MAMMOGRAPHY FACILITY PERFORMANCE FOR CALENDAR YEAR 1995

Quality mammography saves lives. Mammography is a low-dose x ray of the breast to detect small tumors and breast abnormalities. It provides the best means of early detection of breast cancer, the second leading cause of cancer deaths among American women. Studies indicate that widespread use of mammography, especially among women aged 50 to 74, could reduce deaths from this disease by one-third.

The enactment of the Mammography Quality Standards Act of 1992 (MQSA) by the Congress marked the first time that mammography facilities were required by the Federal Government to meet uniform, baseline mammography requirements aimed at strengthening mammography quality. Working in partnership with State, federal, and private organizations, the Food and Drug Administration (FDA) has implemented these requirements. A major focus of the MQSA program is to monitor the performance of each facility in meeting standards for personnel, equipment, quality control, and recordkeeping. Each facility must be accredited by an FDA-approved accreditation body, be FDA-certified, and undergo a yearly inspection.

As required by MQSA, the FDA is providing this first annual report for calendar year 1995, which includes information that is useful in evaluating the performance of mammography facilities. MQSA specifically requires the report to include a listing of facilities that had adverse actions taken against them. In addition to the listing, this report provides physicians and the general public with background information on MQSA and quality mammography standards of performance in an effort to assist in the interpretation of the data compiled below. This report also provides directions for acquiring a list of FDA-certified facilities.

MQSA Standards Yield Immediate Improvements in Mammography Quality

The General Accounting Office (GAO), Congress' oversight body, summarized early results of MQSA by reporting:

> *Early indications are that MQSA has had a positive effect on the quality of mammography services....the standards are having more than a symbolic effect, because in order to become fully certified, many facilities have improved their practices."* [1]

In addition, the GAO report concluded that, although a small number of facilities have voluntarily ceased mammography services rather than correct problems, early indications show no significant adverse impact on women's access to mammography services.

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[1]Mammography Services: Initial Impact of New Federal Law Has Been Positive (GAO/HEHS-96-17, Oct. 27, 1995)

First-Year Inspection Results

Results from the first round of annual MQSA inspections conducted in 1995 show that the vast majority of the 9,510 fully-certified facilities inspected have made great efforts to comply with the new standards. Problems found during inspections are categorized into three groups, with Level 1 being the most serious and Level 3 being minor. The data show that:

- Thirty percent of inspected facilities had perfect inspection results, having avoided even minor problems;

- Fewer than 3 percent of inspected facilities had serious problems.

Second-Year Compared to First-Year Inspections

By August 27, 1996, 9,510 of the 10,000 fully certified facilities had been inspected at least once, with 2,719 fully-certified facilities having completed their second yearly MQSA inspection. As compared to the first round of inspections, the data from the second round of inspections for just these 2,719 fully-certified facilities show that:

- Fifty-four percent of the facilities inspected had perfect inspection results.

- The average number of problems for these facilities decreased from 4 percent to 2.5.

- The number of serious findings for the 2,719 facilities inspected through August, 1996, dropped from 5 percent for that group in the first year to less than 1 percent.

- No facility was found to have repeated a specific serious finding identified in the first year.

Facilities Against Which Adverse Actions Were Taken in Calendar Year 1995

The following summarizes the performance of all FDA fully-certified facilities:

- None was convicted under federal or State laws relating to fraud and abuse, false billings, or kickbacks.

- None was subject to sanctions (such as civil money penalties) under subsection (h) of the MQSA, 42 U.S.C. 263b(h).

- None had its FDA certificate revoked or suspended.

- None was subject to injunctions or restraining orders.

- None had its accreditation revoked.

- Four States reported that they took adverse actions against facilities.

MQSA does not preclude a State from having stricter mammography requirements. In States that have additional requirements, facilities are required to comply with State laws, as well as MQSA regulations, in order to operate lawfully.

In the following list, several facilities are cited by States for operating either without an MQSA certificate or with an expired MQSA certificate. Any actions that FDA may have initiated in 1995 with respect to these citations are still pending.

CALIFORNIA

- **Knohl, Howard R. MD, Incorporated**
  280 Hospital Circle, #103
  Westminster, CA 92683
  FDA# 190868

  Adverse action: Mammography services discontinued until compliance achieved.

