SMG 1122A.42

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 Medical Devices and Radiological Health Inspectorate I

Effective Date: May 13, 2024

1. Division of Medical Devices and Radiological Health Inspectorate I (DCSMB).

A. Manages field inspection within the associated division for medical device and radiological health products regulated by the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) in coordination with CDRH.

B. Manages and evaluates resource use in support of the medical device and radiological health program in coordination with CDRH.

C. Refers inspections and investigations with 483 observations to Center for consideration of appropriate follow-up and, upon request of the Center, assist with execution of legal actions.

D. Recommends legal action to appropriate FDA Centers and Offices and assists in executing approved action.

E. Manages and evaluates medical device and radiological health inspectional program activities and manages the Division's responsibilities in support of the FDA's Government-Wide Quality Assurance Program.

F. Develops short and long-term work plans, staffing needs, and budgetary proposals for the division's assigned portion of the nationwide program in coordination with CDRH.

G. Advises the Office of Medical Device and Radiological Health Inspectorate Director of emerging problems, trends, program needs, and any State or local issues.

H. Manages program and operational activities, including all phases of personnel management, financial management, and supplies for the division.

2. Medical Devices and Radiological Health Investigations Branch 1 (DCSMB1).

A. At the direction of CDRH, inspects medical device and radiological health establishments, collects samples for analysis, performs field examinations, and prepares reports for FDA Centers and Offices.

B. Refers inspections and investigations with 483 observations to Center for consideration of appropriate follow-up.

C. Evaluates corrective actions taken by medical device and radiological health establishments and provides feedback to FDA Centers and Offices, in consultation with the CDRH.

D. Performs special investigations, including division responsibilities under the FDA's Government-wide Quality Assurance Program.

E. Investigates reports of adverse experiences including consumer complaints received by FDA regarding regulated medical device or radiological health products.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences in coordination with CDRH.

G. Provides inspectional and investigational support to other Divisions as needed.

H. Plans, schedules, and conducts domestic medical device and radiological health inspectional operations in coordination with CDRH.

I. Supports the development and implementation of domestic work plans and the execution of foreign inspectional work plans for CDRH-regulated commodities.

J. Provides guidance and training regarding inspectional techniques and technical developments to other Federal, State, local agencies, and foreign counterpart agencies and to industry, as appropriate.

K. Plans, organizes, and implements comprehensive industry education, training, and technical assistance programs designed to promote voluntary compliance in cooperation with other FDA and field components.

L. Assists the Inspectorate in managing, evaluating, and auditing the program aspects of federal-state contracts. Works with State and local officials to provide consultation and assistance relative to regulatory approaches,

including joint inspections with regulatory partners, in coordination with CDRH.

M. Maintains cooperative relationships with State and local counterpart agencies and assists in development of work and information sharing agreements.

3. Medical Devices and Radiological Health Investigations Branch 2 (DCSMB2).

A. At the direction of CDRH, inspects medical device and radiological health establishments, collects samples for analysis, performs field examinations, and prepares reports for FDA Centers and Offices.

B. Refers inspections and investigations with 483 observations to Center for consideration of appropriate follow-up.

C. Evaluates corrective actions taken by medical device and radiological health establishments and provides feedback to FDA Centers and Offices, in consultation with the CDRH.

D. Performs special investigations, including division responsibilities under the FDA's Government-wide Quality Assurance Program.

E. Investigates reports of adverse experiences including consumer complaints received by FDA regarding regulated medical device or radiological health products.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences in coordination with CDRH.

G. Provides inspectional and investigational support to other Divisions as needed.

H. Plans, schedules, and conducts domestic medical device and radiological health inspectional operations in coordination with CDRH.

I. Supports the development and implementation of domestic work plans and the execution of foreign inspectional work plans for CDRH-regulated commodities.

J. Provides guidance and training regarding inspectional techniques and technical developments to other Federal, State, local agencies, and foreign counterpart agencies and to industry, as appropriate.

K. Plans, organizes, and implements comprehensive industry education, training, and technical assistance programs designed to promote voluntary compliance in cooperation with other FDA and field components.

L. Assists the Office of Medical Device and Radiological Health Inspectorate in managing, evaluating, and auditing the program aspects of Federal and State contracts. Coordinates with State and local officials to provide consultation and assistance relative to regulatory approaches, including joint inspections with regulatory partners.

N. Maintains cooperative relationships with State and local counterpart agencies and assists in development of work and information sharing agreements.

4. Medical Devices and Radiological Health Investigations Branch 3 (DCSMB3).

A. At the direction of CDRH, inspects medical device and radiological health establishments, collects samples for analysis, performs field examinations, and prepares reports for FDA Centers and Offices.

B. Refers inspections and investigations with 483 observations to Center for consideration of appropriate follow-up.

C. Evaluates corrective actions taken by medical device and radiological health establishments and provides feedback to FDA Centers and Offices, in consultation with the CDRH.

D. Performs special investigations, including division responsibilities under the FDA's Government-wide Quality Assurance Program.

E. Investigates reports of adverse experiences including consumer complaints received by FDA regarding regulated medical device or radiological health products.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences in coordination with CDRH.

G. Provides inspectional and investigational support to other Divisions as needed.

H. Plans, schedules, and conducts domestic medical device and radiological health inspectional operations in coordination with CDRH.

I. Supports the development and implementation of domestic work plans and the execution of foreign inspectional work plans for CDRH-regulated commodities.

J. Provides guidance and training regarding inspectional techniques and technical developments to other Federal, State, local agencies, and foreign counterpart agencies and to industry, as appropriate.

K. Plans, organizes, and implements comprehensive industry education, training, and technical assistance programs designed to promote voluntary compliance in cooperation with other FDA and field components.

L. Assists the Office of Medical Device and Radiological Health Inspectorate in managing, evaluating, and auditing the program aspects of Federal and State contracts. Coordinates with State and local officials to provide consultation and assistance relative to regulatory approaches, including joint inspections with regulatory partners.

M. Maintains cooperative relationships with State and local counterpart agencies and assists in development of work and information sharing agreements.

5. Medical Devices and Radiological Health Investigations Branch 4 (DCSMB4).

A. At the direction of CDRH, inspects medical device and radiological health establishments, collects samples for analysis, performs field examinations, and prepares reports for FDA Centers and Offices.

B. Refers inspections and investigations with 483 observations to Center for consideration of appropriate follow-up.

C. Evaluates corrective actions taken by medical device and radiological health establishments and provides feedback to FDA Centers and Offices, in consultation with the CDRH.

D. Performs special investigations, including division responsibilities under the FDA's Government-wide Quality Assurance Program.

E. Investigates reports of adverse experiences including consumer complaints received by FDA regarding regulated medical device or radiological health products.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences in coordination with CDRH.

G. Provides inspectional and investigational support to other Divisions as needed.

H. Plans, schedules, and conducts domestic medical device and radiological health inspectional operations in coordination with CDRH.

I. Supports the development and implementation of domestic work plans and the execution of foreign inspectional work plans for CDRH-regulated commodities.

J. Provides guidance and training regarding inspectional techniques and technical developments to other Federal, State, local agencies, and foreign counterpart agencies and to industry, as appropriate.

K. Plans, organizes, and implements comprehensive industry education, training, and technical assistance programs designed to promote voluntary compliance in cooperation with other FDA and field components.

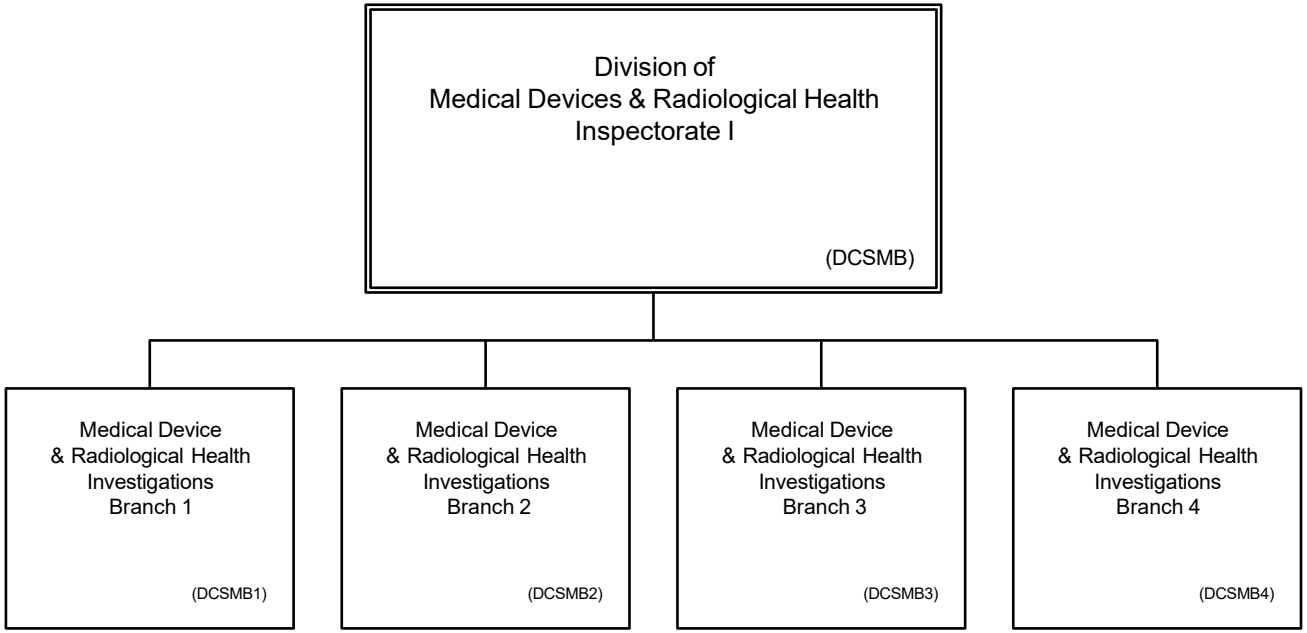
L. Assists the Office of Medical Device and Radiological Health Inspectorate in managing, evaluating, and auditing the program aspects of Federal and State contracts. Coordinates with State and local officials to provide consultation and assistance relative to regulatory approaches, including joint inspections with regulatory partners.

M. Maintains cooperative relationships with State and local counterpart agencies and assists in development of work and information sharing agreements.

6. Authority and Effective Date.

The functional statements for the Division of Medical Devices and Radiological Health Inspectorate I 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
Division of Medical Devices and Radiological Health Inspectorate I



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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 Medical Device and Radiological Health Inspectorate I organization structure depicting all the organizational structures reporting to the Director:

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)