

SMG 1121A.53

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

Division of Bioresearch Monitoring Inspectorate II

Effective Date: May 13, 2024

1. Division of Bioresearch Monitoring Inspectorate II (DCSEC).

- A. Manages field inspection and compliance recommendations to the Centers and Offices within the associated division for Bioresearch Monitoring (BIMO).
- B. Conducts inspections and investigations related to the BIMO program.
- C. Manages and evaluates BIMO program activities and manages the Division's responsibilities towards a Quality Assurance Program.
- D. Develops short and long-range work plans, staffing needs, and budgetary proposals for the Division's assigned portion of the Inspectorate in coordination with Centers and Offices.
- E. Advises the Office of Bioresearch Monitoring Inspectorate Director of emerging problems, trends, program needs, and any local or state issues.
- F. Prepares and provides evidence of investigational findings to Centers and Offices.
- G. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow up, including regulatory or legal action to Centers and Offices when indicated. Assists in implementing approved action.
- H. Performs special investigations; investigates reports of adverse experience with any Agency-regulated products used in clinical or nonclinical research; and conducts inspections and investigations related to any emergencies associated with Agency-regulated products.

- I. Provides inspectional and investigational support to the Office of Inspections and Investigations (OII) Headquarters, the Centers, Offices, and other Divisions as needed.
- J. Provides guidance and training regarding inspectional techniques and technical developments in consultation with Centers and Offices to other Federal agencies, State, local, and foreign counterpart agencies, and industry as appropriate.
- K. Maintains cooperative relationships with other Federal agencies and develops work and information sharing agreements.
- L. Manages and evaluates resource use, operational activities, and all phases of personnel management, financial management, and supplies for the Division, in support of the BIMO program.

2. Bioresearch Monitoring Investigations Branch 1 (DCSEC1).

- A. Inspects BIMO establishments, collects samples for analysis, performs field examinations, and prepares reports for Centers and Offices.
- B. Evaluates corrective actions taken by Bioresearch Monitoring establishments and provides feedback to Centers and Offices.
- C. Prepares and provides evidence of investigational findings to Centers and Offices.
- D. Refers inspections and investigations with 483 observations to Centers and Offices for consideration of appropriate follow-up.
- E. Performs special investigations; investigates reports of adverse experience with any Agency-regulated products used in clinical or nonclinical research; and conducts inspections and investigations related to any emergencies associated with Agency-regulated products.
- F. Provides inspectional and investigational support to OII Headquarters, the Centers, Offices, and other Divisions as needed.
- G. Plans, schedules, and controls BIMO inspectional operations in coordination with Centers and Offices.
- H. Supports the development and implementation of domestic and foreign inspectional work plans.
- I. Provides guidance and training regarding inspectional techniques and technical developments in consultation with Centers and Offices to other Federal agencies, State, local, and foreign counterpart agencies, and industry as appropriate.

- J. Assists in managing, evaluating, and auditing the program aspects of federal-state contracts.
- K. Maintains cooperative relationships with other Federal agencies and develops work and information sharing agreements.

3. Bioresearch Monitoring Investigations Branch 2 (DCSEC2).

- A. Inspects BIMO establishments, collects samples for analysis, performs field examinations, and prepares reports for Centers and Offices.
- B. Evaluates corrective actions taken by Bioresearch Monitoring establishments and provides feedback to Centers and Offices.
- C. Prepares and provides evidence of investigational findings to Centers and Offices.
- D. Refers inspections and investigations with 483 observations to Centers and Offices for consideration of appropriate follow-up.
- E. Performs special investigations; investigates reports of adverse experience with any Agency-regulated products used in clinical or nonclinical research; and conducts inspections and investigations related to any emergencies associated with Agency-regulated products.
- F. Provides inspectional and investigational support to OII Headquarters, the Centers, Offices, and other Divisions as needed.
- G. Plans, schedules, and controls BIMO inspectional operations in coordination with Centers and Offices.
- H. Supports the development and implementation of domestic and foreign inspectional work plans.
- I. Provides guidance and training regarding inspectional techniques and technical developments in consultation with Centers and Offices to other Federal agencies, State, local, and foreign counterpart agencies, and industry as appropriate.
- J. Assists in managing, evaluating, and auditing the program aspects of federal-state contracts.
- K. Maintains cooperative relationships with other Federal agencies and develops work and information sharing agreements.

