

**FDA STAFF MANUAL GUIDES, VOLUME I – ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY

OFFICE OF REGULATORY AFFAIRS

OFFICE OF REGULATORY SCIENCE

OFFICE OF FOOD AND FEED LABORATORY OPERATIONS

PACIFIC NORTHWEST LABORATORY

Effective Date: June 6, 2016

1. PACIFIC NORTHWEST LABORATORY (DLLRKCE).

- 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 Agency.
 - 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 ORA's regulatory mission.
- K. Maintains working liaison with other Federal offices-providing support services to the Agency.
- L. Conducts the equal employment opportunity, internal security, safety and emergency preparedness programs.

2. CHEMISTRY BRANCH (DLLRKCE1).

- A. Performs laboratory analyses of samples to assess each sample's compliance with applicable laws and regulations enforced by the Agency.
- 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 ORS's regulatory mission.

3. MICROBIOLOGY BRANCH (DLLRKCE2).

A. Performs microbiological analyses of samples in order to assess each sample's compliance with applicable laws and regulations enforced by the Agency.

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 (DLLRKCE3).

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 this District Office were approved by the Secretary for Health and Human Services and effective on June 6, 2016.

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PACIFIC NORTHWEST LABORATORY**

OFFICE OF DIRECTOR	
Chemistry Branch	(DLLRKCE)
Microbiology Branch	(DLLRKCE1)
Applied Technology Branch	(DLLRKCE2)
	(DLLRKCE3)

STAFF MANUAL GUIDE 1121.935
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: June 6, 2016

The following is the Food and Drug Administration, Office of Global Regulatory Operations and Policy, 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 Office Director.

OFFICE OF THE DIRECTOR (DLLRKCE):

- Chemistry Branch (DLLRKCE1)
- Microbiology Branch (DLLRKCE2)
- Applied Technology Branch (DLLRKCE3)