

SMG 1122A.4

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

Effective Date: May 13, 2024

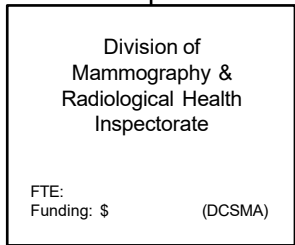
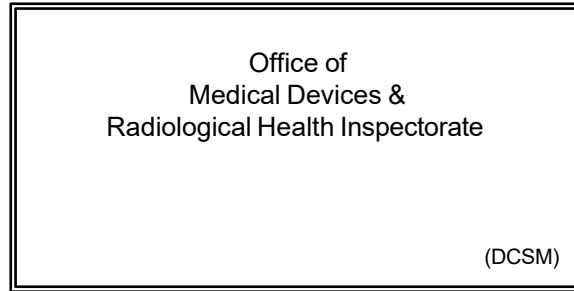
- 1. Office of Medical Devices and Radiological Health Inspectorate (DCSM).**
 - A. Conducts investigations and inspections of medical devices, radiological health products, and other Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) regulated commodities.
 - B. Provides direction and counsel relative to medical device and radiological health field operations, in coordination with CDRH, including response activities posed by potential threat to public health to FDA leaders.
 - C. Coordinates, directs, and assists with medical device and radiological health investigative activities in coordination with CDRH.
 - D. In collaboration with the FDA Centers and Offices, establish inspection goals that align with the resource capacity of Office of Inspections and Investigations (OII).
 - E. Supports the development of inspectorate policy and guidance for investigations and supports compliance activities for medical device and radiological health products in coordination with CDRH.
 - F. Participates, as needed, in system recognition efforts with other FDA components and national and international governments in coordination with CDRH.
 - G. Participates as subject matter experts in the design, implementation, and presentation of medical device and radiological health training programs in coordination with CDRH.
 - H. Monitors emerging issues and advancements in technology and recommends program improvements as necessary in coordination with CDRH.

- I. Serves as subject matter expert on field operations relative to medical device and radiological health on external and internal cross-FDA committees, workgroups, and task forces.
- J. Creates, reviews, and/or facilitates issuance of field assignments with FDA Center and Offices for medical device and radiological health programs. Monitors and serves as technical point of contact for these medical product assignments.
- K. Develops and maintains cooperative relationships with State, local, and other Federal agencies; serves on interagency councils; and encourages improved State and local consumer protection programs pertinent to FDA-enforced laws and regulations related to CDRH-regulated commodities.
- L. Plans and evaluates program activities and manages the Inspectorate's responsibilities in support of the FDA's Government-Wide Quality Assurance Program.
- M. Coordinates emergency activities with and provides assistance to Department of Health and Human Services (HHS) and FDA components and other external stakeholders in the event of a natural disaster or other emergency following HHS and/or FDA direction.
- N. Coordinates implementation of inspection-related activities for user fee programs and collection and analysis of related performance goal data, in coordination with CDRH.
- O. Provides technical assistance regarding medical device and radiological health investigational operations.

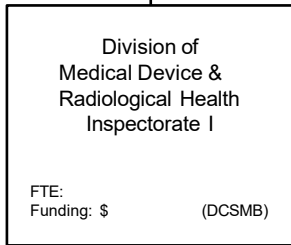
2. Authority and Effective Date.

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

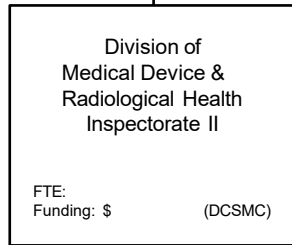
**Department of Health and Human Services
Food and Drug Administration
Office of Inspections and Investigations
Office of Medical Devices and Radiological Health Inspectorate**



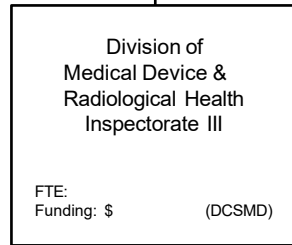
Mammography Operations Branch 1
Mammography Operations Branch 2



