WRITTEN STATEMENT FOR THE RECORD

BY

THE FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCOMMITTEE ON PUBLIC HEALTH
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

AND

SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION
COMMITTEE ON APPROPRIATIONS

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## INTRODUCTION

Madam Chairwoman, Mr. Chairman, Members of the Committees, thank you for giving the Food and Drug Administration (FDA or the Agency) this opportunity to present this statement for the record regarding Mammography Quality Standards Act (MQSA) of 1992.

## BACKGROUND

The MQSA of 1992 was enacted in response to serious concerns about the quality of mammography. This procedure is an aid in combating the mortality associated with the growing incidence of breast cancer. In spite of the current controversy about the studies showing the benefits of mammography screening and in the absence of consensus about the scientific issues, the Department of Health and Human Services (HHS) and FDA support the conclusion reached by the U.S. Preventive Services Task Force. High quality mammography continues to be the best available tool for the early detection of breast cancer and MQSA provides our best assurance of that quality.

Mammography can reveal cancerous lesions up to 2 years before a woman or her doctor can feel a lump, and is a significant contributor to the current 5-year survival rate of 86 percent. Mammography represents life-saving ammunition in the war on breast cancer which is the most common non-skin cancer and, after lung cancer, the second leading cause of cancer deaths among women.

To achieve these benefits, all elements of the mammography system must be of high quality. Mammography is a highly challenging radiographic examination of the breast. The equipment must be capable of producing quality images and be maintained and operated by

qualified individuals. Physicians who interpret these images must also be highly skilled. If the quality of mammography is poor, an incipient cancerous lesion may be missed. False negative diagnoses can delay early treatment and result in avoidable deaths. Poor quality mammography can also lead to false positive diagnoses, in which normal tissue is judged to be abnormal, resulting in needless anxiety for patients, costly additional testing, and unnecessary biopsies.

In the mid-1980s, indications of problems with the quality of mammography began to appear. Significant evidence came from a 1985 study known as the Nationwide Evaluation of X-ray Trends (NEXT), which was conducted by State radiation control agencies in cooperation with the FDA. Based on a survey of a representative national sample of mammography facilities, this study found that the image quality produced in perhaps as many as one-third of the facilities was less than desirable.

The findings from the NEXT study catalyzed efforts by the American College of Radiology (ACR), a private, non-profit association of radiologists, to create a voluntary mammography accreditation program. Begun in 1987, this program included an evaluation of the quality of clinical mammograms provided by facilities seeking accreditation. Although it is reasonable to surmise that facilities participating in this voluntary program were among the better facilities, ACR found that approximately 30 percent of the applicants failed on their first attempt to achieve accreditation.

Other evidence came from a 1990 General Accounting Office (GAO) study that reported that many mammography providers lacked adequate quality assurance programs. In 1992,

hearings held by the Senate Committee on Labor and Human Resources revealed a wide range of problems with mammography services in the United States. These problems included poor quality equipment, lack of quality assurance procedures, poorly trained facility personnel, and inconsistent governmental oversight. At the same time, several States instituted programs to ensure that their residents were being provided with high quality mammography.

Despite these efforts, no national standards for providing safe, reliable, and accurate mammography were in place for the over 25 million American women who undergo the procedure annually. To rectify this situation, Congress enacted the MQSA on October 27, 1992, to ensure uniform high standards for mammography facilities, their equipment and personnel, and the quality of their mammograms. This law required all mammography facilities be certified by the Federal government after October 1, 1994, except for those facilities operated by the Department of Veterans Affairs (DVA). A separate law mandating a similar program governs DVA facilities. Responsibility for implementing MQSA was delegated to FDA by the Secretary of HHS on June 2, 1993.

**IMPLEMENTATION**

Faced with the task of certifying approximately 10,000 mammography facilities in less than 2 years, FDA published interim regulations in December 1993, which became effective in February 1994. As a prerequisite to certification, facilities had to be accredited by an FDA-approved accreditation body, the first of which was ACR approved in March 1994. Subsequently, four States, Arkansas, California, Iowa, and Texas, achieved approval as accreditation bodies.

FDA successfully met its demanding statutory deadline of certifying all qualified mammography facilities by October 1, 1994. While the interim regulations were in effect, FDA developed more exacting regulations, and the MQSA final regulations were published in October 1997, and became effective on April 28, 1999.

