

SMG 1311.1

**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, NORTHEAST REGION, JAMAICA, NY

Effective Date: June 6, 2016

- 1. REGIONAL FIELD OFFICE, NORTHEAST REGION - JAMAICA, NY (DLLRN).**
 - A. Provides managerial direction to the Agency's field programs 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. Coordinates Agency activities with related operations of the PHS Regional Health Administrator and the Department's Regional Director.
 - D. 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.
 - E. Assists State and local cooperative officials in the development of uniform legislation, codes, and regulations.
 - F. 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.
 - G. Plans and evaluates program activities; measures accomplishments against annual field workplan objectives; initiates management and program analyses; manages a Quality Assurance Program; and advises

- Headquarters regarding strategy changes needed to reach existing or modified objectives.
- H. 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.
 - I. 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.
 - J. Advises, commissions, and certifies State personnel; and monitors and evaluates State programs in milk, shellfish, food service sanitation, and radiation safety.
 - K. 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.
 - L. Conducts investigations and inspections, and analyzes samples of foods, drugs, and other commodities for which the Agency has regulatory responsibility.
 - M. Conducts administrative hearings on alleged violations, and initiates appropriate enforcement action.
 - N. 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.
 - O. Detains medical devices and, in cooperation with USDA, detains meat, poultry, or egg products that may be violative.
 - P. Manages recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences.
 - Q. 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.
 - R. Manages, evaluates, and audits the program aspects of Federal-State contracts.

- S. Manages an equal employment opportunity and career development and training program.
- T. Conducts consumer affairs and information programs.
- U. Provides formal mechanisms for receiving consumer input into Agency planning and priority-setting systems.
- V. Directs a freedom of information program consistent with Agency policy.
- W. 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.
- X. Conducts a small business representative program.

2. OPERATIONS STAFF (DLLRN2).

- A. Serves as the focal point in the Region for the development, implementation, and coordination of short- and long-range program planning for the utilization of manpower, equipment, and facilities.
- B. Evaluates work scheduling activities of the Region to assure basic uniformity and effectiveness of program coverage throughout the Region; evaluates proposed and on-going programs, serving as the focal point for directing Regional input and reasoning to the appropriate Headquarters unit; and analyzes the need for new or revised programs, or supplements to existing programs.
- C. Monitors Regional program accomplishments; evaluates staffing arrangements, organizational structure, and manpower assignments; and recommends shifts of resources required to assure maximum accomplishments of program goals.
- D. Analyzes the financial needs of each District and other Regional components, presenting budget requests to Headquarters in proper form and with substantiating justification.
- E. Provides assistance to Districts and other Regional components in obtaining and analyzing data through a variety of special programs and mechanisms.
- F. Makes evaluations and recommendations relating to the development, interpretation, and implementation of domestic and import regulatory policies and procedures within the Region; represents the Regional

Director on FDA Headquarters/Field councils, committees, or other policy-making groups.

- G. Conducts in-depth assessments of procedures and activities through which scientifically-oriented Federal agencies can integrate their enforcement programs and services.
- H. Develops plans and strategies through which Federal, State, and local scientific agencies can integrate regulatory services, establish joint priorities, and implement programs in a coordinated manner to reach mutual objectives.
- I. Manages the Region's Small Business Assistance Program; working with industry groups, associations, and specific firms to identify and meet industry needs for information and assistance regarding Agency-enforced laws, regulations, and programs.
- J. Implements quality assurance programs and other evaluations needed to verify the quality of data reporting in the Region, providing assistance where necessary to resolve identified problems.
- K. Assures the uniform interpretation and application of Regional and Agency voluntary and regulatory compliance procedures and policies; assures that all appropriate actions are taken to encourage voluntary correction, wherever suitable.
- L. Maintains a continuing appraisal of import and domestic case handling and decision making procedures used in both the District Offices and the Office of the Regional Food and Drug Director.
- M. Monitors District actions within the Region to institute appeals to Headquarters for case turn-downs. Evaluates the reason for each turn-down to determine its impact on future case development within the Region.
- N. Manages the Region's Radiological Health Program; provides assistance and training to the Districts, develops agreements with State and local radiation control officials, oversees the development of regulatory actions regarding electronic devices capable of emitting radiation, and monitors the conduct of State and local radiation control programs.

3. INTERGOVERNMENTAL AFFAIRS STAFF (DLLRN3).

- A. Serves as the Region's principal liaison officer between the Agency and State, local and other health officials. Advises both the Regional Director and District Directors as to the needs of these counterpart agencies, and

- the nature and depth of Agency activities required. Provides required coordination with other Agency units, both in and out of the Region, to most effectively meet State and local health program needs.
- B. Develops and implements short- and long-range plans to assure that State-related programs are implemented as effectively as possible throughout the Region.
 - C. Serves as the primary Regional coordinator with State and local officials in the conduct of epidemiological studies and emergencies relating to foods, drugs, and cosmetics.
 - D. Represents the Region on the Regional Response Team; coordinating emergency activities within the Agency and maintaining liaison with other Federal agencies.
 - E. Directs New England States program activities. Specialists operating in food service, milk, and shellfish program areas perform the following functions:
 - 1. Coordinates and evaluates State program activities for conformity with State-FDA guidelines and certify State personnel.
 - 2. 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.
 - 3. 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.
 - 4. Performs special investigations, studies, and evaluations, including foreign program evaluations, epidemiological investigations of food poisonings, and technical assistance projects requested by State officials.
 - 5. 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.
 - 6. Assists State and local cooperative officials in the development of uniform legislation, codes, and regulations. Advises cooperative

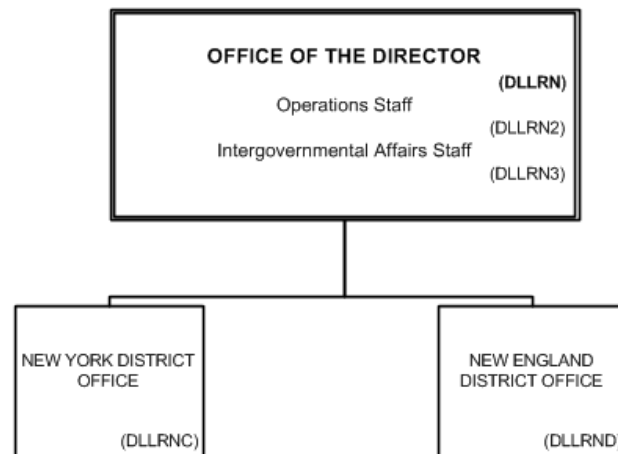
officials on interpretation of Federal laws, regulations, and enforcement policies and consults relative to joint regulatory approaches.

7. Manages, evaluates, and audits the program aspects of Federal-State contracts and programs that are applicable to the special program areas.
8. Plans, schedules, and controls inspection and evaluation operations; and formulates, implement, and coordinates investigation and evaluation workplans.
9. Provides counsel and training regarding inspectional techniques and technical development to other Federal agencies; to State, local, and foreign counterpart agencies; and to industry under the cooperative State-FDA program.

4. 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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ORGANIZATIONS AND FUNCTIONS
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The following is the Food and Drug Administration, Office of Regulatory Affairs, Regional Field Office, Northeast Region, Jamaica, NY organization structure depicting all the organizational structures reporting to the Office of the Director.

OFFICE OF THE DIRECTOR (DLLRN):

- Operations Staff (DLLRN2)
- Intergovernmental Affairs Staff (DLLRN3)
- NEW YORK DISTRICT OFFICE (DLLRNC)
- NEW ENGLAND DISTRICT OFFICE (DLLRND)