

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Regulatory Science

Effective: December 14, 2018

1. Office of Regulatory Science (DCIF).

- A. Provides strategic leadership, coordination, and expertise to the Associate Commissioner for Regulatory Affairs (ACRA), Assistant Commissioner for Operations (ACO), and other Office of Regulatory Affairs (ORA) senior leaders on scientific issues related to policy and regulations.
- B. Advises ACO concerning the management of the ORA's field scientific resources (including national experts) to assure their coordinated, efficient, and effective use.
- C. Provides scientific support in the review of regulatory documents, the development of regulatory decisions, and the analysis of postmarket surveillance issues.
- D. Leads the planning, development, and implementation of ORA's scientific programs including the development, modification, and validation of test methods and measurement techniques, risk assessments and hazard analyses, and generic techniques to enhance public health protection and respond to emergencies.
- E. Fosters development and use of innovative technologies to meet public health needs.
- F. Provides strategic leadership and support for high quality, collaborative, scientific activities and research that advance regulatory science and address important public health issues concerning Food and Drug Administration (FDA) regulated products, including their evaluation, quality, safety and effectiveness.

- G. Coordinates with other FDA components (e.g. Office of the Chief Scientist and Center Offices' of Science) on ORA scientific programs to assure a cohesive approach to public health protection.

2. Automated Laboratory Management Staff (DCIF1).

- A. Coordinates the maintenance of ORA's Laboratory Procedures Manual and the analytical and scientific review of publications relevant to the work of ORA laboratories, such as field assignments and compliance programs.
- B. Liaises with appropriate FDA Information Technology (IT) staff to implement and oversee all ORA scientific computing and knowledge management needs. In addition, serves as business subject matter experts in the development of information technology systems relevant to ORA laboratory operations.
- C. Ensures that work plan obligations and performance metrics are met.
- D. Provides outreach and technical support for laboratory training related to business Program Management (PM) and system training.
- E. Tracks and provides PM support for ORA's method development and validation activities.
- F. Assists ORA Office of Policy and Risk Management in sampling/analytical program evaluation including data aggregation and trending.

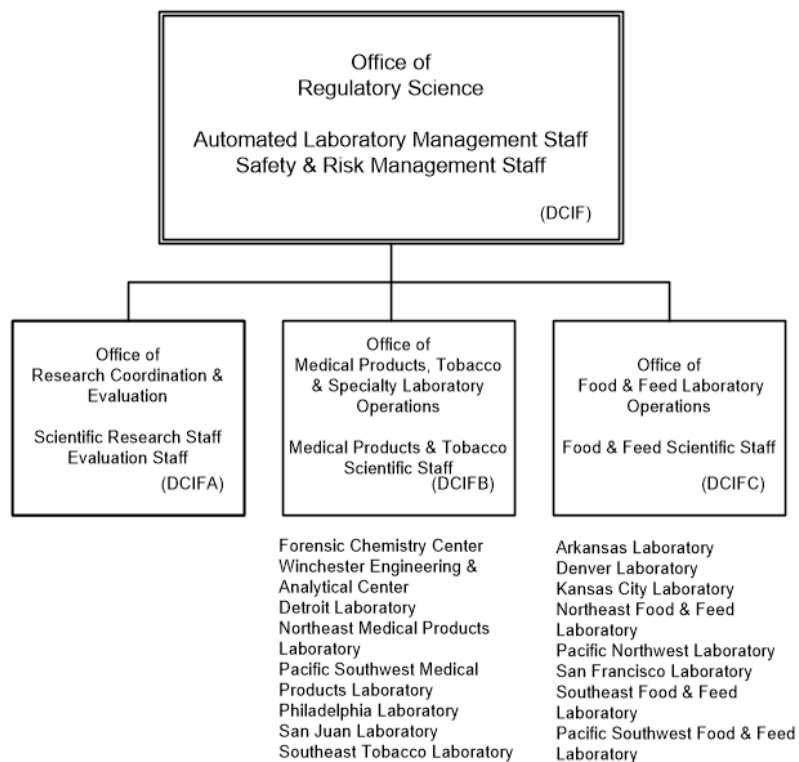
3. Safety and Risk Management Staff (DCIF2).

- A. Oversees personal safety in laboratories, biosafety, and radiation safety programs throughout ORS.
- B. Liaises with the FDA's Employee Safety and Environmental Management (ESEM) program.
- C. Oversees waste stream management and shipping of hazardous materials.
- D. Coordinates with field laboratories to ensure compliance with state and federal Occupational Safety and Health Administration (OSHA) and environmental standards.
- E. Ensures that safety training is being conducted at field laboratories.
- F. Conducts assessments of safety programs at field laboratories.

4. Authority and Effective Date.

The functional statements for the Office of Regulatory Science were approved by the Secretary for Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Regulatory Science**



Staff Manual Guide 1121.90
Organizations and Functions
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Regulatory Science organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Regulatory Science (DCIF):

Automated Laboratory Management Staff

Safety and Risk Management Staff

Office of Research Coordination & Evaluation (DCIFA)

Office of Medical Products, Tobacco & Specialty Laboratory Operations (DCIFB)

Office of Food & Feed Laboratory Operations (DCIFC)

These organizations report to the Office of Research Coordination & Evaluation (DCIFA):

Scientific Research Staff

Evaluation Staff

These organizations report to the Office of Medical Products, Tobacco & Specialty Laboratory Operations (DCIFB):

Medical Products & Tobacco Scientific Staff

Forensic Chemistry Center

Winchester Engineering & Analytical Center

Detroit Laboratory

Northeast Medical Products Laboratory

Pacific Southwest Medical Products Laboratory

Philadelphia Laboratory

San Juan Laboratory

Southeast Tobacco Laboratory

These organizations report to the Office of Food & Feed Laboratory Operations (DCIFC):

Food & Feed Scientific Staff

Arkansas Laboratory

Denver Laboratory

Kansas City Laboratory

Northeast Food & Feed Laboratory

Pacific Northwest Laboratory

San Francisco Laboratory

Southeast Food & Feed Laboratory

Pacific Southwest Food & Feed Laboratory

[Back to Organizations and Functions, Volume I \(1000-1300\)](#)