



An Effective Defense Against Breast Cancer: FDA's Mammography Quality Standards Program

Mammography is the best method for detecting breast cancer in its earliest stages, when the disease is most successfully treated and there are more treatment options. Good mammograms—images provided by well-maintained equipment and interpreted by well-trained professionals—can help detect 85 percent to 90 percent of breast cancers and can identify a tumor up to two years before a lump can be felt.

Today, American women can be sure that their mammograms are of the highest quality thanks to the Food and Drug Administration's successful implementation of the Mammography Quality Standards Act (MQSA) of 1992. Under this law, all of the over 9,100 mammography facilities in the United States and its territories are required to be certified, inspected each year, and meet the stringent standards that are a prerequisite for top-notch, reliable mammograms.

Here are some of the requirements that the facilities must meet in order to stay in business:

- All **technologists who perform mammography** must be adequately trained and qualified to operate the mammography equipment, and must maintain

their skills by performing an average of 200 mammograms every two years.

- All **physicians** who interpret mammograms must meet specific initial and continuing training, education, and experience requirements, including interpreting at least 960 mammograms every two years.

- Mammography **equipment** must be of appropriate design and meet certain performance characteristics, which are

checked yearly at the time of inspection.

- The mammographic **images** must meet high standards of quality for a facility to initially become accredited and certified, and must be reviewed by an accrediting body every three years.

- Women and their physicians must be **promptly and fully informed in writing** of the mammography results so that any follow-up tests or treatment can begin in a timely manner.

To make certain that the program brings the nation's women maximum benefits, the FDA publishes a brochure for consumers: *Mammography Today*, which explains patients' rights under the MQSA. Together with the National Institutes of Health, the FDA also posts the addresses of all certified mammography facilities on the Internet at www.fda.gov/cdrh/mammography/certified.html and makes them available through the Cancer Information Service hotline, (800) 4-CANCER (800-422-6237).

For more information, refer to the FDA's MQSA Web site, www.fda.gov/cdrh/mammography.

Mammography Inspections

To ensure compliance with the MQSA standards, the FDA trains its own and state inspectors who perform the annual inspections of all mammography facilities. The inspectors determine the radiation dose used by each facility; assess the image quality using a special device that simulates the breast; evaluate the quality of the facility's film processing; and review the facility's medical reports, medical audits, and quality assurance and control records. In addition, each facility's darkroom is tested for unsafe light levels that may affect image quality. The program increased the number of facilities that met the image quality standards from 76 percent in 1994 to 99 percent in 2003.