PERFORMANCE EVALUATION OF ACCREDITATION BODIES UNDER THE MAMMOGRAPHY QUALITY STANDARDS ACT OF 1992 AS AMENDED BY THE MAMMOGRAPHY QUALITY STANDARDS REAUTHORIZATION ACT OF 1998

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 this process, FDA issues certificates to the facilities so that they can legally operate. MQSA requires annual reports to Congress on accreditation body performance. This fifth annual report covers the period from January 1, 2000, through December 31, 2000.

To determine if mammography facilities meet MQSA quality standards, accreditation bodies review specified information the facilities submit. Then the accreditation bodies provide FDA with each facility's evaluation and FDA uses this information to certify mammography facilities.

FDA's approach to evaluating accreditation bodies consists of the following:

- 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.

To assess overall performance, the Agency evaluates this information against administrative resource criteria, 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. FDA's evaluations include onsite visits and ongoing written and oral communications with the accreditation bodies.

The MQSA final regulations became effective on April 28, 1999 and required all existing accreditation bodies to apply for renewal. All four accreditation bodies applied for renewal and a fifth accreditation body, the State of Texas, was approved on April 28, 1999, as a new accreditation body under the final regulations. The American College of Radiology, a private, nonprofit organization, and the State of Iowa were approved for renewal. The renewal approval for the States of Arkansas and California are pending.

Among the report's highlights:

- Resources are generally sufficient, but staffing levels are not uniformly adequate. FDA addressed this issue in recommendations to the appropriate accreditation bodies.
- Accreditation data (data on the facility, the facility's mammography machine, and information if the facility fails accreditation) are secure and appropriately maintained, but there are some inconsistencies in data entries and transmissions and some instances where ABs do not transmit reasons for denying accreditation. This data entries and transmission element is an action item

*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.

for all the ABs. The majority of the ABs have already addressed this issue. (Note: For current status, please see the section entitled "Action Items from the 2000 AB Performance Evaluation Reports.")

- Data entries and transmission error rates for each accreditation body decreased from the previous report.
- All accreditation bodies have both an adequate serious consumer complaint mechanism and appeals process.
- Three of the five accreditation bodies 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. The two remaining accreditation bodies' renewal approvals are pending until these ABs finalize their mammography standards.
- FDA staff found that overall the procedures for reviewing clinical images by ABs were acceptable, but need some improvements. FDA addressed this issue in recommendations to the appropriate accreditation bodies.
- Overall, the ABs' procedures for reviewing phantom images were adequate, but need some improvements. FDA addressed this issue in recommendations to the appropriate accreditation bodies. One AB did not have an adequate phantom image review procedure in place. (Note: For current status, please see the section entitled "Action Items from the 2000 AB Performance Evaluation Reports.")
- Of the four accreditation bodies that review phantom images, two have an adequate audit procedure for its phantom image reviewers while two did not. (Note: For current status, please see the section entitled "Action Items from the 2000 AB Performance Evaluation Reports.")
- Three of the five accreditation bodies had an appropriate process to review the medical physicist survey report. Two of the ABs did not address this procedure adequately. (Note: For current status, please see the section entitled "Action Items from the 2000 AB Performance Evaluation Reports.")
- Three of the five accreditation bodies met their obligation to conduct AB onsite visits to facilities the body accredits. One AB did not perform any AB onsite visits while one AB's performance of onsite visits did not meet the MQSA required AB onsite visit plan. (Note: For current status, please see the section entitled "Action Items from the 2000 AB Performance Evaluation Reports.")
- Two accreditation bodies met their obligation to conduct a random clinical image review of at least 3% of the facilities the body accredits. One AB performed a random clinical image review of 1.7% of its facilities while two ABs have not yet developed or implemented a random clinical image review procedure. (Note: For current status, please see the section entitled "Action Items from the 2000 AB Performance Evaluation Reports.")
- Additional mammography reviews were performed when indicated.
- Accreditation revocations and suspensions were implemented when indicated.
- Facilities' phantom image scores showed no significant differences across accreditation bodies.
- The rates for facilities that failed accreditation decreased since the last report, while rates increased for facilities that did not complete the process or allowed their accreditation to expire.
- In general, the average radiation dose measured for mammography units remained unchanged from the previous report and was still about half the MQSA limit.
- Generally, the average processing speeds noted among the facilities of all the ABs remained about the same as those reported in the previous report. The averages fell within the normal processing range for producing satisfactory clinical images.

Given that the FDA's AB program promotes collaboration and cooperation, each 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.