

SMG 1122A.41

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Inspections and Investigations

Office of Medical Devices and Radiological Health Inspectorate

Division of Mammography and Radiological Health Inspectorate

Effective Date: May 13, 2024

- 1. Division of Mammography and Radiological Health Inspectorate (DCSMA).**
 - A. Manages mammography and radiological health related to inspectional operations within the Office of Medical Devices and Radiological Health Inspectorate (OMDRHI).
 - B. Obtains resources and identifies strategic objectives for the organization.
 - C. Conducts inspections, audits, and supports the Food and Drug Administration (FDA) field organizations addressing the Mammography Quality Standards Act (MQSA) and support the Center for Devices and Radiological Health (CDRH) Division of Mammography Quality Standards (DMQS) on enforcement, if needed.
 - D. Manages and evaluates MQSA program and operational activities, including all phases of personnel management, financial management, property, and supplies for the Division.
 - E. Advises the OMDRHI director of emerging problems, program needs, and any State, local, or international issues.
 - F. Manages Radiological Health Representatives who are liaisons within FDA, with States, and with other federal agencies. Communicates frequently with States' Radiological Health Managers.
 - G. Acts as points of contact for management as Radiological Emergency Response including membership of the Advisory Team (primarily composed of FDA, Centers for Disease Control and Prevention (CDC), Environmental Protection Agency (EPA), and Department of Agriculture (USDA)) that was established to assist in international and domestic nuclear emergencies.

- H. Serves as subject matter expert for the Mammography Program (aka MQSA), specializing in training and audits.
- I. Serves as program contact for MQSA State contracts, interagency agreements, information sharing, and general inquiries.

2. Mammography Operations Branch 1 (DCSMA1).

- A. Provides specific technical and administrative guidance to MQSA Specialists.
- B. Defines work assignments and assigns work to employees.
- C. Works with the inspectors, State MQSA Program Managers, MQSA facilities, Division of Mammography Quality and Radiation Programs (DMQRP), and the Regional Radiological Health Representative (RRHR) to resolve problems and unusual situations.
- D. Defines technical work requirements and identifies potential health-related issues within the industry.
- E. Provides employees resources and information that ensures a safe and healthy work environment.
- F. Directs the activities of, and has first-level supervisory responsibilities over, a staff of Consumer Safety Officers (MQSA Specialists) performing professional inspections and investigations of regulated industry, focusing primarily on MQSA facilities.
- G. Establishes guidelines and performance expectations for staff, which are clearly communicated.
- H. Develops short and long-range work plans, staffing needs, and budgetary needs.
- I. Provides reports on audit activities to State MQSA Program Managers, Division of Mammography Quality Standards (DMQS), and the Radiological Health Representative.
- J. Conducts audits of state MQSA Certified inspectors.
- K. Operates with workforce made of MQSA Specialists who are required to maintain certification.

3. Mammography Operations Branch 2 (DCSMA2).

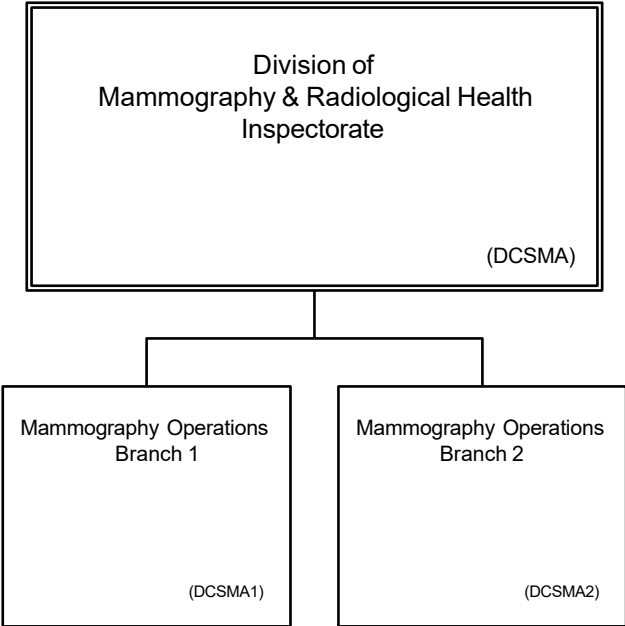
- A. Provides specific technical and administrative guidance to MQSA Specialists.
- B. Defines work assignments and assigns work to employees.

- C. Works with the inspectors, State MQSA Program Managers, MQSA facilities, DMQRP, and the RRHR to resolve problems and unusual situations.
- D. Defines technical work requirements and identifies potential health-related issues within the industry.
- E. Provides employees resources and information that ensures a safe and healthy work environment.
- F. Directs the activities of, and has first-level supervisory responsibilities over, a staff of Consumer Safety Officers (MQSA Specialists) performing professional inspections and investigations of regulated industry, focusing primarily on MQSA facilities.
- G. Establishes guidelines and performance expectations for staff, which are clearly communicated.
- H. Develops short and long-range work plans, staffing needs, and budgetary needs.
- I. Provides reports on audit activities to State MQSA Program Managers, DMQS, and the Radiological Health Representative.
- J. Conducts audits of state MQSA Certified inspectors.
- K. Operates with workforce made of MQSA Specialists who are required to maintain certification.

4. Authority and Effective Date.

The functional statements for the Division of Mammography and Radiological Health Inspectorate were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Medical Devices and Radiological Health Inspectorate, Division of Mammography and Radiological Health Inspectorate organization structure depicting all the organizational structures reporting to the Director:

Mammography Operations Branch 1 (DCSMA1)

Mammography Operations Branch 2 (DCSMA2)