

**SMG 1121A.8**

**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 Field Operations and Response**

Effective Date: May 13, 2024

**1. Office of Field Operations and Response (DCSH).**

- A. Provides direction and guidance to the Office of Inspections and Investigations (OII) senior leaders, and other Food and Drug Administration (FDA) senior leaders concerning inspectorate policies and field enforcement activities.
- B. Provides direction and guidance to the OII leaders and other senior FDA leaders concerning tobacco and cosmetic inspectorate activities.
- C. Provides direction and guidance to the OII leaders and other senior FDA leaders on FDA's emergency preparation, management, and response efforts.
- D. Leads Office of Field Operations and Research (OFOR) Office Directors in the coordination, interpretation, and evaluation of emergency response, field enforcement, inspectional policy, inspections, investigations, and quality systems.
- E. Develops and provides oversight for strategic plans and the implementation of field operations and response activities.
- F. Manages and initiates all FDA financial requirements for budget execution and formulation for the office.

**2. Organizational Quality Staff (DCSH1).**

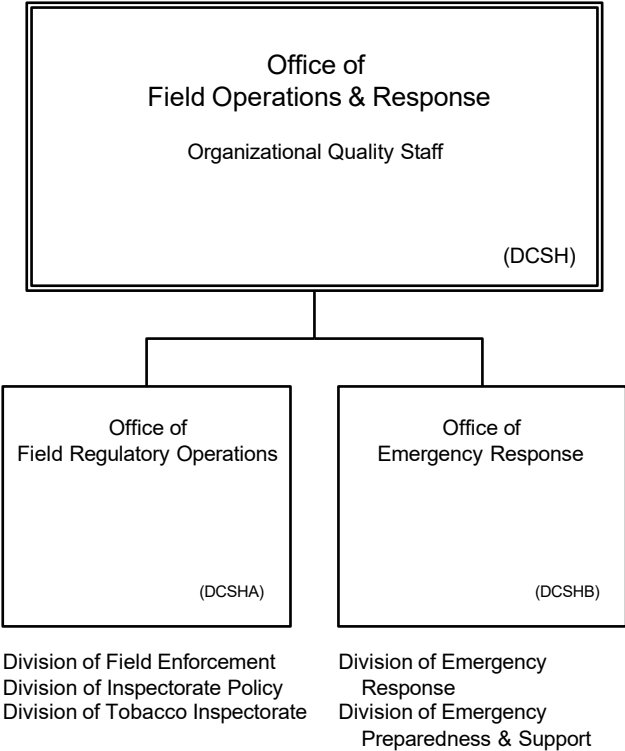
- A. Provides advice and guidance to the OII leaders, OII managers, and Quality System Managers in the development of strategies for applying quality management to OII processes.

- B. Plans, develops, and implements OII-wide quality policies, programs, procedures, and tools in coordination with FDA Centers and Offices.
- C. Communicates relevant quality-related information to the OII leaders and senior managers.
- D. Manages the training and certification of OII staff on Quality Management System (QMS) principles and requirements.
- E. Reviews OII QMS programs according to documented procedures to ensure continuing suitability, adequacy, and effectiveness.
- F. Represents OII during external audits of OII's programs.
- G. Supports enterprise-wide process improvement and quality projects.
- H. Conducts quality controls and system audits in coordination with FDA Centers and Offices.

**3. Authority and Effective Date.**

The functional statements for the Office of Field Operations and Response 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 Field Operations and Response**



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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 Field Operations and Response organization structure depicting all the organizational structures reporting to the Director:

Organizational Quality Staff (DCSH1)  
Office of Field Regulatory Operations (DCSHA)  
Office of Emergency Response (DCSHB)

These organizations report to the Office of Field Regulatory Operations (DCSHA):  
Division of Field Enforcement  
Division of Inspectorate Policy  
Division of Tobacco Inspectorate

These organizations report to the Office of Emergency Response (DCSHB):  
Division of Emergency Response  
Division of Emergency  
Preparedness and Support