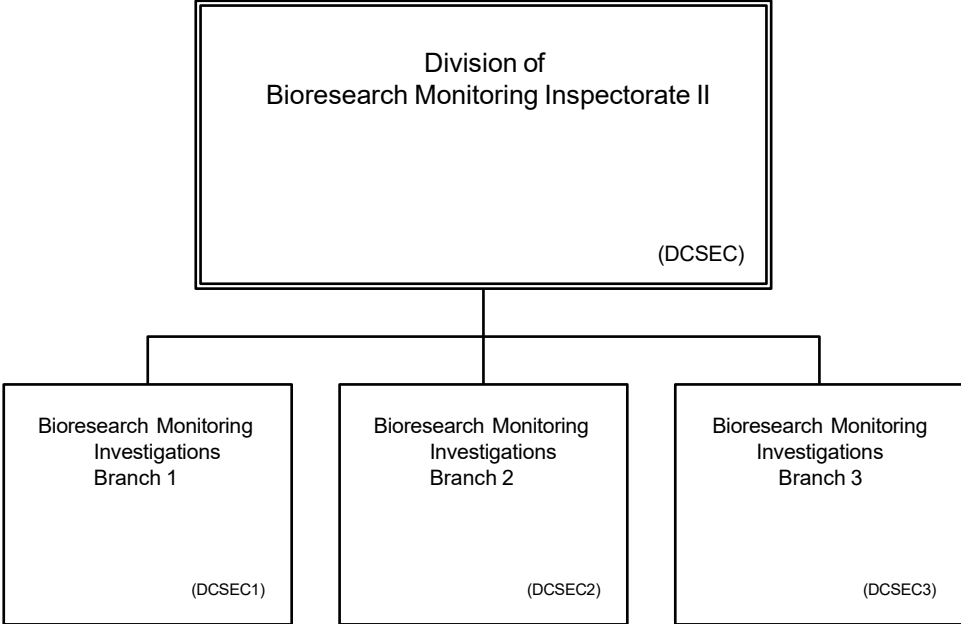
4. Bioresearch Monitoring Investigations Branch 3 (DCSEC3).

- A. Inspects BIMO establishments, collects samples for analysis, performs field examinations, and prepares reports for Centers and Offices.
- B. Evaluates corrective actions taken by Bioresearch Monitoring establishments and provides feedback to Centers and Offices.
- C. Prepares and provides evidence of investigational findings to Centers and Offices.
- D. Refers inspections and investigations with 483 observations to Centers and Offices for consideration of appropriate follow-up.
- E. Performs special investigations; investigates reports of adverse experience with any Agency-regulated products used in clinical or nonclinical research; and conducts inspections and investigations related to any emergencies associated with Agency-regulated products.
- F. Provides inspectional and investigational support to OII Headquarters, the Centers, Offices, and other Divisions as needed.
- G. Plans, schedules, and controls BIMO inspectional operations in coordination with Centers and Offices.
- H. Supports the development and implementation of domestic and foreign inspectional work plans.
- I. Provides guidance and training regarding inspectional techniques and technical developments in consultation with Centers and Offices to other Federal agencies, State, local, and foreign counterpart agencies, and industry as appropriate.
- J. Assists in managing, evaluating, and auditing the program aspects of federal-state contracts.
- K. Maintains cooperative relationships with other Federal agencies and develops work and information sharing agreements.

5. Authority and Effective Date.

The functional statements for the Division of Bioresearch Monitoring Inspectorate II 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
Division of Bioresearch Monitoring Inspectorate II**



Staff Manual Guide 1121A.53

Organizations and Functions

Effective Date: May 13, 2024

The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Bioresearch Monitoring Inspectorate, Division of Bioresearch Monitoring Inspectorate II organization structure depicting all the organizational structures reporting to the Director:

Bioresearch Monitoring Investigations Branch 1 (DCSEC1)

Bioresearch Monitoring Investigations Branch 2 (DCSEC2)

Bioresearch Monitoring Investigations Branch 3 (DCSEC3)