  Reason: Equipment problems.

  Date of inspection/adverse action: 11/28/95

  Date of corrective action/reinstatement: 12/27/95

  Status of facility: Performing mammography.

- **Torrance Memorial Breast Diagnostic Center**
  3275 Skypark Drive
  Torrance, CA 90508
  FDA# 143545

  Adverse action: Mammography services discontinued until compliance achieved.

  Reason: Equipment problems.

  Date of inspection/adverse action: 10/31/95

  Date of corrective action/reinstatement: 11/1/95

  Status of facility: Performing mammography.

- **Bellwood Imaging Center Medical Group**
  10230 Artesia Boulevard, #310
  Bellflower, CA 90706
  FDA# 154914

  Adverse action: Mammography services discontinued until compliance achieved.

  Reason: Radiation dose exceeded California limit.

  Date of inspection/adverse action: 10/26/95

  Date of corrective action/reinstatement: 10/29/95

  Status of facility: Performing mammography.

- **Womankind - A Medical Group**
  3200 Park Center Drive, #120
  Costa Mesa, CA 92626
  FDA# 206573

  Adverse action: Mammography services discontinued until compliance achieved.

  Reason: Radiation dose exceeded California limit.

  Date of inspection: 4/24/95 Adverse action: 5/4/95

  Date of corrective action/reinstatement: 5/18/95

  Status of facility: Performing mammography.

- **Centro Medico Universal**
  3411 East Tweedy Boulevard
  South Gate, CA 90280
  FDA# 204396

  Adverse action: Physician violated agreement to cease performing mammography.

  Reason: Lacked certification, quality assurance program, and current physicist report; equipment, personnel, and reporting problems.

  Date of inspection/adverse action: Notice given on 2/7/95

  Date of corrective action/reinstatement: None, because facility closed.

  Status of facility: Closed.

- **Diagnostic Imaging Medical Group of Kent**
  711 North Alvarado Street
  Los Angeles, CA 90026
  FDA# 204420

  Adverse action: Mammography services discontinued until compliance achieved.

  Reason: Physicist report not performed within required time frame.

  Date of inspection/adverse action: 1/11/95

  Date of corrective action/reinstatement: 1/95

  Status of facility: Facility ceased performing mammography services on 8/29/96.

- **Japan International Medical Clinic**
  360 East 2nd Street, #101
  Los Angeles, CA 90012
  FDA# 204446

  Adverse action: Mammography operations discontinued until compliance achieved.

  Reason: Operating without MQSA certification. Also lacked: a physicist report, standing orders for exams, repeat policy, biannual review by supervising physician, complete quality control program.

  Date of inspection/adverse action: 9/21/95

  Date of corrective action/reinstatement: 3/7/96

  Status of facility: Facility ceased performing mammography services on 7/9/96.

- **Community Hospital of Santa Rosa**
  3325 Chanate Road
  Santa Rosa, CA 95404
  FDA# 173633

  Adverse action: Mammography discontinued until compliance achieved.

  Reason: Unqualified personnel.

  Date of inspection/adverse action: 5/22/95

  Date of corrective action/reinstatement: 6/8/95

  Status of facility: Performing mammography.

- **Thelma L. Chisholm, MD, South Figueroa Radiology**
  5260 S. Figueroa Street, #106
  Los Angeles, CA 90037
  FDA# 197392

  Adverse action: Mammography services discontinued until compliance achieved.

  Reason: Mammography machine not registered with the State of California; operating with expired FDA certificate from 6/29/95 to 11/12/95.

  Date of inspection/adverse action: 11/12/95

  Date of corrective action/reinstatement: 11/13/95

  Status of facility: Performing mammography.

- **Sutter North Medical Foundation**
  251 Cohasset Road
  Chico, CA 95926
  FDA# 106518

  Adverse action: Radiologic technologist prohibited from conducting mammographic exams.

  Reason: California Radiologic Technologist Mammography Certification not documented.

  Date of inspection/adverse action: 5/17/95

  Date of corrective action/reinstatement: 5/18/95

  Status of facility: Performing mammography.

