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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 Device and Radiological Health Inspectorate

Division of Medical Device and Radiological Health Global Operations

Effective Date: May 13, 2024

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

A. Coordinates and directs international medical device and radiological health regulatory activities, including the planning of all foreign medical device and radiological health inspections and investigations with direction from the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH).

B. Serves as subject matter experts on domestic and foreign operations relative to medical device and radiological health on internal cross-FDA committees, workgroups, and task forces.

C. Supports medical device and radiological health outbreak and emergency response activities.

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

E. Manages the foreign medical device and radiological health inspection cadre, Operations Staff, and Risk Mitigation Staff.

F. Analyzes inspectional outcomes with FDA Center and Office counterparts to develop follow-up strategy to reduce risk to public health due to repeat violative medical device and radiological health establishments.

G. Provides technical and inspectional training to FDA Centers, Offices, and other programs. Monitors emerging issues and advancements in medical device and radiological health technology.

H. Responds to inquiries from other Federal agencies, foreign regulatory entities, and industry associations.

I. Maintains cooperative relationships with State and local counterpart agencies and develops work and information sharing agreements.

J. Plans, organizes, and implements comprehensive industry education, training, and technical assistance programs designed to promote voluntary compliance and self-regulation in cooperation with other FDA Centers, Offices, and field components.

K. Provides technical review, offers comments, and advises on clearance of guidance documents and new regulations.

2. Medical Device and Radiological Health Foreign Operations Branch (DCSME1).

A. Coordinates and directs international medical device and radiological health regulatory activities, including the planning of medical device and radiological health foreign inspections and investigations in coordination with CDRH.

B. Serves as operational liaison for foreign medical device and radiological health products inspection programs to FDA's foreign and other offices with a dedicated cadre.

C. Inspects foreign medical device and radiological health establishments, documents evidence of inspectional findings, and prepares reports.

D. Evaluates inspectional and analytical findings and recommends appropriate follow-up in coordination with CDRH.

E. Prepares additional interpretation of inspection and investigation findings.

F. Advises the Inspectorate director of emerging inspectional, scientific, and regulatory issues related to medical device and radiological health products.

G. Collaborates with FDA Centers, Offices, imports, and global offices in response to medical device and radiological health product concerns that may impact global supply chain. Provides counsel and training regarding inspectional techniques and technical developments to other Federal agencies and to foreign counterpart agencies and to industry, as appropriate.

3. Medical Device and Radiological Health Operations Branch (DCSME2).

A. Coordinates, directs, and assists the FDA Center, Offices and field organizations with domestic and international investigative activities related to medical device and radiological health products regulated by CDRH and other FDA Centers and Offices.

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 FDA Centers, Offices, and field organizations through national experts, senior operations officers, and program experts.

D. Performs medical device and radiological health inspections, as needed, in coordination with CDRH.

E. Creates, reviews, and/or facilitates issuance of field assignments with CDRH, FDA Centers and Offices, or other programs 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 Office of Inspections and Investigations (OII) 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.

J. Provides radiological health technical assistance and training; develops agreements with State and local radiation control officials; supports 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 as requested by CDRH or other FDA Centers and Offices.

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

A. Monitors patient risk indicators such as recalls in collaboration with FDA Centers, Offices, and OII partners to ensure appropriate oversight.

B. Works with program investigators when they find unreported corrections and removals to establish violation of 21 CFR Part 806 and poses a risk to public health.

C. Operates with other branches of global operations for early identification of potential supply chain issues and the possibility of medical device shortages.

D. Develops domestic and foreign inspection follow-up assignments, in coordination with CDRH, when medical device recalls indicate potential of imminent health risk.

E. Supports the development of domestic and foreign inspectional work plans by providing program signal information.

F. Monitors recall status and performs follow-up activities to assess recall effectiveness, including review of monthly status reports as required by 21 CFR Part 7, and ensures completion of medical device and radiological health establishments actions.

G. Conducts technical reviews of medical device and radiological health establishments stated root causes and recall strategies and corresponds with the medical device and radiological health establishments to reach a resolution. Requests inspections in coordination with CDRH.

H. Reviews medical device and radiological health establishments corrective actions plans for adequacy of proposed risk mitigation.

I. Requests assignments for witness of destruction when modifications to devices would be an inadequate correction to mitigate risk.

5. Authority and Effective Date.

The functional statements for the Division of Medical Device and Radiological Health Global Operations 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
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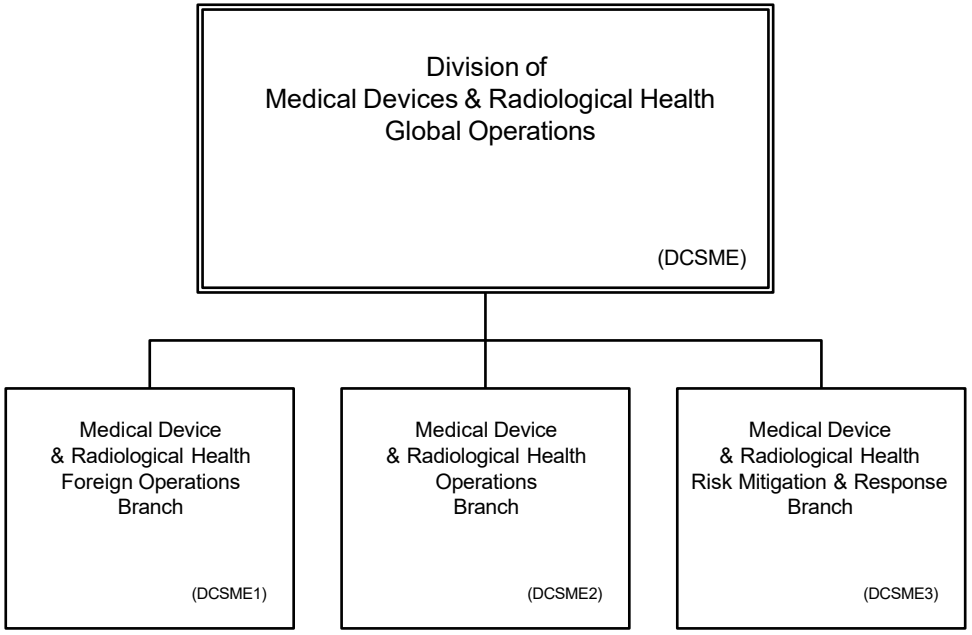

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Medical Devices and Radiological Health Inspectorate, Division of Medical Device and Radiological Health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

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)