the State's legislative process.
- Overall, the ABs use acceptable procedures to review clinical images submitted by facilities and FDA's oversight revealed that the quality of clinical image review remains high and has not deviated from past performance.
- Overall, the ABs had adequate procedures to review phantom images. Several ABs corrected minor deviations in their procedures to conform to FDA standards.
- Overall, the ABs had adequate audit procedures for their phantom image reviewers. One AB had some deficiencies and an action item was included for the AB to enhance its audit procedures.
- FDA found that the ABs differ on how they review the mammography equipment evaluation. FDA is currently working with the ABs as a group to develop a consistent review process that best addresses both the regulatory requirements and public health needs.

- Two ABs conducted the required number of AB on-site visits to facilities they accredit, while three did not. Of the three, one did not meet its obligation because of the effect the events of September 11, 2001 had on travel. Because the remaining two ABs did not provide any explanation for not meeting the required number of visits, their performance evaluations identified this failure as an action item. FDA is working closely with the ABs to ensure that they fulfill this requirement.
- One of the two ABs meeting the required number of AB on-site visits did not include all of the required elements of an on-site visit. Therefore, the report includes a related action item.
- Four of the five ABs met their obligation to conduct a random clinical image review of at least three percent of the facilities the body accredits. The fifth AB conducted one fewer review than required.
- All ABs performed additional mammography reviews when indicated.
- No AB revoked or suspended facility accreditation in CY 2001.
- Facilities' phantom image scores showed no significant differences across the ABs. However, phantom image scores increased from those reported in the 2000 report, which shows an improvement in past years.
- Rates for facilities that failed accreditation remained about the same as those in the last report, while rates increased for facilities that did not complete the process, withdrew from the process, or allowed their accreditation to expire.
- 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 remained about the same as those reported in the previous report, within the range to produce satisfactory clinical images.
- In CY 2001, over half (59 percent) of the accredited mammography facilities received no violations during their MQSA inspection, while only 3 percent of facilities had a violation characterized as "most serious." FDA actively works with these facilities on corrective measures.

FDA is working cooperatively and collaboratively with each AB to address all issues noted in this report and as described in the ABs' CY 2001 Performance Evaluations.

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