

SMG 1121A.5

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 Bioresearch Monitoring Inspectorate

Effective Date: May 13, 2024

1. Office of Bioresearch Monitoring Inspectorate (DCSE).

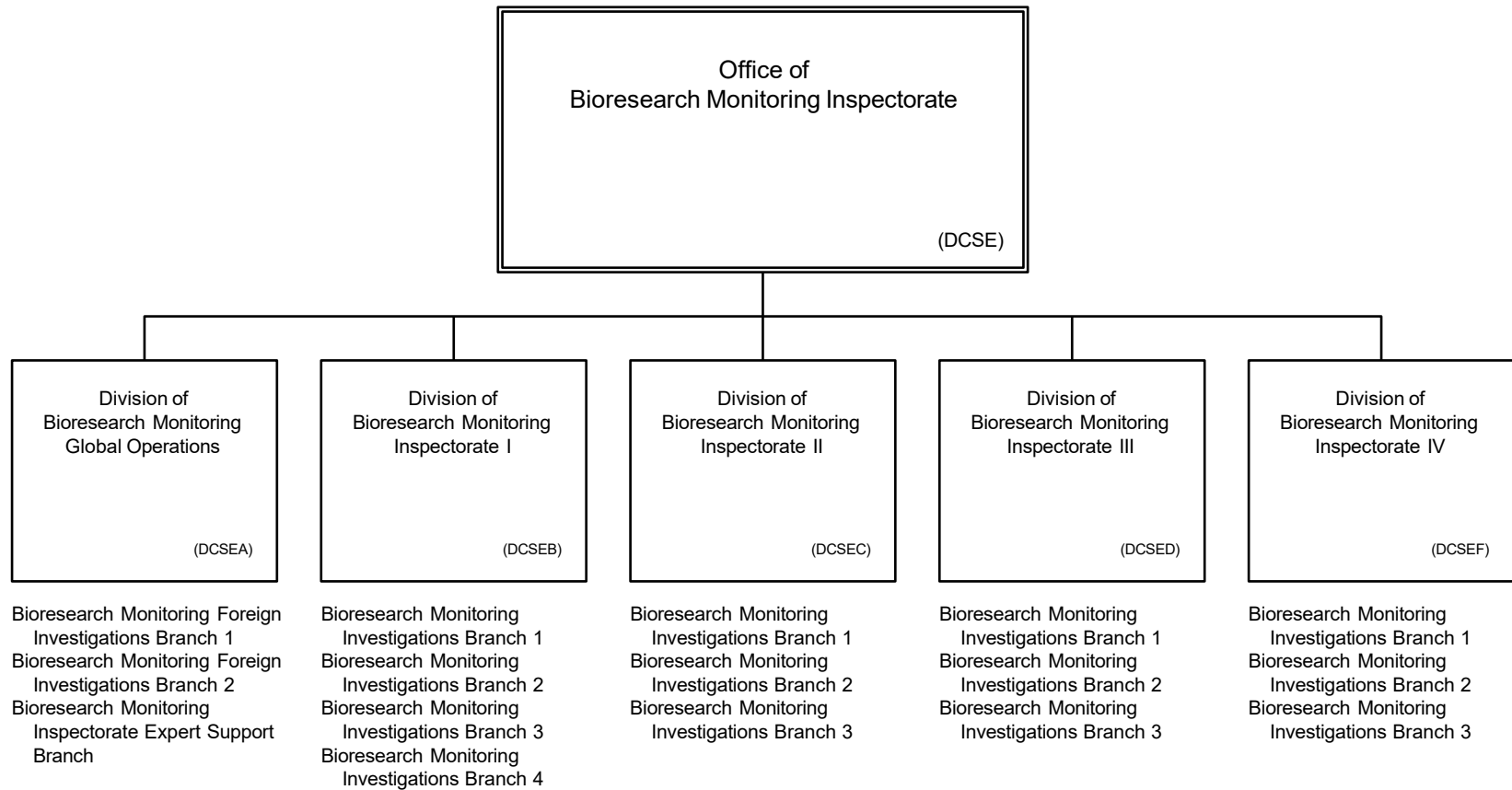
- A. Conducts all domestic and foreign Food and Drug Administration (FDA) field inspectional operations related to the Bioresearch Monitoring (BIMO) Program, including all clinical and nonclinical research conducted in support of preapproval, licensing, premarket and marketing clearance applications submitted to the agency for products regulated in coordination with Centers and Offices.
- B. Provides advice and guidance to Office of Inspections and Investigations (OII) and FDA leaders relative to BIMO field operations including emergency response activities.
- C. In collaboration with the Centers and Offices, establish inspection goals that align with the resource capacity of OII.
- D. Coordinates, directs, and assists with Office of Bioresearch Monitoring Inspectorate investigative activities.
- E. Directs and coordinates OII's response to reports of adverse events relative to clinical and nonclinical research in collaboration with the Centers and Offices.
- F. Supports the development of inspectorate policy and guidance for investigations for BIMO.
- G. Serves as an operational liaison for BIMO inspection programs to FDA's foreign offices.
- H. Coordinates with Centers and Offices on international BIMO regulatory activities, including the planning and conduct of BIMO foreign inspections and investigations.

