DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 1, 1997

Dear Mammography Quality Advocate:

Because of your expressed interest in mammography, the Food and Drug Administration (FDA) is sending you the enclosed document, ***Mammography Facility Performance for Calendar Year 1996,*** which was mandated by Congress in the Mammography Quality Standards Act (MQSA) of 1992. The purpose of the report is to assist health professionals and consumers in evaluating the performance of mammography facilities. In the future, we will continue to send you annual reports as they are published. We encourage you to make this information available to your constituents, especially physicians and the general public, and to announce the report's availability in your organization's publication.

The report includes the following:

- background information;
- a list of mammography facilities against which adverse actions were taken in 1996; and
- directions for obtaining a list of FDA-certified facilities in one's locale.

You may also find this report, along with other MQSA-related documents, on the MQSA Internet home page, located at http://www.fda.gov/cdrh/index.html. Click your mouse on the icons for "Program Areas" and "Mammography Quality and Radiation Programs." You will then be presented with a list of documents to view. To read these documents -- those labeled "PDF Format" -- you'll need Acrobat Reader. To access Acrobat, click on "PDF Reader" in the introduction of the Mammography Quality and Radiation Programs home page, and then click on "Instructions."

If you have any questions regarding this report, send them to Pat Hoage, 1350 Piccard Drive, Rockville, Maryland 20850, or by fax at 301-594-3306.

Sincerely yours,

Florence Houn

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MAMMOGRAPHY FACILITY PERFORMANCE FOR CALENDAR YEAR 1996

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 second annual report for calendar year 1996. The report 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, as required by the Act, this report includes those State adverse actions that are comparable to FDA actions. In an effort to assist in the interpretation of the data compiled below, it also provides physicians and the general public with background information on MQSA, quality mammography standards of performance, and directions for acquiring a list of FDA-certified facilities.

MQSA Standards Yielded 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....these standards are having more than a symbolic effect, because in order to become fully certified, many facilities have had to improve 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.
A year later, GAO noted the reduction in facility violations:

> *. . . second-year inspections have shown a considerable reduction in the proportion of facilities cited for violations--an indication that the inspection process is having positive results.*[2]

First-Year Inspection Results

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

[2] FDA's Mammography Inspections: While Some Problems Need Attention, Facility Compliance Is Growing (GAO/HEHS-97-25, Jan. 27, 1997).

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

Third-Year Results Show Continued Improvement in Compliance

By August 30, 1997, 10,136 facilities had been inspected at least once, with 2,707 fully-certified facilities having completed their third yearly MQSA inspection. As compared to the first round of inspections, the data from the third round of inspections for just these 2,707 fully-certified facilities show that:

- Sixty percent of the facilities inspected had perfect inspection results.

- The number of serious findings for the 2,707 facilities inspected through August 1997, 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 1996

- The Health Care Financing Administration reported that the Mt. Graham Medical Imaging facility (FDA #186759), 1620 20th Avenue, Safford, Arizona, was convicted and excluded from the Medicare program in 1996 for charges ranging from falsifying information on applications to billing for procedures not performed. No other facility was convicted under federal or State laws relating to fraud and abuse, false billings, or kickbacks.

- Mobile Diagnostics Services, Inc. (FDA #186635), 1303 Carolina Street, Greensboro, NC 27401, was issued a sanction by FDA in the form of a directed plan of correction on March 19, 1996, under subsection (h) of the MQSA, 42 U.S.C. 263b(h). Specifically, the non-compliances relate to image quality and quality control problems. This facility voluntarily is no longer performing mammography.

- The American College of Radiology reported **revoking the accreditation** of the following facilities:

Downey Breast Diagnostic Clinic
8301 Florence Avenue, Suite 101
Downey, CA 90240
Adverse action: FDA suspended the certificate without a hearing.
FDA #168062
Date of action: 9/20/96
Reason: No response to random film check request.
Current status: Deficiencies corrected. Reinstated by the State of California Accreditation Body.

Lamar Regional Hospital
507 5th Street, SW
Vernon, AL 35592
Adverse action: FDA supported the action taken by the accreditation body.
FDA #203273
Date of Action: 8/26/96
Reason: No response to random film check request.
Current status: Not performing mammography.

- The Accreditation Bodies of the States of Arkansas, California, and Iowa reported no accreditation revocations.

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

FDA polled the States and U.S. Territories and received numerous adverse event reports taken under their legislation. The Agency elected to include in this listing only those cases that compare to the severity levels identified by sanctions under MQSA. Those state action reports follow.

CALIFORNIA

- Central Medical Center
  214 North Central Avenue
  Glendale, CA 91203
  Facility ID # 201962

  Adverse action: Facility licence suspension.

  Reason for action: Equipment testing, radiation dose; lack of MQSA certification.

