

SMG 1312.1

**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 OPERATIONS

REGIONAL FIELD OFFICE, CENTRAL REGION, CHICAGO, IL

Effective Date: June 6, 2016

1. REGIONAL FIELD OFFICE, CENTRAL REGION - CHICAGO, IL (DLLRL).

- A. Provides managerial direction to that portion of the Agency's field programs assigned to the region to achieve compliance with the laws and regulations for which the Agency is responsible through appropriate voluntary correction or regulatory action.
- B. Manages resource allocations, money, and people.
- C. Manages a field management information system.
- D. Coordinates Agency activities with related operations of the PHS Regional Health Administrator and the Department's Regional Director.
- E. Develops and maintains cooperative relationships with State, local, and other Federal agencies; serves on interagency councils, encourages improved State and local consumer protection programs pertinent to Agency-enforced laws and regulations.
- F. Assists State and local cooperative officials in the development of uniform legislation, codes, and regulations.
- G. Represents the Agency, or provides policy and direction for Agency representation, in dealing with public and private organizations, such as governmental agencies, volunteer agencies, educational institutions, industry and professional associations, and the local media within the Region.

- H. Plans and evaluates program activities; measures accomplishments against annual field workplans objectives; initiates management and program analyses; manages a Quality Assurance Program; and advises Headquarters regarding strategy changes needed to reach existing or modified objectives.
- I. Advises Headquarters on new or emerging problems and trends, future program needs and priorities; State legislative activities; manpower, equipment, financial needs, and long-range planning.
- J. Coordinates emergency activities by maintaining liaison with Department components, and other Federal departments and agencies and by providing assistance to States and localities in the event of a national disaster or other emergency.
- K. Advises, commissions, and certifies State personnel; and monitors and evaluates State programs in milk, shellfish, food service sanitation, and radiation safety.
- L. Determines the acceptability of items, subject to the Agency's jurisdiction, for entry into this country through examination of available records, inspection of the product or by sampling and laboratory examination of the product followed by release, detention, and/or rejection.
- M. Conducts investigations and inspections, and analyzes samples of foods, drugs, and other commodities for which the Agency has regulatory responsibility.
- N. Conducts administrative hearings on alleged violations, and initiates appropriate enforcement action.
- O. Recommends legal action to Headquarters, to the Office of the Chief Counsel, or to the responsible U.S. attorney (when such direct reference is authorized), and assists in implementing approved action.
- P. Detains medical devices and, in cooperation with USDA, detains meat, poultry, or egg products that may be violative.
- Q. Manages recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences.
- R. Conducts research to develop and refine analytical methodology and to explore new systems of analysis; maintains liaison with scientists and scientific bodies with interest pertinent to laboratory activities.

- S. Manages, evaluates, and audits the program aspects of Federal-State contracts.
- T. Manages an equal employment opportunity and career development and training program.
- U. Conducts consumer affairs and information programs.
- V. Provides formal mechanisms for receiving consumer input into Agency planning and priority-setting systems.
- W. Directs a freedom of information program consistent with Agency policy.
- X. Maintains liaison with the medical community to share the Agency's position on pertinent issues, and to obtain feedback regarding the concerns of physicians and other health-related scientists.
- Y. Conducts a small business representative program.

2. STATE COOPERATIVE PROGRAMS STAFF I (DLLRL1).

Cooperative State-FDA functions include all areas of the Agency's responsibility, but this staff is generally limited to Food Service, Milk, and Shellfish Sanitation, Radiological Health, and Laser Safety program responsibilities. Specialists operating in these program areas perform the following functions:

- A. Coordinates and evaluates State program activities for conformity with State-FDA guidelines and certifies State personnel.
- B. Inspects establishments subject to laws and regulations enforced by the Agency; collects samples for laboratory analysis; performs field analyses and prepares reports on findings of each inspection.
- C. Analyzes inspectional and analytical findings relative to compliance or noncompliance and determines appropriate follow up. Makes recommendations to district compliance branches when regulatory action is required, or to firm and/or State program officials when voluntary corrective action is appropriate.
- D. Performs special investigations, studies, and evaluations, including foreign program evaluations, epidemiological investigations of food poisonings, and technical assistance projects requested by State officials.
- E. Prepares, as appropriate, State program evaluation reports, meets with State program officials to provide technical and administrative

consultations; and maintains cooperative relationships with State counterpart agencies.

- F. Assists State and local cooperative officials in the development of uniform legislation, codes, and regulations. Advises cooperative officials on interpretation of Federal laws, regulations, and enforcement policies and consults relative to joint regulatory approaches.
- G. Manages, evaluates, and audits the program aspects of Federal-State contracts and programs that are applicable to the special program area.
- H. Plans, schedules, and controls inspectional and evaluational operations; and formulates, implements, and coordinates investigation and evaluation work plans.
- I. Provides counsel and training regarding inspectional techniques and technical developments to other Federal agencies; to State, local, and foreign counterpart agencies; and to industry under the cooperative State-FDA program.