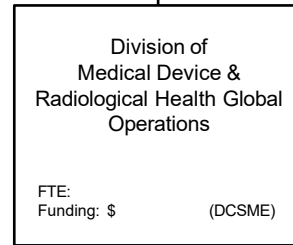
Medical Device & Radiological Health Investigations Branch 1
Medical Device & Radiological Health Investigations Branch 2
Medical Device & Radiological Health Investigations Branch 3
Medical Device & Radiological Health Investigations Branch 4



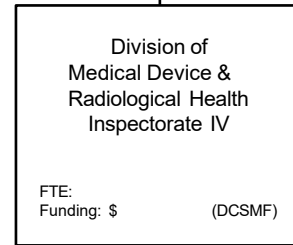
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Medical Device & Radiological Health Investigations Branch 5



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Medical Device & Radiological Health Investigations Branch 5



Medical Device & Radiological Health Foreign Operations Branch
Medical Device & Radiological Health Operations Branch
Medical Device & Radiological Health Risk Mitigation & Response Branch



Medical Device & Radiological Health Investigations Branch 1
Medical Device & Radiological Health Investigations Branch 2
Medical Device & Radiological Health Investigations Branch 3
Medical Device & Radiological Health Investigations Branch 4

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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 organization structure depicting all the organizational structures reporting to the Director:

Division of Mammography and Radiological Health Inspectorate (DCSMA)

Division of Medical Device and Radiological Health Inspectorate I (DCSMB)

Division of Medical Device and Radiological Health Inspectorate II (DCSMC)

Division of Medical Device and Radiological Health Inspectorate III (DCSMD)

Division of Medical Device and Radiological Health Global Operations (DCSME)

Division of Medical Device and Radiological Health Inspectorate IV (DCSMF)

These organizations report to the Division of Mammography and Radiological Health Inspectorate (DCSMA):

Mammography Operations Branch 1 (DCSMA1)

Mammography Operations Branch 2 (DCSMA2)

These organizations report to the Division of Medical Device and Radiological Health Inspectorate I (DCSMB):

Medical Device and Radiological Health Investigations Branch 1 (DCSMB1)

Medical Device and Radiological Health Investigations Branch 2 (DCSMB2)

Medical Device and Radiological Health Investigations Branch 3 (DCSMB3)

Medical Device and Radiological Health Investigations Branch 4 (DCSMB4)

These organizations report to the Division of Medical Device and Radiological Health Inspectorate II (DCSMC):

Medical Device and Radiological Health Investigations Branch 1 (DCSMC1)

Medical Device and Radiological Health Investigations Branch 2 (DCSMC2)

Medical Device and Radiological Health Investigations Branch 3 (DCSMC3)

Medical Device and Radiological Health Investigations Branch 4 (DCSMC4)

Medical Device and Radiological Health Investigations Branch 5 (DCSMC5)

These organizations report to the Division of Medical Device and Radiological Health Inspectorate III (DCSMD):

Medical Device and Radiological Health Investigations Branch 1 (DCSMD1)

Medical Device and Radiological Health Investigations Branch 2 (DCSMD2)

Medical Device and Radiological Health Investigations Branch 3 (DCSMD3)

Medical Device and Radiological Health Investigations Branch 4 (DCSMD4)

Medical Device and Radiological Health Investigations Branch 5 (DCSMD5)

These organizations report to the Division of Medical Device and Radiological Health Global Operations (DCSME):

Medical Device and Radiological Health Foreign Operations Branch (DCSME1)

Medical Device and Radiological Health Operations Branch (DCSME2)

Medical Device and Radiological Health Risk Mitigation and Response Branch (DCSME3)

These organizations report to the Division of Medical Device and Radiological Health Inspectorate IV (DCSMF):

Medical Device and Radiological Health Investigations Branch 1 (DCSMF1)

Medical Device and Radiological Health Investigations Branch 2 (DCSMF2)

Medical Device and Radiological Health Investigations Branch 3 (DCSMF3)

Medical Device and Radiological Health Investigations Branch 4 (DCSMF4)