

FDA FACT SHEET

MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) CONTRACT PROGRAM

Program Description

- The Mammography Quality Standards Act (MQSA) was signed into law in 1992.
- The Act authorizes FDA to obtain state, local, and territorial assistance in enforcing the MQSA requirements including annual inspections of all certified facilities.
- As part of the Mammography Quality Standards Act (MQSA), Congress mandated annual reporting of adverse actions taken against mammography facilities. Congress stipulated that the report be made available to physicians and the general public and that it should include information that is useful in evaluating the performance of mammography facilities nationwide.

Intended Outcomes

- To obtain state and local assistance in the inspection of certified non-federal mammography facilities.
- To document compliance with the mammography quality standards issued under 21 CFR Part 900.
- To ensure facilities that fail accreditation cease providing mammography services.
- To require all facilities have a system in place to address and resolve complaints.
- To ensure women receive high quality mammography for early breast cancer detection by requiring the establishment of a federal certification and inspection program.

Program Metrics

- Current program funding: \$9.72M
- Current number of awards: 43
- Total contracted Inspections: 6,843

Success Story

- FDA New Jersey District Office (NWJ-DO)
 - State of NJ conducted a contract MQSA inspection at a radiological firm.
 - Inspection resulted in multiple Level 2 findings.
 - NWJ-DO issued a Warning Letter on 01/28/2014.
 - Ultimately, America College of Radiology (ACR) revoked certification of the firm.

Figure 1. MQSA Contract States (2016-2017)

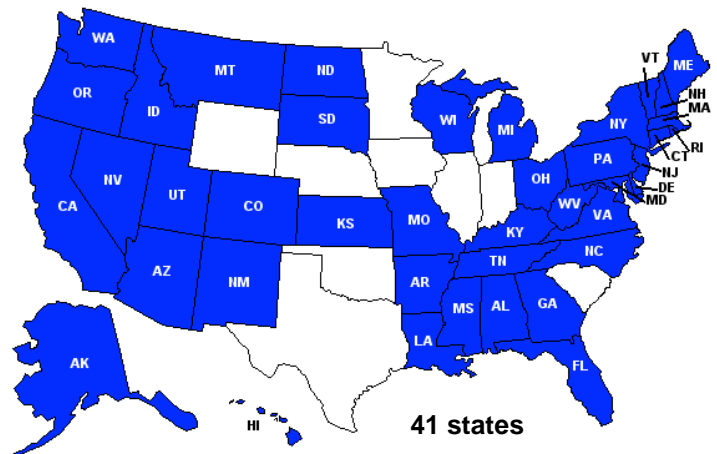
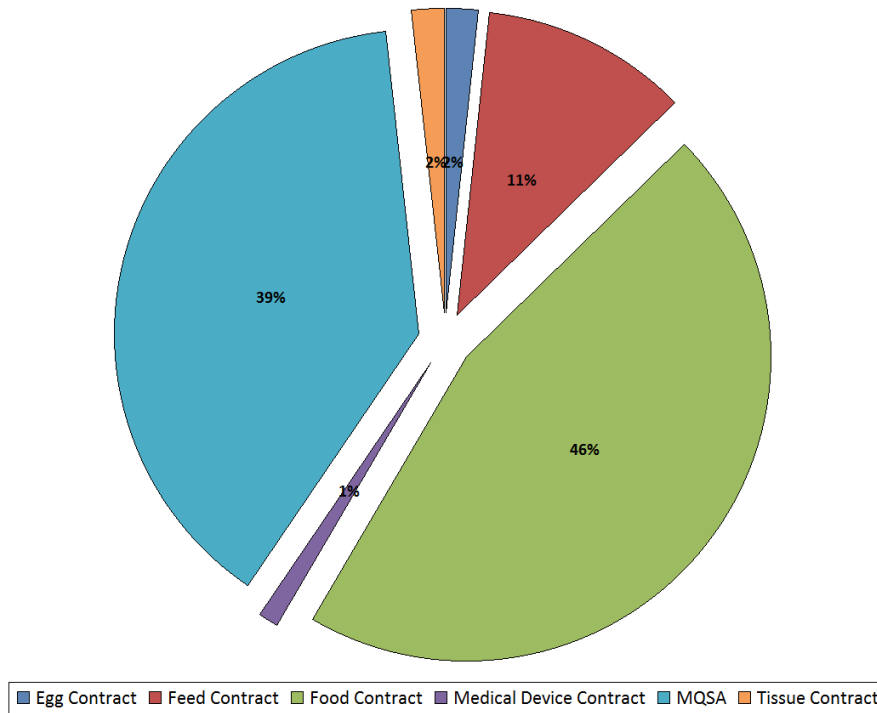


Figure 2. Pie Chart showing the MQSA Contract Program’s budget in relation to the budgets of all other FDA Office of Partnerships administered state contracts (2016-2017)



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