

SMG 1257.6

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

OFFICE OF IN VITRO DIAGNOSTICS AND RADIOLOGICAL HEALTH

DIVISION OF MAMMOGRAPHY QUALITY STANDARDS

Effective Date: 09/25/2012

1. DIVISION OF MAMMOGRAPHY QUALITY STANDARDS (DKKWJF).

- A. Develops, revises, and interprets standards and regulations for mammography facilities and their equipment, personnel and procedures, as well as for organizations approved to accredit mammography facilities, with the assistance of the National Mammography Quality Assurance Advisory Committee.
- B. Approves and maintains oversight of bodies that accredit mammography facilities and states that certify mammography facilities under the Mammography Quality Standards Act; establishes and maintains a system for the periodic certification and annual inspection of all mammography facilities; and develops and implements enforcement processes and procedures for facilities found to be out of compliance with the requirements of the Mammography Quality Standards Act.
- C. Establishes and maintains a program for the training, certification, and continuing education of Federal and State mammography facility inspectors.
- D. Develops and maintains mechanisms for ongoing liaison and routine communication with Federal, State and local government agencies, with relevant health professional and consumer groups, and with all certified mammography facilities about issues related to the Mammography Quality Standards Act and provides appropriate reports on the Mammography Quality Standards Act to the Department, Congress, and the public.

2. PROGRAM MANAGEMENT BRANCH (DKKWJF1).

- A. Serve as the national focal point for the implementation of the Mammography Quality Standards Act in regards to planning, education, communication, guidance, and enforcement. This is accomplished through national collaborative effort that includes other federal agencies, state regulatory agencies, and third party regulatory entities.
- B. Maintains oversight of bodies that accredit mammography facilities and states that certify mammography facilities under the Mammography Quality Standards Act; develops and maintains mechanisms for ongoing communication with relevant health professional and consumer groups, and with all certified mammography facilities about issues related to the Mammography Quality Standards Act; provides appropriate reports to the Department, Congress, and the public. Monitors, integrates, and regulates emerging technologies in mammography.
- C. Establishes and maintains national work plan for the annual inspection of all mammography facilities; develops and implements enforcement processes and procedures for facilities found to be out of compliance with the requirements of the Mammography Quality Standards Act; develops and maintains mechanisms for ongoing liaison and routine communication with Federal and State government agencies regarding the inspections and compliance programs; provides oversight and monitoring of inspection contract fulfillment; establishes and maintains a program for the training, certification, and continuing education of Federal and State mammography facility inspectors; develops, revises, and interprets standards and regulations for mammography facilities and their equipment, personnel and procedures, as well as for accreditation bodies; develops, disseminates, and maintains the policies, procedures and instructions for the performance of annual Mammography Quality Standards Act facility inspections; develops and maintains the compliance guide for Mammography Quality Standards Act compliance activities; provides Mammography Quality Standards Act compliance case management.

3. INFORMATION MANAGEMENT BRANCH (DKKWJF2).

- A. Operates as a matrix organization to provide information technology and support services to all aspects of the Mammography Quality Standards Act program, including the design, development, and maintenance of the Mammography Program Reporting and Information System and its components; develops and maintains the systems used for the periodic certification, annual inspection, and compliance of all mammography facilities; ensures the overall quality, reliability, integrity, and accessibility of facility certification, inspection, and compliance data; works with

Division senior staff and the Program Management Branch to create and disseminate reports on the Mammography Quality Standards Act to the Department, Congress, and the public.

- B. The Quality Assurance Team identifies, analyzes, documents, traces, and prioritizes system and infrastructure requirements; provides data and system analyses; ensures data quality; provides database administration; provides Help Desk support to all Mammography Program Reporting and Information System stakeholders; manages the configuration and distribution of Mammography Quality Standards Act inspector laptops; oversees contractor infrastructure support; oversees system security activities; develops system and software test scripts and conducts system and software testing; conducts user acceptance testing; maintains system security assessment documentation and responds to security assessment review data calls; provides risk management; responds to data calls and other request for information; provides project management services to radiological health information technology projects.
- C. Provides services throughout the software development lifecycle, including software architecture design and documentation, code development and coding, code and application prototyping, code modification, code reuse and re-engineering, application maintenance, software configuration management, software change control, software release management, contingency planning, data management, and project management and stakeholder communications.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Commissioner of Food and Drugs on September 25, 2012.

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OFFICE OF THE DIRECTOR

Program Management Branch
Information Management Branch

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of In Vitro Diagnostics and Radiological Health, Division of Program Operations and Management organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR