

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

Northeast Food and Feed Laboratory

Effective Date: December 14, 2018

1. Northeast Food and Feed Laboratory (DCIFCD).

- A. Plans, schedules, and controls Office of Regulatory Science (ORS) food and feed laboratory operations; and formulates, implements, and coordinates domestic and import analytical workplans and schedules with district offices being serviced.
- B. Maintains an effective internal quality assurance program (ISO 17025 accredited).
- C. Conducts laboratory testing and analysis of samples for Food and Drug Administration (FDA) Food and Feed programs, as requested, to:
 - 1. Assess their compliance with applicable laws and regulations enforced by the FDA;
 - 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.
- D. Provides evidence regarding analytical findings as requested.
- E. Conducts reviews of data provided from contract, state, and private laboratories in support of Office of Regulatory Affairs (ORA's) regulatory mission.

- F. Conducts research and participates in collaborative studies to develop and refine methodology used in the analysis of samples and to explore new systems of analysis.
- G. Serves as the Regional 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, academia, and industry.
- H. Provides assistance to ORA Staff in the conduct of complex food and feed inspections requiring an in-depth knowledge of laboratory techniques and practices and potential causes of adulteration.
- I. Serves as a national resource for analyses requiring mass spectroscopic instrumentation, as well as food chemistry, and microbiological analyses.
- J. Conducts the equal employment opportunity, internal security, safety and emergency preparedness programs.
- K. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.

2. Chemistry Branch 1 (DCIFCD1).

- A. Performs laboratory analyses and examination of samples for chemotherapeutics, toxic elements, mycotoxins, colors, and food additives. These samples are analyzed to assess each sample's compliance with laws and regulations enforced by the FDA; and if applicable, to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.
- B. Maintains an effective internal quality assurance program (ISO 17025 accredited).
- C. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in adulterated food and feed products.
- D. 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.
- E. Provides court testimony regarding analytical findings as requested.
- F. Plans, schedules, and controls Branch operations; and formulates, implements, and coordinates workplans for ORA offices served.

- G. 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.
- H. Maintains liaison with scientists and scientific institutions, with interest pertinent to laboratory activities.
- I. Conducts research in a variety of aspects regarding food and feed samples.

3. Chemistry Branch 2 (DCIFCD2).

- A. Performs laboratory analyses and examination of samples of filth, decomposition, pesticides, selected allergens, and other industrial chemicals. These samples which are collected under the food and feed program areas are analyzed to assess each sample's compliance with laws and regulations enforced by the FDA; and if applicable, to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.
- B. Maintains an effective internal quality assurance program (ISO 17025 accredited).
- C. Conducts research and participate in collaborative studies to develop and refine methodology used in the analysis of food and feed samples and to explore new systems of analysis.
- D. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agency officials; to State, local and foreign counterpart agencies officials, and to industry.
- E. Provides court testimony regarding analytical findings as requested.
- F. Plans, schedules, and manages Branch operations; formulates, implements, and coordinates workplans with district offices served.
- G. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in adulterated food and feed products.
- H. Maintains liaison with scientists and scientific institutions with interests pertinent to laboratory activities.

- I. Conducts research in a variety of aspects regarding food and feed products.

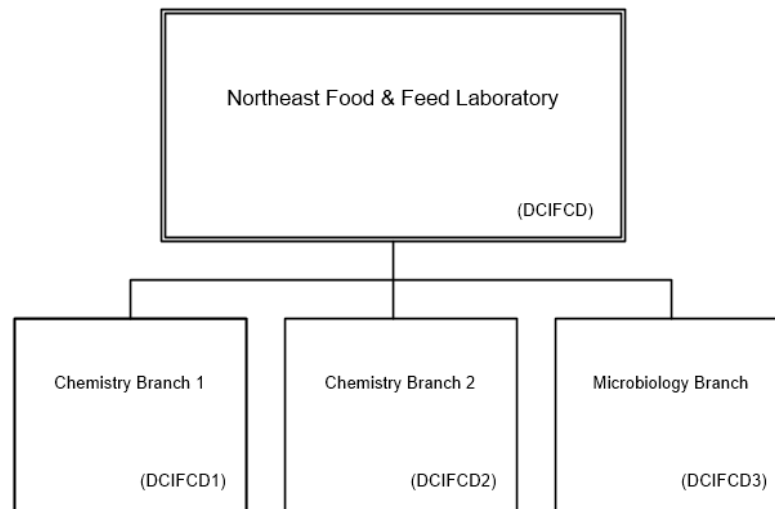
4. Microbiological Sciences Branch (DCIFCD3).

- A. Performs microbiological analyses of samples for field offices, in order to assess each sample's compliance with applicable laws and regulations enforced by the FDA and if applicable, to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.
- B. Conducts research and participates in collaborative studies to develop and refine methodology used in the analysis 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, academia, and industry.
- D. Provides court testimony regarding analytical findings, as requested.
- E. Serves as a Food and Feed program resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to microbiological analyses.
- F. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in microbiologically contaminated products.
- G. Maintains liaison with scientists and scientific institutions with interest pertinent to their respective scientific specialties.
- H. Maintains an effective internal quality assurance program (ISO 17025 accredited).
- I. Plans, schedules, and manages Branch operations; formulates, implements, and coordinates workplans with district offices served.
- J. Conducts research in a variety of aspects regarding microbiological concerns.

5. Authority and Effective Date.

The functional statements for this Northeast Food and Feed 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
Northeast Food and Feed 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, Northeast Food and Feed Laboratory organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Northeast Food and Feed Laboratory (DCIFCD):

Chemistry Branch 1 (DCIFCD1)

Chemistry Branch 2 (DCIFCD2)

Microbiology Sciences Branch (DCIFCD3)