

**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

SAN FRANCISCO LABORATORY

Effective Date: June 6, 2016

1. SAN FRANCISCO LABORATORY (DLLRKCF).

- A. Plans, schedules, and controls laboratory operations; and formulates, implements, and coordinates laboratory workplans.
- B. Performs laboratory analysis of samples to:
 - 1. Assess their compliance with laws and regulations enforced by the Agency.
 - 2. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.
 - 3. Provides evidence regarding analytical findings as requested.
- C. Conducts research to develop and refine methodology used in the analysis of samples and to explore new systems of analysis.
- D. 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.
- E. Conducts reviews of data provided from contract, state, and private laboratories in support of ORA's regulatory mission.

- F. Conducts the equal employment opportunity, internal security, safety and emergency preparedness programs.
- G. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.
- H. Provides analytical support to Headquarters components as needed.
- I. Participates in team inspections as necessary.

2. CHEMISTRY BRANCH (DLLRKCF1).

- A. Performs laboratory analyses and examination of samples for decomposition, toxic elements, colors, and food additives. These samples, which are collected by district offices and assigned to the laboratory by the ORA Workplan and Center Assignments , are analyzed to assess each sample's compliance with laws and regulations enforced by the Agency; and if applicable, to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.
- B. Covers a full-range of difficult, complex, or unusual samples and analytical requests by Investigations, Compliance, and Centers including food, feed, cosmetic, and dietary food supplements, analyses.
- C. Maintains an effective internal quality assurance program (17025 accredited).
- D. Conducts and participates in research and collaborative studies to develop and refine methodology used in the analysis of food, feed, cosmetic, and drug samples and to explore new techniques and systems of analysis.
- E. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes.
- F. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies; to State, local and foreign counterpart agencies, academia, and industry.
- G. Provides court testimony regarding analytical findings as requested.
- H. Plans, schedules, and controls Branch operations; and formulates, implements, and coordinates workplans for district offices served.

- I. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in adulterated food, feed, and cosmetic products.
- J. Maintains liaison with scientists and scientific institutions, with interest pertinent to laboratory activities.
- K. Conducts and participates in methodology development and collaborative research in a variety of aspects regarding food, feed, cosmetic, and dietary food supplements samples.

3. MICROBIOLOGICAL BRANCH (DLLRKCF2).

- A. Performs microbiological analyses of samples for district offices, as assigned by the ORA Workplan or as directed by assignments, in order to assess each sample's compliance with applicable laws and regulations enforced by the Agency and if applicable, to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.
- B. Conducts and participates in collaborative and validation studies to develop and refine methodology used in the analysis of microbiological samples and to explore new techniques and systems of screening and detection.
- C. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies, to State, local, and foreign counterpart agencies, academia, and industry.
- D. Covers a full-range of difficult, complex, or unusual samples and analytical requests by Investigations, Compliance, and Centers including drug and devices analyses, select agents and toxins analyses, cosmetics analyses, and can food and container integrity analyses relating to adverse events investigations.
- E. Provides court testimony regarding analytical findings, as requested.
- F. Serves as a Food & Feed program resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to microbiological analyses.
- G. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in microbiologically contaminated products.

- H. Maintains liaison with scientists and scientific institutions with interest pertinent to their respective scientific specialties.
- I. Maintains an effective internal quality assurance program (17025 accredited).
- J. Plans, schedules, and manages Branch operations; and formulates, implements, and coordinates workplans with district offices served.
- K. Conducts research in a variety of aspects regarding microbiological concerns.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Laboratory were approved by the Secretary for Health and Human Services and effective on June 6, 2016.

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OFFICE OF THE DIRECTOR

Chemistry Branch	(DLLRKCF)
Microbiology Branch	(DLLRKCF1)
	(DLLRKCF2)

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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, San Francisco Laboratory organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DLLRKCF):

- Chemistry Branch (DLLRKCF1)
- Microbiology Branch (DLLRKCF2)