

**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**

**Office of Food and Feed Laboratory Operations**

**Pacific Northwest Laboratory**

Effective Date: December 14, 2018

**1. Pacific Northwest Laboratory (DCIFCE).**

- A. Plans, schedules, and controls regional laboratory operations; and formulates, implements, and coordinates analytical laboratory workplans.
- B. Conducts laboratory analysis of samples to:
  - 1. Assess each sample's compliance with applicable laws and regulations enforced by the Food and Drug Administration (FDA).
  - 2. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.
  - 3. Analyzes samples in support of foodborne illness outbreak investigations and consumer complaint investigations.
- C. Provides evidence regarding analytical findings as requested.
- D. Conducts research to develop and refine methodology used in the analysis of samples and explore new techniques and systems of analysis.
- E. Serves as a resource in scientific knowledge and provides expert-advice and training regarding laboratory techniques and technological developments to other Federal agencies, State and local agencies, foreign counterpart agencies, and industry.
- F. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.

- G. Provides management support for program and operational activities, including-all phases of personnel management, financial management, management of facilities, services, property, and supplies.
- H. Provides a robust quality management system to ensure that continuous improvement occurs in the quality and integrity of work performed at the laboratory.
- I. Ensures that the laboratory facility and laboratory policies optimize safety for all personnel working in the laboratory.
- J. Conducts reviews of data provided from contract, state, and private laboratories in support of Office of Regulatory Affairs's (ORA) regulatory mission.
- K. Maintains working liaison with other Federal offices-providing support services to the FDA.
- L. Conducts the equal employment opportunity, internal security, safety and emergency preparedness programs.

## **2. Chemistry Branch (DCIFCE1).**

- A. Performs laboratory analyses of samples to assess each sample's compliance with applicable laws and regulations enforced by the FDA.
- B. Conducts research to develop and refine methodology used in the analysis of samples and to explore new techniques and systems of analysis.
- C. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies, and to State, local and foreign counterpart agencies, and to industry.
- D. Provides court testimony regarding analytical findings as requested.
- E. Actively supports the laboratory quality system.
- F. Plans, schedules, and controls branch operations to formulate, implement, and coordinate work plans for districts serviced.
- G. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.

- H. Conducts reviews of data provided from contract, state and private laboratories in support of Office of Regulatory Science's (ORS) regulatory mission.

### **3. Microbiology Branch (DCIFCE2).**

- A. Performs microbiological analyses of samples in order to assess each sample's compliance with applicable laws and regulations enforced by the FDA.
- B. Conducts research to develop and refine methodology used in the analysis of samples and to explore new techniques and systems of analysis.
- C. Serves as a national resource in scientific knowledge, laboratory methodology, and techniques applicable to sterility testing.
- D. Provides court testimony regarding analytical findings as requested.
- E. Actively supports the laboratory quality system.
- F. Plans, schedules, and controls branch operations to formulate, implement, and coordinate work plans for districts serviced.
- G. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.
- H. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies, and to State, local and foreign counterpart agencies, and to industry.
- I. Conducts reviews of data provided from contract, state and private laboratories in support of ORS's regulatory mission.

### **4. Applied Technology Branch (DCIFCE3).**

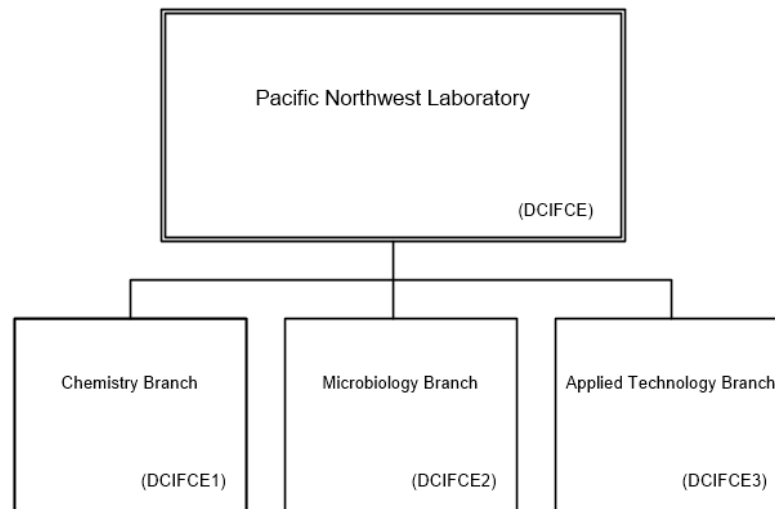
- A. Conducts collaborative research on emerging technologies and develops new rapid screening methodology for effective detection of pathogenic microorganisms, hazardous chemical residues, and chemical indices of decomposition on FDA regulated products.
- B. Works with allied public health laboratories to develop, validate and demonstrate "fit for purpose" new methods and approaches to characterize foodborne pathogens.

- C. Conducts collaborative research on microbiology, chemical residues, parasitology, and virology in support of regulatory food safety programs, including technology platform expansion and exploration that will increase sample throughput and confirmative capability of regulatory laboratories.
- D. Supports the laboratory quality system.
- E. Provide advisory and subject matter expertise for food safety and food emergency related activities at the local and national level.
- F. Conducts investigations to determine the existence of new and/or unusual potentially hazardous pathogens, chemical residues, and marine toxins of special public health concern in food products.

**5. Authority and Effective Date.**

The functional statements for the Pacific Northwest Laboratory 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  
Office of Food and Feed Laboratory Operations  
Pacific Northwest Laboratory**



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

These organizations report to the Pacific Northwest Laboratory (DCIFCE):

Chemistry Branch (DCIFCE1)

Microbiology Branch (DCIFCE2)

Applied Technology Branch (DCIFCE3)