3. STATE COOPERATIVE PROGRAMS STAFF II (DLLRL2).

Cooperative State-FDA functions include all areas of the Agency's responsibility, but this staff is generally limited to Food Service, Milk, and Shellfish Sanitation, Radiological Health, and Laser Safety program responsibilities. Specialists operating in these program areas perform the following functions:

- A. Coordinates and evaluates State program activities for conformity with State-FDA guidelines and certifies State personnel.
- B. Inspects establishments subject to laws and regulations enforced by the Agency; collects samples for laboratory analysis; performs field analyses and prepares reports on findings of each inspection.
- C. Analyzes inspectional and analytical findings relative to compliance or noncompliance and determines appropriate follow up. Makes recommendations to district compliance branches when regulatory action is required, or to firm and/or State program officials when voluntary corrective action is appropriate.
- D. Performs special investigations, studies, and evaluations, including foreign program evaluations, epidemiological investigations of food poisonings, and technical assistance projects requested by State officials.

- E. Prepares, as appropriate, State program evaluation reports, meets with State program officials to provide technical and administrative consultations; and maintains cooperative relationships with State counterpart agencies.
- F. Assists State and local cooperative officials in the development of uniform legislation, codes, and regulations. Advises cooperative officials on interpretation of Federal laws, regulations, and enforcement policies and consults relative to joint regulatory approaches.
- G. Manages, evaluates, and audits the program aspects of Federal-State contracts and programs that are applicable to the special program area.
- H. Plans, schedules, and controls inspectional and evaluational operations; and formulates, implements, and coordinates investigation and evaluation work plans.
- I. Provides counsel and training regarding inspectional techniques and technical developments to other Federal agencies; to State, local and foreign counterpart agencies; and to industry under the cooperative State-FDA program.

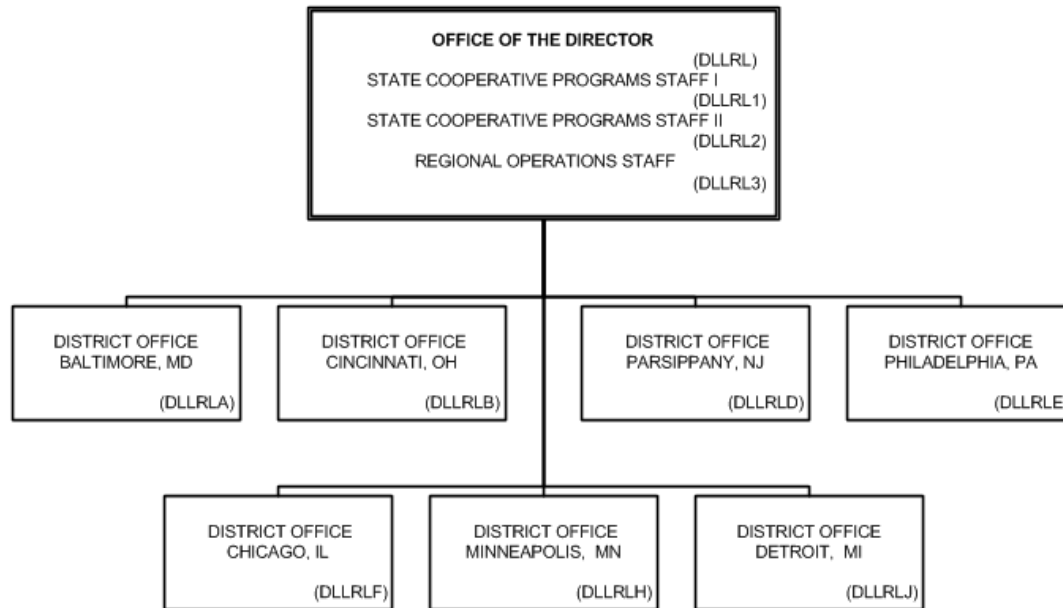
4. REGIONAL OPERATIONS STAFF (DLLRL3).

Assists the Regional Food and Drug Director in the planning and evaluation of program activities; operates a regional system of monitoring program accomplishments against annual work plan objectives; undertakes management and program analyses; and, advises the Regional Food and Drug Director regarding changes required to reach existing or modified objectives.

5. AUTHORITY AND EFFECTIVE DATE.

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

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CHICAGO, IL**



STAFF MANUAL GUIDE 1312.1
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: June 6, 2016

The following is the Food and Drug Administration, Office of Regulatory Affairs, Regional Field Office, Central Region, Chicago, IL organization structure depicting all the organizational structures reporting to the Office of the Director.

OFFICE OF THE DIRECTOR (DLLRL):

- State Cooperative Programs Staff I (DLLRL1)
- State Cooperative Programs Staff II (DLLRL2)
- Regional Operations Staff (DLLRL3)
- DISTRICT OFFICE BALTIMORE, MD (DLLRLA)
- DISTRICT OFFICE CINCINNATI, OH (DLLRLB)
- DISTRICT OFFICE PARSIPPANY, NJ (DLLRLD)
- DISTRICT OFFICE PHILADELPHIA, PA (DLLRLE)
- DISTRICT OFFICE CHICAGO, IL (DLLRLF)
- DISTRICT OFFICE MINNEAPOLIS, MN (DLLRLH)
- DISTRICT OFFICE DETROIT, MI (DLLRLJ)