

**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

KANSAS CITY LABORATORY

Effective Date: June 6, 2016

1. KANSAS CITY LABORATORY (DLLRKCC).

- A. Plans, schedules, and controls laboratory operations; formulates, implements, and coordinates domestic and import analytical work plans and schedules with district offices being serviced.
- B. Performs laboratory analysis of samples to:
 - 1. Assess their compliance with laws and regulations enforced by the Agency; and
 - 2. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.
- C. Provides evidence regarding analytical findings as requested.
- D. Advises Deputy Director for Laboratory Operations for Food and Feed on new or emerging problems and trends, future program needs and priorities, manpower, equipment, financial needs, and long-range planning.
- 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. Conducts studies and surveys of issues, operations and procedures, and evaluations to measure program effectiveness and accomplishments against the field work plan objectives.
- H. Conducts research to develop and refine methodology used in the analysis of samples and to explore new systems of analysis.
- I. 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.
- J. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.
- K. Provides analytical support to Headquarters components as needed.
- L. Participates in team inspections as necessary.

2. CHEMISTRY BRANCH I (DLLRKCC1).

- A. Performs laboratory analyses and examinations of samples collected to assess each sample's compliance with laws and regulations enforced by the Agency; and to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.
- B. Plans, schedules and manages branch operations; formulates, implements and coordinates work plans with offices served.
- C. Implements an effective internal quality assurance program to assure the reliability of analytical results.
- D. Develops, refines, and extends analytical methodology for determining nutritional and toxic elements, mycotoxins, active pharmaceutical ingredients and other chemical residues in foods, animal feeds, dietary supplements and related materials.
- E. Develops and maintains the capability to conduct complex analyses for determining nutritional and toxic elements, mycotoxins, active pharmaceutical ingredients and other chemical residues of special public health concern. Performs these types of analyses as necessary. Develops systems to automate analysis and data handling.
- F. Conducts and participates in collaborative studies of analytical methods.

- G. Provides expert technical scientific assistance and consultative services to the Agency in areas related to mycotoxins, and elemental analyses.
- H. Investigates and conducts research to determine the existence of new/and or unusual potentially hazardous findings of toxic elements in foods, animal feeds, dietary supplements and related materials. Conducts research to identify significant unidentified chemical contaminants in foods, animal feeds, dietary supplements and related materials.
- I. Assists the Center for Food Safety and Applied Nutrition in the development of protocols for the analysis of mycotoxins and toxic and nutritional elements.

3. CHEMISTRY BRANCH II (DLLRKCC2).

- A. Performs laboratory analyses and examinations of samples collected to assess each sample's compliance with laws and regulations enforced by the Agency; and to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.
- B. Plans, schedules and manages branch operations; formulates, implements and coordinates work plans with offices served.
- C. Implements an effective internal quality assurance program to assure the reliability of analytical results.
- D. Develops, refines, and extends analytical methodology for determination of pesticide, herbicides, fungicides and industrial chemical residues in foods, animal feeds, dietary supplements and related materials,
- E. Conducts studies to develop and adapt analytical methodology, techniques, and instrumentation for use in the Total Diet Study (TDS). Performs as the national servicing center for TDS, coordinating and collaborating with the Center for Food Safety and Applied Nutrition in design and execution of the study objectives by planning collection, preparation and analysis of samples.
- F. Performs difficult and/or unusual analyses of TDS samples. Develops systems to automate analysis and data handling for the TDS.
- G. Conducts and participates in collaborative studies of analytical methods. Transfers methodology developed through research efforts to ORA regulatory laboratories and the TDS as appropriate.

- H. Provides expert technical scientific assistance and consultative services to the Agency in areas related to detection of contaminants and adulterants. Trains FDA and other visiting chemists on analytical procedures used in Total Diet Study and regulatory analyses.
- I. Assists the Center for Food Safety and Applied Nutrition in the:
 - 1. Development of revised model diets;
 - 2. Development of protocols for analysis of individual foods to determine contaminant or nutrient levels in the complete diet;
 - 3. Preparation of scientific and consumer oriented documents covering the total diet studies.
- J. Assists headquarters program managers in preparing compliance programs for the TDS.
- K. Investigates and conducts research to determine the existence of new/and or unusual potentially hazardous pesticide and industrial chemical residues in foods, animal feeds and related materials; gathers information on pesticide usage. Conducts research to identify significant unidentified chemical contaminants in foods, animal feeds, dietary supplements and related materials.
- L. Assists the Center for Veterinary Medicine in the development of protocols for the analysis to determine pesticide, herbicides, fungicides, industrial chemicals, and other adulterants and contaminant residues.

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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KANSAS CITY LABORATORY**

OFFICE OF THE DIRECTOR

Chemistry Branch I	(DLLRKCC)
Chemistry Branch II	(DLLRKCC1)
	(DLLRKCC2)

STAFF MANUAL GUIDE 1121.933
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, Kansas City Laboratory organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DLLRKCC):

- Chemistry Branch I (DLLRKCC1)
- Chemistry Branch II (DLLRKCC2)