

SMG 1121.931

**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

ARKANSAS LABORATORY

Effective Date: June 6, 2016

1. ARKANSAS LABORATORY (DLLRKCA).

- A. Plans, schedules, and controls laboratory operations; formulates, implements, and coordinates domestic and import analytical work plans and schedules with offices being served.
- B. Conducts laboratory testing and analysis of samples to:
 - 1. Assess their compliance with applicable laws and regulations enforced by the Agency;
 - 2. Determine the extent to which findings provide evidence of violative conditions and practices; and
 - 3. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.
- C. Provides evidence related to analytical findings as requested.
- D. Conducts research to develop and refine methodology used in the analysis of samples and to explore new systems of analysis.
- E. Conducts reviews of data provided from contract, state, and private laboratories in support of ORA's regulatory mission
- F. Serves as an ORS 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.

- G. Provides assistance to Office of Regulatory Affairs (ORA) food and feed program areas in the conduct of complex food and animal drug inspections requiring an in-depth knowledge of laboratory techniques and practices, and potential causes of adulteration.
- H. Conducts equal employment opportunity, internal security, safety and emergency preparedness programs.
- I. Serves as a resource for analyses requiring complex instrumental analyses.
- J. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.

2. CHEMISTRY BRANCH I (DLLRKCA1).

- 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. Conducts research to develop and refine methodology used in the analyses 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; to state, local and foreign counterpart agencies, and to industry.
- D. Provides court testimony regarding analytical findings as requested.
- E. Plans, schedules and manages branch operations; formulates, implements and coordinates work plans with offices served.
- F. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes.
- G. Maintains liaison with scientists and scientific institutions, with interest pertinent to laboratory activities.

- H. Implements an effective internal quality assurance program to assure the reliability of analytical results.
- I. Serves as a resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to chemical analyses.

3. CHEMISTRY BRANCH II (DLLRKCA2).

- A. Performs pesticide and industrial chemical residue analyses and examinations of samples to assess each sample's compliance with applicable 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. Conducts research to develop and modify methodology used in the analysis of samples and to explore new techniques and systems of analysis.
- C. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes.
- D. Provides expert advice and training related to pesticide techniques and technological developments to other Federal agencies; to State, local and foreign counterpart agencies, and to industry.
- E. Provides court testimony regarding analytical findings as requested.
- F. Maintains liaison with scientists and scientific institutions, with interest pertinent to laboratory activities.
- G. Plans and monitors branch operations; formulates, implements and coordinates the accomplishment of pesticide work plans for offices served.
- H. Implements an effective internal quality assurance program to assure the reliability of analytical results.
- I. Serves as a resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to chemical analyses.

4. MICROBIOLOGY BRANCH (DLLRKCA3).

- A. Performs microbiological analyses of samples collected to assess each sample's compliance with laws and regulations enforced by the Agency;

and to assess each sample's compliance with laws and regulations enforced by the Agency.

- B. Conducts research to develop and refine methodology used in the analyses of microbiological 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; to state, local and foreign counterpart agencies, and to industry.
- D. Serves as a resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to microbiological analyses.
- E. Provides court testimony regarding analytical findings as requested.
- F. Plans, schedules and manages branch operations; formulates, implements and coordinates work plans with offices served.
- G. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and processes which may result in microbiologically contaminated products.
- H. Maintains liaison with scientists and scientific institutions, with interest pertinent to laboratory activities.
- I. Implements an effective internal quality assurance program.
- J. Conducts research in a variety of aspects regarding microbiological concerns.

5. 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 GLOBAL REGULATORY OPERATIONS AND POLICY
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ARKANSAS LABORATORY**

OFFICE OF THE DIRECTOR

Chemistry Branch I	(DLLRKCA)
Chemistry Branch II	(DLLRKCA1)
Microbiology Branch	(DLLRKCA2)
	(DLLRKCA3)

STAFF MANUAL GUIDE 1121.931
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, Arkansas Laboratory organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DLLRKC):

- Chemistry Branch I (DLLRKCA1)
- Chemistry Branch II (DLLRKCA2)
- Microbiology Branch (DLLRKCA3)