MISSOURI

- **Olive Family Medical Center**
  9352 Olive Boulevard
  St. Louis, MO 63132
  FDA# 169193

  Adverse action: Revocation of State license; notification/recall of 521 patients.

  Reason: Unqualified staff, inadequate equipment, and poor quality exams.

  Date of inspection/adverse action: 6/1/95 - withdrawal.

  Date of corrective action: Recall of all patients completed 10/25/95.

  Status of facility: No longer performing mammography.

NEW JERSEY

- **Allwood Imaging Corporation**
  335 Broad Street
  Clifton, NJ 07013
  FDA# 205450

  Adverse action: Notice of Prosecution; paid a $2,500 penalty.

  Reason: No quality assurance program.

  Date of inspection/adverse action: 1/24/95

  Date of corrective action/reinstatement: 3/27/95

  Status of facility: Performing mammography.

TEXAS

- **The Women's Hospital of Texas**
  Dba Houston Imaging Center
  7000 Fannin, Suite M-50
  Houston, TX 77054
  FDA# 204057

  Adverse action: Emergency Cease and Desist Order.

  Reason: Performing mammography services without State authorization; inadequate quality control.

  Date of inspection/adverse action: 2/22/95 (Posted in the Texas Register on 3/7/95)

  Date of corrective action/reinstatement: 3/14/95 (Posted in the Texas Register on 3/24/95)

  Status of facility: Performing mammography.

- **Angelo Clinic Association**
  120 East Beauregard
  San Angelo, TX 76902
  FDA# 168641

  Adverse action: Emergency Cease and Desist Order

  Reason: Initiated mammographic screening program without prior approval from Texas Department of Health; unqualified personnel.

  Date of inspection/adverse action: 3/14/95 (Posted in the Texas Register on 3/24/95)

  Date of corrective action/reinstatement: 4/13/95 (Posted in the Texas Register on 5/9/95)

Status of facility: Performing mammography.

- **Doctor's Office Center Medical Group of Houston, P.A.**
  Dba University Medical Group
  1806 Southgate, 2nd Floor
  Houston, TX 77030
  FDA# 200121

  Adverse action: Emergency Cease and Desist Order.

  Reason: Failure to meet quality control/quality assurance and equipment requirements.

  Date of inspection/adverse action: 4/10/95 (Posted in the Texas Register on 5/ 9/95)

  Date of corrective action/reinstatement: 4/28/95 (Posted in the Texas Register on 5/12/95)

  Status of facility: Performing mammography.

- **Memorial Hospital Southwest**
  7600 Beechnut
  Houston, TX 77074
  FDA# 202788

  Adverse action: Emergency Cease and Desist Order.

  Reason: Inadequate quality control program.

  Date of inspection/adverse action: 4/10/95 (Posted in the Texas Register on 5/9/95)

  Date of corrective action/reinstatement: 5/2/95 (Posted in the Texas Register on 5/23/95)

  Status of facility: Performing mammography.

- **RHD Memorial Medical Center**
  7 Medical Parkway
  Dallas, TX 75230
  FDA # 173138

  Adverse action: Emergency Cease and Desist Order.

  Reason: Performing mammography screening examinations without authorization from the Texas Department of Health.

  Date of inspection/adverse action: 4/10/95 (Posted in the Texas Register on 5/9/95)

  Date of corrective action/reinstatement: 4/18/95 (Posted in the Texas Register on 5/9/95)

  Status of facility: Performing mammography.

- **Lake Pointe Medical Center**
  6800 Scenic Drive
  Rowlett, TX 75088-1550
  FDA# 119891

  Adverse action: Enforcement conference.

  Reason: Failure to perform equipment tests; failed to meet darkroom cleanliness standards; failed to have adequate technique chart or manual.

  Date of inspection/adverse action: 5/25/95

  Date of corrective action/reinstatement: Not applicable. (Attended Enforcement Conference and submitted written documentation indicating that all violations had been adequately corrected.)

  Status of facility: Performing mammography.

- **Colorado Fayette Medical Center**
  400 Youens Drive
  Weimar, TX 78962
  FDA# 179556

  Adverse action: Emergency Cease and Desist Order.

  Reason: Unqualified personnel; not authorized by State to perform mammography; inadequate quality control program.