- I. As needed, participates in system recognition efforts with Centers and Offices and national and international governments.
- J. Participates as subject matter experts in the design, implementation, and presentation of BIMO training programs in coordination with the Office of Training, Education, and Development as appropriate.
- K. Monitors emerging issues and advancements in technology and recommends program improvements as necessary.
- L. Develops and maintains cooperative relationships with other Federal agencies; serves on interagency councils, encourages improved consumer protection programs pertinent to FDA-enforced laws and regulations.
- M. Plans and evaluates program activities and manages a Quality Assurance Program.
- N. Coordinates emergency activities with and provides assistance to Department of Health and Human Services components and other external stakeholders in the event of a natural disaster or other emergency.
- O. Conducts investigations and inspections related to the BIMO program.
- P. Provides technical assistance to internal and external partners regarding BIMO investigational operations.

2. Authority and Effective Date.

The functional statements for the Office of Bioresearch Monitoring Inspectorate were approved by the Secretary for 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 Bioresearch Monitoring Inspectorate**



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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 Bioresearch Monitoring Inspectorate organization structure depicting all the organizational structures reporting to the Director:

Division of Bioresearch Monitoring Global Operations (DCSEA)
Division of Bioresearch Monitoring Inspectorate I (DCSEB)
Division of Bioresearch Monitoring Inspectorate II (DCSEC)
Division of Bioresearch Monitoring Inspectorate III (DCSED)
Division of Bioresearch Monitoring Inspectorate IV (DCSEF)

These organizations report to the Division of Bioresearch Monitoring Global Operations (DCSEA): Bioresearch Monitoring Foreign Investigations Branch 1
Bioresearch Monitoring Foreign Investigations Branch 2
Bioresearch Monitoring
Inspectorate Expert Support Branch

These organizations report to the Division of Bioresearch Monitoring Inspectorate I (DCSEB):

Bioresearch Monitoring Investigations Branch 1
Bioresearch Monitoring Investigations Branch 2
Bioresearch Monitoring Investigations Branch 3
Bioresearch Monitoring Investigations Branch 4

These organizations report to the Division of Bioresearch Monitoring Inspectorate II (DCSEC):

Bioresearch Monitoring Investigations Branch 1
Bioresearch Monitoring Investigations Branch 2
Bioresearch Monitoring Investigations Branch 3

These organizations report to the Division of Bioresearch Monitoring Inspectorate III (DCSED):

Bioresearch Monitoring Investigations Branch 1
Bioresearch Monitoring Investigations Branch 2
Bioresearch Monitoring Investigations Branch 3

These organizations report to the Division of Bioresearch Monitoring Inspectorate IV (DCSEF):

Bioresearch Monitoring Investigations Branch 1

Bioresearch Monitoring Investigations Branch 2
Bioresearch Monitoring Investigations Branch 3