

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Office of the Commissioner**

**Office of the Chief Scientist**

**Office of Science and Laboratory Advancement**

Effective Date: May 13, 2024

- 1. Office of Science and Laboratory Advancement (DCPL).**
  - A. Identifies and advises the Office of the Chief Scientist (OCS) on applied research priorities for OCS regulatory testing and specialty labs that align with the Food and Drug Administration’s (FDA) risk-informed analytical needs, in collaboration with FDA Centers and Offices, including the Human Foods Program.
  - B. Coordinates with the Office of Analytical Regulatory Laboratories (OARL), Office of Specialty Labs and Enforcement Support (OSLES), and FDA Centers and Offices, including the Human Foods Program, on laboratory science activities to facilitate a cohesive approach to public health protection by cultivating scientific connectivity and fostering analytical cross-collaboration for synergistic FDA-wide operational efficiency.
  - C. Convenes and leads scientific meetings and collaborative forums for OCS labs to foster unity and crosstalk.
  - D. Establishes and manages a safety program for FDA’s inspections and investigations program and regulatory testing laboratory operations.
  - E. Provides scientific support and identifies applied research priority areas for laboratory science and regulatory testing labs that align with FDA’s risk-informed analytical needs.
  - F. Reviews scientific publications related to OARL and OSLES activities prior to submission.
  - G. Conducts technical reviews of scientific equipment requests from regulatory testing laboratories to advise on strategic funding prioritization.

- H. Oversees the quality management system of regulatory testing labs, including continual evaluation and improvement activities.
- I. Leads in the development, implementation, assessment, monitoring and maintenance of laboratory accreditation standards and oversight programs in regulatory testing labs.
- J. Trains regulatory testing laboratory managers and staff on Quality Management Systems (QMS) principles and requirements.
- K. Executes the proficiency testing program and oversees lab accreditation activities for regulatory testing laboratories.
- L. Coordinates with OARL and OSLES on strategic planning efforts.

## **2. Regulatory Operations Safety Staff (DCPL1).**

- A. Plans, develops, and implements procedures for safe work operations at FDA locations that house various regulatory and surveillance activities, including FDA's inspections and investigations program.
- B. Advises program areas and laboratories on strategies to mitigate operational risks and hazards to employees' safety and health.
- C. Plans and executes robust training, education, and outreach programs to inform employees and managers of safety-related procedures and safe work practices.
- D. Implements and coordinates for regulatory testing laboratories and FDA inspections and investigations program staff, risk assessment and hazard surveillance programs, in partnership with the Office of Occupational Health and Safety.
- E. Plans, coordinates, and oversees robust specialty services including radiation safety, laser safety, biological safety/security, respiratory protection and select agent possession and use management across program areas.
- F. Provides management oversight, including an effective audit process, for programs affecting the health and safety of field employees or the environmental compliance of program facilities; examples include incident reporting, Occupational Safety and Health Administration (OSHA) recordkeeping, radiation dosimetry and safety training reviews.
- G. Advises regulatory testing laboratories on hazardous waste and environmental management and advises program areas on regulatory compliance for the shipping of dangerous goods.

H. Monitors compliance with OSHA standards and federal, state, territorial and local environmental regulations at all FDA inspections and investigations program facilities and regulatory testing laboratories.

**3. Authority and Effective Date.**

The functional statements for the Office of Science and Laboratory Advancement 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 the Chief Scientist  
Office of Science and Laboratory Advancement**

Office of  
Science & Laboratory Advancement  
  
Science and Laboratory Safety Staff  
  
(DCPL)

Staff Manual Guide 1119A.10  
Organizations and Functions  
Effective Date: May 13, 2024

The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of the Chief Scientist, Office of Science and Laboratory Advancement organizational structures reporting to the Director:

Regulatory Operations Safety Staff