SMG 1121.24a

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Medical Products and Tobacco Operations

Office of Medical Devices and Radiological Health Operations

Effective Date: December 14, 2018

1. Office of Medical Devices and Radiological Health Operations (DCIGD).

A. Provides direction and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other Food and Drug Administration (FDA) leaders relative to medical device and radiological health field operations including emergency response activities.

B. Coordinates, directs and assists with medical device and radiological health investigative activities.

C. Supports the development of policy and guidance for investigations and compliance for medical device and radiological health.

D. Participates, as needed, in system recognition efforts with other FDA components and national and international governments.

E. Participates as subject matter experts in the design, implementation and presentation of medical device and radiological health training programs.

F. Monitors emerging issues and advancements in technology and recommends program improvements as necessary.

G. 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.

H. Creates, reviews, and/or facilitates issuance of field assignments with Centers for medical device and radiological health programs. Monitors and serves as technical point of contact for these assignments.

I. Develops and maintains cooperative relationships with State, local and other Federal agencies; serves on interagency councils, encourages improved State and local consumer protection programs pertinent to FDA-enforced laws and regulations.

J. Plans and evaluates program activities and manages a Quality Assurance Program.

K. Coordinates emergency activities with and provides assistance to Department components and other external stakeholders in the event of a natural disaster or other emergency.

L. Conducts investigations and inspections of medical devices, radiological health products, and other Center for Devices and Radiological Health (CDRH)-regulated commodities.

M. Coordinates implementation of user fee programs and collection and analysis of related performance goal data.

N. Provides technical assistance regarding medical device and radiological health investigational operations.

2. Medical Devices and Radiological Health Operations Staff (DCIGD1)

A. Coordinates, directs, and assists the field and Headquarters with domestic and international investigative activities related to medical device and radiological health products regulated by CDRH.

B. Provides inspectional and technical support to other offices on medical device and radiological health inspectional and regulatory matters.

C. Provides technical and programmatic expertise to the field and Centers through national technical and program experts.

D. Performs medical device and radiological health inspections, as necessary.

E. Creates, reviews, and/or facilitates issuance of field assignments with CDRH for medical device and radiological health. Monitors and serves as technical point of contact for these assignments.

F. Implements the medical device and radiological health work plan within the Office. Assists other offices and divisions in interpretation of work plan implementation.

G. Reviews and evaluates implementation of existing procedures and guidance related to medical device and radiological health.

H. Serves as subject matter expert on field operations relative to the medical device and radiological health program on external and internal cross-FDA committees, workgroups and task forces.

I. Coordinates and participates in international harmonization with other national regulatory authorities and standards setting organizations as appropriate.

J. Provides radiological health technical assistance and training; develops agreements with State and local radiation control officials; oversees the development of regulatory actions regarding electronic devices capable of emitting radiation; and monitors the conduct of State and local radiation control programs.

K. Represents the medical device and radiological health program on emergency responses involving radiation safety; coordinates emergency activities within the FDA and with other Federal agencies; provides assistance to States and localities in the event of natural disaster or other emergency involving radiation safety.

3. Foreign Medical Devices and Radiological Health Inspections Staff (DCIGD2)

A. Coordinates and directs foreign medical device and radiological health inspection activities.

B. Serves as operational liaison for foreign medical device and radiological health products inspection programs to FDA’s foreign and other offices.

C. Inspects foreign medical device and radiological health establishments for which CDRH has regulatory responsibility, collects samples for analysis, performs field examinations and prepares reports.

D. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow-up.

E. Prepares and provides evidence of investigational findings as requested.

F. Provides dedicated inspectional and investigational support to the Headquarters and other divisions, as needed.

G. Coordinates international medical device and radiological health regulatory activities, including the planning of all medical device and radiological health foreign inspections and investigations.

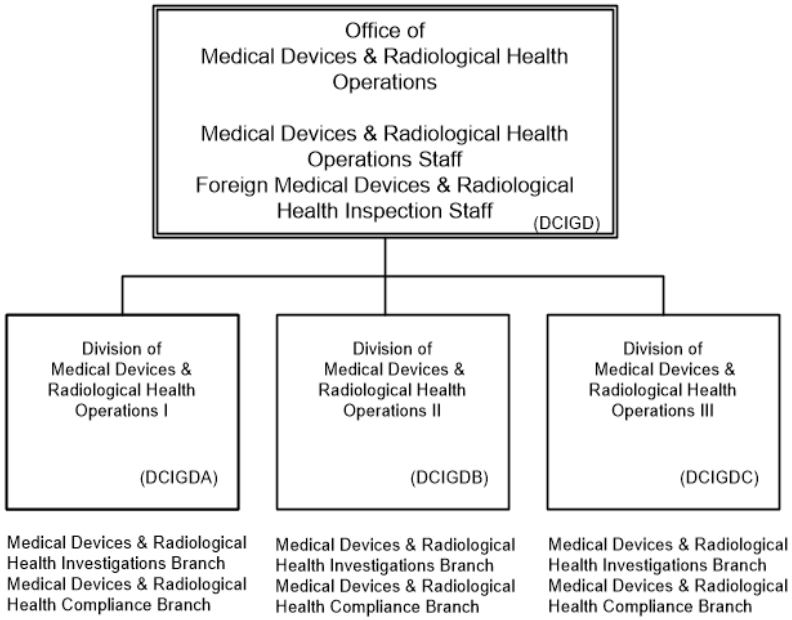
H. Advises the Medical Device Program Director of emerging inspectional, scientific and regulatory issues related to medical device and radiological health products.

I. Provides counsel and training regarding inspectional techniques and technical developments to other Federal agencies and to foreign counterpart agencies and to industry, as appropriate.

4. Authority and Effective Date.

The functional statements for the Office of Medical Devices and Radiological Health Operations were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Medical Products and Tobacco Operations
Office of Medical Devices and Radiological Health Operations



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Medical Products and Tobacco Operations, Office of Medical Devices and Radiological Health Operations organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Medical Devices and Radiological Health Operations (DCIGD):

Medical Devices & Radiological Health Operations Staff

Medical Devices & Radiological Health Inspection Staff

Division of Medical Devices & Radiological Health Operations I (DCIGDA)

Division of Medical Devices & Radiological Health Operations II (DCIGDB)

Division of Medical Devices & Radiological Health Operations III (DCIGDC)

These organizations report to the Division of Medical Devices & Radiological Health Operations I (DCIGDA)

Medical Devices & Radiological Health Investigations Branch

Medical Devices & Radiological Health Compliance Branch

These organizations report to the Division of Medical Devices & Radiological Health Operations II (DCIGDB)

Medical Devices & Radiological Health Investigations Branch

Medical Devices & Radiological Health Compliance Branch

These organizations report to the Division of Medical Devices & Radiological Health Operations III (DCIGDC)

Medical Devices & Radiological Health Investigations Branch

Medical Devices & Radiological Health Compliance Branch

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