  Corrective action: Facility closed.

  Date of inspection/adverse action: 4/26/96

  Date of corrective action/reinstatement: N/A

  Status of facility: Not performing mammography.

MISSOURI

- Madison Medical
  100 South Wood at West College
  Frederick Town, MO 63645
  Facility ID # 178285

  Adverse action: Facility licence revocation.

  Reason for action: Quality control program.

  Corrective action: Restarted Quality Assurance program; recalled patients. Facility was reauthorized by the State.

  Date of inspection/adverse action: 6/20/96

  Date of corrective action/reinstatement: 8/15/96

  Status of facility: Performing mammography.

- Samaritan Memorial Hospital
  1205 North Mission
  Macon, MO 63552
  Facility ID # 199182

  Adverse action: Facility licence revocation.

  Reason for action: Quality control program.

  Corrective action: Began Quality Assurance program; replaced the tech responsible for falsification of reports; recalled patients. Facility was re-authorized by the State.

  Date of inspection/adverse action: 5/25/96

  Date of corrective action/reinstatement: 2/10/97

  Status of facility: Performing mammography.

NEVADA

- Advanced Diagnostic Medical Imaging
  3830 Meadow Lane
  Las Vegas, NV 89107
  Facility ID # 212787

  Adverse action: Fines/penalties.

  Reason for action: Lack of State authorization.

  Corrective action: Facility obtained proper State credential.

  Date of inspection/adverse action: 7/17/96

  Date of corrective action/reinstatement: 2/12/97

  Status of facility: Performing mammography.

TEXAS

- Amarillo Family Physicians Clinic, PA
  6842 Plum Creek Drive
  Amarillo, TX 79124
  Facility ID # 177824

  Adverse action: Other (Emergency and Desist Order).

  Reason for action: Personnel qualifications; other (facility was performing mammography without a Radiation Safety Officer).

  Corrective action: Technician who was performing mammography no longer works for this facility. No further actions taken to date.

  Date of inspection/adverse action: 9/17/96

  Date of corrective action/reinstatement: Not reinstated as of July 1997.

  Status of facility: Not performing mammography.

- Bee County Regional Medical Center
  1500 East Houston
  Beeville, TX 78102
  Facility ID # 198069

  Adverse action: Other (Emergency Cease and Desist Order).

  Reason for action: Equipment testing, phantom; quality control program.

  Corrective action: Attended Enforcement Conference and submitted written documentation. Facility was reinspected prior to Conference.

  Date of inspection/adverse action: 4/26/96 (Posted in *Texas Register* 5/17/96)

  Date of corrective action/reinstatement: 5/21/96 (Posted in *Texas Register* 7/2/96)

  Status of facility: Performing mammography.

- Corpus Christie Radiology Center
  1621 South Brownlee
  Corpus Christi, TX 78404
  Facility ID # 181198

  Adverse action: Other (Emergency Cease and Desist Order).

  Reason for action: Equipment testing, phantom; quality control program.

  Corrective action: Attended Enforcement Conference and submitted written documentation. Facility required to conduct patient notification to begin in 30 days and be completed in 90 days. A reinspection was conducted.

  Date of inspection/adverse action: 4/3/96 (Posted in the *Texas Register* 4/23/96)

  Date of corrective action/reinstatement: 4/26/96 (Posted in the *Texas Register* 5/14/96)

  Status of facility: Performing mammography.

- Corpus Christi Radiology Center
  3554 South Alameda
  Corpus Christi, TX 78411
  Facility ID # 168609

  Adverse action: Other (Emergency Cease and Desist Order).

  Reason for action: Equipment testing, phantom; quality control program.

  Corrective action: Attended Enforcement Conference and submitted written documentation. Facility required to conduct patient notification to begin in 30 days and be completed in 90 days. A reinspection was conducted.

  Date of inspection/adverse action: 4/3/96 (Posted in the *Texas Register* 4/23/96)

  Date of corrective action/reinstatement: 4/26/96 (Posted in the *Texas Register* 5/14/96)

  Status of facility: Performing mammography.

How to Find an FDA-Certified Facility

Cancer Information Service. 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 1-800-4-CANCER (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.

Internet. The MQSA Internet home page (http://www.fda.gov/cdrh/dmqrp.html) provides a listing of all FDA-certified mammography facilities by selected state (or territory) and zip code.

National Technical Information Service. For a computer diskette containing a complete list of all FDA-certified facilities, contact:

The National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The list is available for a fee on 3 1/2" DOS diskettes in ASCII format.

- To order a single disk, call 1-703-487-4650. The NTIS order number is SUB-5386/Code D01.

- To order a 1-year subscription of the list, updated quarterly, call 1-703-487-4630. The NTIS order number is SUB-5386.