Another hurdle was obtaining qualified personnel to annually inspect the nearly 10,000 mammography facilities. FDA developed special training courses for both FDA and State personnel, and trained and eventually deployed 250 inspectors to conduct annual facility inspections. These inspections began in January 1995. During this time, FDA implemented the Mammography Program Reporting and Information System (MPRIS), a dynamic, interactive data system, designed to tie the pieces of the program together. MPRIS provides and tracks information on accreditation and certification of facilities, facility inspections, inspection violations, and the billing of inspection fees. MPRIS also allows inspectors to use uniform software on a laptop computer while in the field, and to directly upload inspection results to the headquarters database, thus streamlining the inspection process and facilitating data analysis. In addition, the database transmits daily certification information to the Centers for Medicare and Medicaid Services, thereby facilitating efficient facility reimbursement, and allowing consumers to search for certified mammography facilities by zip code.

In order to educate facilities about the regulations and how to comply with them, FDA published a quarterly newsletter that was mailed to facilities and other interested parties. The printed newsletter eventually evolved into web page updates and articles on matters of

importance to facilities. A mammography website (www.fda.gov/cdrh/mammography) was created, a principal component of which is an extensive policy guidance help system.

**DEVELOPING PROGRAMS**

MQSA allowed States that desired to do so to take on the role of a certifying body, with FDA approval and oversight. In August 1998, the States as Certifiers (SAC) pilot was initiated with two participating States. During this time, regulations were promulgated and published in February 2002. These regulations will become effective in May 2002. Several additional States have expressed interest in the SAC program, and FDA expects this program to expand.

**PROGRAM COMPLIANCE**

Compliance with the final regulations continues to improve. Currently, 60 percent of all certified facilities are in total compliance with MQSA. The Government Performance Results Act goal for most serious violations is less than 3 percent. At this time, only 2.4 percent of facilities are exceeding the goal. This exemplary compliance rate can in large part be attributed to the program's extensive outreach efforts, including facility education by inspectors, and the availability, both on the web and in hard copy, of all guidance and policy determinations.

**PROGRAM ASSESSMENT**

In 1995 and 1997, the GAO evaluated aspects of the MQSA program. These favorable reports found that the initial impact of the new Federal law had been positive, while the report that looked at mammography inspections found that facility compliance was continuing to improve.

FDA performed facility satisfaction surveys under both the interim and the final regulations to review how facilities perceive the inspection process and the program's educational and guidance materials. Based on these results, it is clear that the vast majority of facilities see the MQSA inspection program as beneficial, particularly the educational approach of the inspectors that helps facilities identify areas for improvement.

FDA continues to fine-tune the MQSA program to better serve the mammography community, leading to higher quality care for the women of America.

**REAUTHORIZATION**

MQSA was reauthorized in October 1998, with the enactment of the Mammography Quality Standards Reauthorization Act (MQSRA). MQSRA mandated that patients be directly notified of their mammogram results, in lay language. The regulations were amended to reflect this mandate. Facilities quickly complied, and currently, there are almost no inspection violations in this area. In addition, a study published in the February 2002 American Journal of Roentgenology surveyed patients before and after this requirement went into effect. The study found that there was a substantial increase in the number of patients who reported timely receipt of mammography results, and a substantial decrease in patients dissatisfied with their results, all without an appreciable increase in patient anxiety.

Congress also requested FDA to determine if best-performing mammography facilities can maintain their high standards without the scrutiny of annual inspections. With input from the conference of Radiation Control Program Directors, FDA designed a demonstration program whereby citation-free facilities from States who agreed to participate were randomly assigned

to study and control groups. Those study group participants would begin skipping their next annual inspection, beginning in May 2002. After data collection is completed in the summer of 2004, data analysis will be performed and a report will be presented to Congress in mid-2005.

Reauthorization of the appropriations authority for the Certification of Mammography Facilities would allow the Federal government to continue to ensure that all mammography facilities provide high quality mammograms as an aid in the early detection of breast cancer.

**CONCLUSION**

FDA has successfully implemented the MQSA program and has improved the overall quality of mammography by constructing and implementing an effective program that holds all providers of mammography to the same standard. The MQSA program in an invaluable tool in promoting public health and merits reauthorization.