

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

Office of Field Regulatory Operations

Division of Inspectorate Policy

Effective Date: May 13, 2024

1. Division of Inspectorate Policy (DCSHAB).

- A. Reviews, leads, or contributes to the development and publication of proposed regulations, final regulations, and other Food and Drug Administration (FDA) documents regarding the practice and operational policies of the Office of Inspections and Investigations (OII) surveillance and regulatory operations.
- B. Proposes or develops Office of Management and Budget (OMB) Circular A-19 requests for FDA consideration regarding potential statutory changes related to field operational activities.
- C. Serves on the Compliance Policy Council.
- D. Upon the request FDA Centers and Offices, reviews Center and Office policy to determine the needs and impacts on inspectorate policy.
- E. Consults on information collection processes and procedures regarding the Paperwork Reduction Act of 1995 across OII.

2. Food Inspectorate Policy Branch (DCSHAB1).

- A. Supports work by FDA Centers and Offices to develop, coordinate, and manage new or modified FDA operational policies, procedures, and guidance for human and animal food and cosmetics regulated by the FDA.

- B. Supports the development, coordination, and management of new or modified field operational policies, procedures, and guidance for imported human and animal food and cosmetics regulated by the FDA.

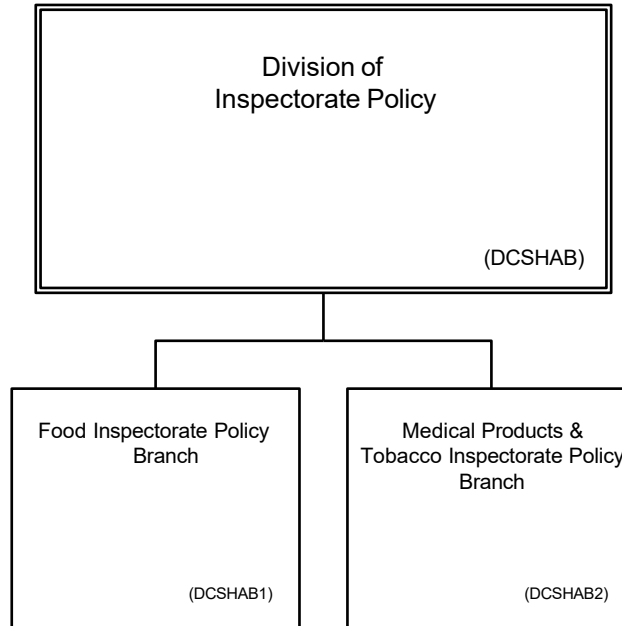
3. Medical Products and Tobacco Inspectorate Policy Branch (DCSHAB2).

- A. Supports the development, coordination, and management of new or modified operational policies, procedures, and guidance for medical products and tobacco products regulated by the FDA.
- B. Supports the development, coordination, and management of new or modified field operational policies, procedures, and guidance for imported medical products and tobacco products regulated by the FDA.
- C. Reviews all domestic and imported medical products and tobacco products regulatory initiatives to determine the need for an enforcement strategy as it relates to field operations.

4. Authority and Effective Date.

The functional statements for the Division of Inspectorate Policy 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
Office of Field Regulatory Operations
Division of Inspectorate Policy**



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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, Office of Field Regulatory Operations, Division of Inspectorate Policy organization structure depicting all the organizational structures reporting to the Director:

Food Inspectorate Policy Branch (DCSHAB1)

Medical Products and Tobacco Inspectorate Policy Branch (DCSHAB2)