  Date of inspection/adverse action: 6/13/95 (Posted in the Texas Register on 6/30/95)

  Date of corrective action/reinstatement: 7/7/95 (Posted in the Texas Register on 7/28/95)

  Status of facility: Performing mammography.

- **Austin Regional Clinic, P.A.**
  6835 Austin Center Boulevard
  Austin, TX 78731
  FDA# 101998

  Adverse action: Emergency Cease and Desist Order.

  Reason: Failed to document and implement an adequate quality assurance program; failure to cease mammography services when the analysis of quality control tests indicated regulatory limits were exceeded.

  Date of inspection/adverse action: 6/20/95 (Posted in the Texas Register on 7/11/95)

  Date of corrective action/reinstatement: 7/11/95 (Posted in the Texas Register on 7/28/95)

  Status of facility: Performing mammography.

- **Rodelka Incorporated**
  3 Ted Hunt Boulevard, Suite 110
  Brownsville, TX 78521
  FDA# 198648

  Adverse action: Emergency Cease and Desist Order.

  Reason: Inadequate quality assurance program and quality control violations.

  Date of inspection/adverse action: 7/25/95 (Posted in the Texas Register on 8/8/95)

  Date of corrective action/reinstatement: 10/19/95 (Posted in the Texas Register on 11/7/95)

  Status of facility: Performing mammography.

- **Capital Imaging Centers**
  4207 James Casey, Suite 111
  Austin, TX 78745
  FDA# 105452

  Adverse action: Emergency Cease and Desist Order.

  Reason: Failure to implement adequate quality assurance program.

  Date of inspection/adverse action: 9/6/95 (Never posted in the Texas Register)

  Date of corrective action/reinstatement: 9/13/95 (Posted in the Texas Register on 10/3/95)

  Status of facility: Performing mammography.

- **Austin Diagnostic Medical Center**
  12221 Mopac Expressway North
  Austin, TX 78708-5075
  FDA# 101931

  Adverse action: Emergency Cease and Desist Order.

  Reason: Failed to implement an adequate quality assurance program.

  Date of inspection/adverse action: 12/1/95 (Posted in the Texas Register on 12/15/95)

  Date of corrective action/reinstatement: 12/4/95 (Posted in the Texas Register on 12/15/95)

  Status of facility: Performing mammography.

- **Del Mar Clinic, Inc.**
  607 East Rio Grande
  Eagle Pass, TX 78852
  FDA# 174797

  Adverse action: Emergency Cease and Desist Order.

  Reason: Equipment not certified; inadequate quality control; unqualified radiologic technologist.

  Date of inspection/adverse action: 6/6/95 (Posted in the Texas Register on 6/20/95)

  Date of corrective action/reinstatement: 7/19/95 (Posted in the Texas Register on 8/4/95)

  Status of facility: Performing mammography.

- **Memorial Hospital and Medical Center**
  2200 West Illinois
  Midland, TX 79701-6499
  FDA# 164681

  Adverse action: Emergency Cease and Desist Order.

  Reason: Failure to implement a quality control program.

  Date of inspection/adverse action: 10/13/95 (Posted in the Texas Register on 10/24/95)

  Date of corrective action/reinstatement: 1/5/96 (Posted in the Texas Register on 1/19/96)

  Status of facility: Performing mammography. File open as of 9/18/96, pending reinspection results.

How to Find an FDA-Certified Facility

To operate legally, a mammography facility must have and prominently display an FDA-certificate. This certificate shows that the facility is meeting the baseline standards under MQSA. Consumers and health professionals can locate FDA-certified facilities in their geographical area by calling the Cancer Information Service at 1-800-4CANCER (1-800-422-6237). Information Specialists at this number have been trained to answer questions on mammography. Written information on mammography is also available on request.

For a computer diskette containing a complete list of FDA-certified facilities, contact the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161. The diskette, sold either as a subscription (updated quarterly) or a single issue (most recent update), includes each certified facility's name, address, phone number, and accreditation body. The phone number for NTIS subscriptions is 703-487-4630; the fax number is 302-321-9467. To order a single issue, call 703-498-4650 or send a fax to

703-321-8547. The U.S. price for 4 diskettes is $195; a single issue is $55. **Be sure to designate subscription or single issue and cite the NTIS order number SUB-5386.**